Medicaid Services Manual
Transmittal Letter

June 24, 2025

To: Custodians of Medicaid Services Manual

From: Casey Angres *Casey Angres* Casey Angres (Jul 22, 2025 08:50 PDT)
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

**Background And Explanation**

Revisions to Medicaid Services Manual (MSM) Chapter MSM 1200 – Prescribed Drugs are being proposed to add Statins to Maintenance Medications in Section 1203.1 – Coverage and Limitations. Added Ohtuvayre™ to Daliresp® in a Caution subsection; added a subsection for Zepbound® in Incretin Mimetics; added a subsection for Alyftrek® in Cystic Fibrosis Agents; added a subsection for Refractory Atopic Dermatitis and updated age requirements under Plaque Psoriasis in Immunomodulator Drugs. Added new sections for Filsuvez®, Juxtapid™, Tryngolza™, Yorvipath®, Ocaliva®, Iqirvo®, and Livdelzi®.

Throughout the chapter, grammar, punctuation and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These changes are effective June 30, 2025.

| Material Transmitted | Material Superseded |
|---|---|
| MTL 15/25<br>Chapter 1200– Prescribed Drugs | MTL 06/18, 23/19<br>Chapter 1200– Prescribed Drugs |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| **1203.1** | **Coverage and Limitations** | Added Statins to Maintenance Medications. |
| **Appendix A Section L** | **Immunomodulator Drugs** | Added Subsection n for Refractory Atopic Dermatitis including policy for initial requests and updated age requirements under Plaque Psoriasis. |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| **Appendix A Section II** | **Daliresp® (roflumilast)** | Added Ohtuvayre™ to this section. Added a Caution section to attest Ohtuvayre™ will be used with caution in recipients with hepatic impairment. |
| **Appendix A Section KK** | **Incretin Mimetics** | Added a subsection for Zepbound® (tirzepatide), including policy for initial requests, and recertification requests. |
| **Appendix A Section LL** | **Cystic Fibrosis Agents** | Added Subsection e for Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor), including policy for initial requests and renewal requests. |
| **Appendix A Section FFFFF** | **Filsuvez® (Birch Triterpenes)** | New section for the therapeutic class Dystrophic and Junctional Epidermolysis Bullosa; includes policy for initial requests, dosing limits, renewal requests, and initial and recertification prior authorization (PA) guidelines. |
| **Appendix A Section GGGGG** | **Juxtapid™ (Lomitapide)** | New section for the therapeutic class Antilipemic Agent, homozygous familial hypercholesterolemia (HoFH), includes policy for initial requests, dosing limits, renewal requests, and initial and recertification PA guidelines. |
| **Appendix A Section HHHHH** | **Tryngolza™ (Olezarsen)** | New section for therapeutic class Antilipemic Agent, familial chylomicronemia syndrome (FCS), includes policy for initial requests, dosing limits, renewal requests, and initial and recertification PA guidelines. |
| **Appendix A Section IIIII** | **Yorvipath® (Palopegteriparatide)** | New section for therapeutic class Parathyroid Hormone Analog includes policy for initial requests, dosing limits, renewal requests, and initial and recertification PA guidelines. |
| **Appendix A Section JJJJJ** | **Ocaliva® (obeticholic acid), Iqirvo® (elafibranor), Livdelzi® (seladelpar)** | New section for therapeutic class Primary Biliary Cholangitis (PBC) Agents includes policy for initial requests, dosing limits, renewal requests, and initial and recertification PA guidelines. |

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL
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# 1200 INTRODUCTION

The Nevada Medicaid Pharmacy Services program pays for medically necessary prescription services for eligible Medicaid recipients under the care of the prescribing practitioner. Such services shall maintain a high standard of quality and shall be provided within the limitations and exclusions hereinafter specified.

All providers participating in the Medicaid program must furnish services in accordance with the rules and regulations of the Medicaid program. Conditions of participation are available from Provider Services.

This Chapter describes covered services, service limitations, and general reimbursement methodology.

This manual obsoletes all previous policy and procedure manuals, bulletins, and policy news.

All Medicaid policies and requirements (such as prior authorizations (PA), etc.) are the same for Nevada Check Up (NCU), with the exception of the four areas where Medicaid and NCU policies differ as documented in the NCU Manual Chapter 1000.

# 1201 AUTHORITY

A. The Code of Federal Regulations (CFR), Title 42, Public Health, Chapter IV, Center for Medicare and Medicaid Services (CMS), Subchapter C Medical Assistance Programs, Parts 430 through 456, states prescription drug coverage is an optional service under Title XIX.

B. The Omnibus Budget Reconciliation Act (OBRA) of 1989 mandates additional preventive health care services for infants, children, and young adults (newborn through age 20) eligible for Medicaid. These mandates provide that children and adolescents under age 21 receive follow-up services for a medically necessary condition discovered in a screening examination, Early Preventative Screening and Diagnostic Testing (EPSDT), see Medicaid Services Manual (MSM) Chapter 1500; this includes prescription services.

C. CFR Title 42 and Section 1927 of the Social Security Act (SSA), require states to provide for a Drug Utilization Review (DUR) program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results SSA, Title 19, (g)(1)(A).

D. Section 1927 of the SSA allows a state to require a PA on any covered outpatient drug, providing the PA program complies with the requirements outlined in the act.

The SSA requires the establishment of a DUR board to monitor therapeutic appropriateness, use of generic products, overutilization and underutilization of drugs and quality of care consistent with protecting the health of program beneficiaries.

E. Chapter 422 of Nevada Revised Statute (NRS) amended by Assembly Bill (AB) 384 to require the Department of Health and Human Services (DHHS) to:

1. develop a list of preferred prescription drugs;

2. manage prescription drug use through the use of PA and step therapy; and

3. create the Pharmacy and Therapeutics (P&T) Committee.

F. U.S. Troop Readiness, Veteran's Health Care, Katrina Recovery and Iraq Accountability Appropriations Act 2007, Section 7002(b) of the act requires Medicaid outpatient drugs (defined in Section 1927(k)(2) of the SSA) will be reimbursable only if non-electronic written prescriptions are executed on a tamper-resistant prescription pad.

G. The Deficit Reduction Act of 2005 requires Fee-for-Service (FFS) State Medicaid programs to capture and report National Drug Codes (NDC) for outpatient drugs in order for the state to receive federal financial participation.

1202 RESERVED

# 1203 POLICY

The Division of Health Care Financing and Policy (DHCFP), Nevada Medicaid, reimburses pharmacies and practitioners for legend (prescription) and non-legend (over the counter) pharmaceuticals dispensed or administered to Medicaid recipients. All prescribers must have a license as a healthcare practitioner, such as a physician, podiatrist, osteopath, dentist, Advanced Practice Registered Nurse (APRN), physician's assistant, etc., keeping within the scope of their practice. DHCFP requires that pharmaceuticals are written, dispensed, and prescribed in accordance with the Nevada State Board of Pharmacy (BOP) regulations and enforcement.

## 1203.1 COVERAGE AND LIMITATIONS

A. Covered drugs are subject to PA and/or quantity limits and the following:

1. Section 1927(d)(1)(B)(i) of the SSA allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication, including any prescription dietary supplement/vitamin/mineral (other than prescription pre-natal vitamins or fluoride) without a Food and Drug Administration (FDA)-approved indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug, which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:

    a. American Hospital Formulary Service Drug Information;

    b. United States Pharmacopeia;

    c. DRUGDEX Information System; or

    d. Peer-reviewed medical literature.

2. Pharmaceuticals must be manufactured by companies participating in the Federal Medicaid Drug Rebate Program (MDRP).

3. Medicaid is mandated by federal statute to require all written (non-electronic) prescriptions for all outpatient drugs for Medicaid recipients to be on tamper-resistant prescription pads. This requirement does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. Refer to the MSM Addendum for more information on tamper-resistant prescription pads.

4. The Preferred Drug List (PDL) is a list of preferred outpatient drugs established by the Silver State Scripts Board (SSSB) (formerly known as the Pharmacy and Therapeutics (P&T) Committee). Reference Medicaid Operations Manual (MOM)

Chapter 200 for the SSSB bylaws. Pharmaceuticals not on the PDL, but within drug classes reviewed by the SSSB, require PA, unless exempt under NRS or federal law or excluded through recommendations of the SSSB or excluded by DHCFP.

a. Per NRS 422.4025 the following drug classes are excluded from any PDL restrictions:

1. Prescribed drugs for the treatment of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS);

2. Antirejection medications for organ transplants; and

3. Antihemophilic medications.

Additionally, the PDL must include the following drug classes as covered and preferred:

4. Any prescription essential for treating sickle cell disease and its variants; and

5. Prescribed drugs to prevent the acquisition of HIV/AIDS.

b. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard PDL Exception PA until, or if, the SSSB adds the drug class to the PDL and reviews the product or evidence.

c. New FDA approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the PDL and are not excluded under state plan or by NRS, are covered with an approved Standard PDL Exception prior authorization until SSSB can review the new evidence or drug.

d. Pharmaceuticals may require PA due to step therapy protocols regardless of inclusion in the PDL.

e. If the SSSB determines that there are no significant differences between drugs within specific classes based on clinical efficacy, safety, and outcomes for patients, DHCFP or its Quality Improvement Organization (QIO)-like vendor, may consider cost in determining which drugs are selected for inclusion on the PDL.

B. Standard PDL Exception Criteria

Drugs that have a "non-preferred" status are a covered benefit for recipients if they meet the coverage criteria.

1. Coverage and Limitations

   a. Allergy to all preferred medications within the same class;

   b. Contraindication to or drug-to-drug interaction with all preferred medications within the same class;

   c. History of unacceptable/toxic side effects to all preferred medications within the same class;

   d. Therapeutic failure of two preferred medications within the same class;

   e. If there are not two preferred medications within the same class, therapeutic failure only needs to occur on the one preferred medication;

   f. An indication which is unique to a non-preferred agent, and is supported by peer-reviewed literature or an FDA-approved indication;

   g. Psychotropic, Antidepressant Medication – Continuity of Care;

      Recipients discharged from an institution on non-preferred psychotropic and/or non-preferred anti-depressant medication(s), their drugs will continue to be covered by Medicaid for up to six months to allow the recipient time to establish outpatient mental health services;

   h. For atypical or typical antipsychotic, anticonvulsant, and antidiabetic medications, the recipient demonstrated therapeutic failure on one preferred agent.

   i. The drug is being prescribed for a psychiatric condition and all of the following criteria have been met:

      1. The drug has been approved by the FDA with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is supported by medical or scientific evidence; and the prescriber provides supportive clinical documentation demonstrating the approved diagnosis or evidence for use;

      2. The prescriber of the drug is one of the following:

         a. A psychiatrist;

b. A physician assistant under the supervision of a psychiatrist;

c. An APRN who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or

d. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph a., b., or c., if the closest practitioner listed in subparagraph a., b., or c., who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured, and

3. The prescriber believes based on the medical history of the insured or reasonably expects each preferred drug within the same class to be ineffective at treating the psychiatric condition and the prescriber provides supportive clinical documentation demonstrating the reasoning for use of the drug.

4. For the purposes of this section, "psychiatric condition" means a mental disorder for which criteria are prescribed in the current version of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), published by the American Psychiatric Association (APA).

3. PA forms are available through the Nevada Medicaid Pharmacy Portal.

C. Excluded

DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight management.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

5. Drug Efficacy Study Implementation (DESI) list "Less than Effective Drugs": In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is identical, related or similar to the DESI

drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the MDRP. This listing is available on the CMS website.

This includes pharmaceuticals designated "ineffective" or "less than effective" (including identical, related, or similar drugs) by the FDA as to substance or diagnosis for which prescribed.

6. Pharmaceuticals considered "experimental" as to substance or diagnosis for which prescribed. Pharmaceuticals manufactured by companies not participating in the federal MDRP unless rated "1-A" by the FDA.

7. Agents used for impotence/erectile dysfunction.

8. Prescription dietary supplements/vitamins/minerals (other than prescription pre-natal vitamins or fluoride) without an FDA-approved indication.

D. Refills

A refill is a prescription subject to the limitations below:

1. Authorized refills are valid only from the pharmaceutical provider dispensing the original prescription, pursuant to Nevada Administrative Code (NAC) Chapter 639.

2. Refill intervals must be consistent with the dosage schedule indicated on the original prescription. If a prescription is for a 34-day supply, a consistent refill would be filled in 30 days; an inconsistent refill date would be filled in 20 days from the original fill. Lost medications: Nevada Medicaid does not pay for replacement of lost, stolen or otherwise destroyed medications even if a physician writes a new prescription for the medication. It is the responsibility of the recipient to replace these medications. PA may be granted in life-threatening situations and for maintenance medications only. See "Maintenance Medications" section for more information on maintenance medications.

E. Early Refills

1. Nevada Medicaid only pays for up to a 34-day supply of medications (100-day supply for maintenance medications) for recipients each month. A prescription refill will be paid for by Nevada Medicaid only when 80% of the non-controlled substance prescription, and 90% of the controlled substance prescription, is used in accordance with the prescriber's orders on the prescription and on the label of the medication.

2. In areas for which an emergency or disaster has been declared, Medicaid will waive the requirement for 80% of a non-controlled substance prescription to be used before paying for refills. Prescriptions for non-controlled substances will be

covered up to 30 days after the declaration or until the end of the emergency or disaster, whichever is later.

3. In the instance that a recipient will be out of town when a refill is due, the pharmacist may enter the appropriate override code to allow an early refill. This override will be monitored by Nevada Medicaid for misuse/abuse by the recipient and/or provider.

4. Medicaid will not pay for an early prescription refill when gross negligence or failure to follow prescriber's prescription instructions has been displayed by the recipient.

F. Maintenance Medications

1. Exceptions to the 34-day supply of medications are allowed for maintenance medications.

2. Maintenance medications are required to be filled in three-month (100-day) supplies.

3. A one-time initial fill of <3 months will be allowed for the first fill to assure tolerability and compliance.

4. Prescription quantities may be reviewed; in those cases where less than a 30-day supply of maintenance drug is dispensed without reasonable medical justification, the dispensing fee may be disallowed.

5. The following drug categories are considered maintenance medications and are required to be filled in three-month (100-day) supplies:

a. Antianginals;

b. Antiarrhythmics;

c. Antidiabetics;

d. Antihypertensives;

e. Cardiac Glycosides;

f. Diuretics;

g. Estrogens;

h. Progesterone; and

i. Statins.

6. Contraceptive drugs are considered maintenance medication. Contraceptive drugs that are approved by the FDA are covered up to a 12-month supply.

   a. This includes a drug for contraception or its therapeutic equivalent; insertion of a device for contraception; removal of such a device that was inserted while the insured was covered by the same policy of health insurance; education and counseling relating to contraception; management of side effects relating to contraception; and voluntary sterilization for women.

   b. Up to three months of contraception may be dispensed immediately, and up to nine months of contraception may be dispensed at the subsequent visit.

   c. For a refill following the initial dispensing of a contraceptive drug, the provider may dispense up to a 12-month supply or any amount that covers the remainder rolling year.

   d. If a prescription for a contraceptive drug is less than a one-year period, the provider must dispense the contraceptive in accordance with the quantity specified in the prescription order.

7. Anticonvulsants and thyroid preparations are considered maintenance medications but are not required to be filled in a three-month (100-day) supply.

8. Medications administered in a skilled nursing facility or physician's office are exempt from the three-month (100-day) supply requirement.

9. In long-term care facilities, if the prescriber fails to indicate the duration of therapy for a maintenance drug, the pharmacy must estimate and provide at least a 30-day supply. Exceptions may be based on reasonable stop orders. (For oral liquid medications only, a 16 fluid ounce quantity will be considered sufficient to fulfill the 30-day supply requirement).

G. Emergency supply of medication

1. In an emergency situation, dispensing of up to a 96-hour supply of covered outpatient drugs that require PA will be allowed.

2. Nevada Medicaid requires prior payment authorization for medications identified as requiring PA.

3. The physician must indicate the diagnosis on the prescription (preferably with an International Classification of Disease (ICD) code) to support the use of the emergency policy.

4. As a follow-up to the dispensing of the emergency supply of medication, the provider must contact the QIO-like vendor to obtain a verbal verification number.

5. An approved PA (if required) will be necessary to get additional medication.

H. NCU

All coverage and limitation policies and rules, including any PA requirements, outlined in this chapter apply to NCU recipients as well as Nevada Medicaid FFS recipients. There are no exceptions.

I. Vaccines

Nevada Medicaid recognizes the importance of preventative health care through vaccines and immunizations. Unless otherwise stated in this chapter, vaccines are covered without PA. Reference Appendix A of this chapter.

1. Childhood vaccines: All childhood vaccines are covered without PA under the Healthy Kids Program. Refer to MSM Chapter 1500, Healthy Kids Program for more information on childhood vaccines.

2. Adult vaccines: Adult vaccines such as tetanus, flu vaccine, and pneumococcal vaccine are covered without PA. For a list of covered adult vaccines, please reference the Physician's Fee Schedule.

3. Human Papillomavirus (HPV) Vaccine: The 9-valent HPV vaccine (for both males and females) is covered for Medicaid eligible recipients ages nine years through 45 years, based on the US FDA approved indications.

   The HPV vaccines are available through the State Division of Public and Behavioral Health (DPBH) as part of the Vaccines for Children (VFC) program for eligible females and males age nine through 18 years. Please refer to MSM Chapter 1500 for more information on the VFC program.

4. Pharmacies may administer childhood and adult vaccines/immunizations.

   a. Pharmacies must adhere to all Nevada State BOP regulations regarding vaccine/immunization administration including certification to administer as documented in NAC Chapter 639.

b. Pharmacies must receive childhood vaccinations through the VFC Program. DHCFP or Nevada Medicaid and NCU do not reimburse for vaccines included in the VFC Program.

c. Covered vaccinations not included in the VFC Program will be reimbursable per the Nevada Medicaid and NCU Pharmacy Manual.

d. If the pharmacist administers the vaccinations, the dispensing fee will not be reimbursed. An administration fee is paid instead.

J. Pharmacist Submitted PAs

1. DHCFP will allow pharmacists to submit a PA if:

a. The requesting pharmacist has access to the recipient's medical records.

K. Dispensing Practitioners:

1. Must have a current Certificate of Registration through the Nevada State BOP. Refer to NRS 639.070 and NAC 639.390; and

2. Must be enrolled with Nevada Medicaid provider enrollment as a Provider Type (PT) 28; and

3. Dispensing practitioners' offices must be located in the State of Nevada; and

4. All PA criteria and quantity limitations apply to dispensing practitioner claims; and

5. Only PT 28 can be reimbursed for a dispensing fee; and

6. All claims must be submitted in the National Council for Prescription Drug Programs (NCPDP) format through Medicaid's Point of Sale (POS) system; and

7. All dispensing practitioners must be compliant with all applicable BOP statutes and regulations.

1203.1A PROVIDER RESPONSIBILITY

1. The pharmaceutical provider will maintain records for all prescriptions dispensed to eligible recipients as may be required.

a. The provider will allow, upon request of proper representative, access to all records that pertain to Medicaid recipients for fiscal review, audit, or utilization review.

b. All fiscal records are to be maintained for a period of six years or as specified in federal regulation.

2. Utilization Control

a. Prospective (Concurrent) Drug Utilization Review (Pro-DUR)

Pro-DUR functions will be carried out via the POS Systems.

1. Pro-DUR edits apply to POS claims.

2. Long Term Care (LTC) claims are subject to all Pro-DUR edits that apply to retail.

3. Providers may submit override codes using the NCPDP standard interactive DUR codes. Override codes may be submitted on the initial claim. A denied claim does not have to be on file.

4. No long-term override codes are issued; codes must be entered each time errors occur. Reference the Nevada Medicaid and NCU Pharmacy Manual for more information on the current Pro-DUR edits and override procedures.

5. All drugs are subject to quantity limitations. Refer to the Nevada Medicaid and NCU Pharmacy Manual for established quantity limits.

b. Retro DUR

Both recipient and provider profiles (i.e. claim payments) are reviewed to identify patterns of excess. Verification of receipt of services is ongoing on a sample basis. Providers may be audited on site.

c. DUR

Nevada Medicaid policy and federal law allows the state appointed DUR Board to conduct review of the information compiled about individual clients and providers and allows the DUR Board to educate Medicaid providers about the changes in drug therapeutics. Educational programs may include information such as drug interactions between medications that physicians have prescribed for the clients and medications they are prescribing that are unnecessarily expensive. In this case, educational efforts will be directed to help providers improve their efficiency in the allocation of the finite resources available for Medicaid clients.

d. Eligibility

Please refer to MSM Chapter 100 for information on Medicaid eligibility, eligibility verification, and the Eligibility Verification System (EVS).

e. Pharmacy Lock-In Program

The Pharmacy Lock-In Program is intended to prevent recipients from obtaining excessive quantities of controlled substances through multiple visits to physicians, clinics, and pharmacies. When a recipient has shown patterns of abuse/misuse of Nevada Medicaid benefits, or DHCFP has determined that the recipient requires close medical management, the recipient may be "locked-in" to a specific pharmacy. This means that Medicaid will only pay for controlled substance prescriptions at a single pharmacy.

1. Pharmacy Lock-In Criteria.

a. DHCFP conducts a comprehensive clinical review to determine whether a recipient should be "locked-in" to a single pharmacy using the following criteria:

1. The recipient has filled ten or more controlled substance prescriptions in the past 60-day period (includes controlled substance pharmaceuticals given in the emergency room); and

2. One of the following:

a. The recipient has utilized more than one pharmacy in the past 60-day period; or

b. The recipient has utilized more than three physicians in the past 60-day period; or

c. The recipient has utilized the emergency room(s) for receiving controlled substances; or

d. The recipient has been diagnosed with a drug dependency related condition; or

e. The dispensed quantity per prescription of controlled substances appears excessive by the clinical review team; or the recipient has other noted drug seeking behaviors.

b. Recipients who are locked-in to one pharmacy are issued a written Notice of Decision (NOD) 15 days prior to the implementation of the pharmacy restriction. The NOD includes the individual's right to request a fair hearing within 90 days if he/she disagrees with the findings and/or DHCFP's action.

c. DHCFP assigns the pharmacy most frequently used by the recipient for access of controlled substance prescriptions. Recipients may change their locked-in pharmacy by contacting their Medicaid District Office.

d. Upon implementation of pharmacy lock-in, the POS system will not allow another pharmacy to bill for controlled substance prescriptions, and a message will be given at the time of service to notify the pharmacy that the recipient is locked-in. Any non-controlled substance prescriptions can be filled at any pharmacy.

2. Duration of Lock-In Status.

a. Initially, a recipient remains in lock-in status for a period lasting 36 months. Utilizing the pharmacy lock-in criteria, DHCFP conducts a clinical review not less than a month prior to the 36-month mark to determine whether the recipient will remain or may be removed from lock-in status.

1. A recipient may be placed on a second lock-in period lasting 108 months, if determined by DHCFP that the recipient is continuing to obtain excessive and/or inappropriate controlled substance prescription or requires additional close medical management or monitoring. Recipients placed on a second lock-in period are re-evaluated at every 108-month period to determine whether lock-in status is still appropriate or may be removed from lock-in status.

2. A written NOD is issued by DHCFP 15 days prior to the effective date of continuation or removal of the pharmacy restriction. The NOD includes the individual's right to request a fair hearing within 90 days if he/she disagrees with the findings and/or DHCFP action.

b. Recipients in lock-in status who are transitioning from a Nevada Medicaid contracted Managed Care Organization (MCO) will start a new initial 36-month lock-in period.

3. Pharmacy Lock-In Exemption

a. Some circumstances allow a recipient to receive medications from a pharmacy other than their assigned locked-in pharmacy. A Pharmacy may call the Technical Call Center to request an override if:

1. The locked-in pharmacy is out of stock.

2. The locked-in pharmacy is closed.

3. The recipient is out of town and cannot access the locked-in pharmacy.

3. Generic Substitution

Per NRS Chapter 639, if the practitioner has not indicated that generic substitution is prohibited, the pharmacy provider must dispense, in substitution, another drug which is available to him/her if the other drug:

a. is less expensive than the drug prescribed by brand name;

b. is biologically equivalent to the drug prescribed by brand name;

c. has the same active ingredient or ingredient of the same strength, quantity, and form of dosage as the drug prescribed by brand name; and

d. is of the same generic type as the drug prescribed by brand name the least expensive of the drugs that are available to him for substitution.

The pharmacy provider shall substitute the least expensive of the drugs available to him/her for substitution.

4. Prescriber Brand Certification

Upper Limit cost limitations specified in this Chapter will not apply when a prescriber certifies that a specific brand of medication is medically necessary for a particular patient.

The physician should document in the patient's medical record the need for the brand name product in place of the generic form. The procedure for certification must comply with the following:

a. The certification must be in the physician's own handwriting.

b. Certification must be written directly on the prescription blank.

c. The phrase "Dispense as written" is required on the face of the prescription. For electronically transmitted prescriptions "Dispense as written" must be noted. Not acceptable: A printed box on the prescription blank checked by the prescriber to indicate "brand necessary" or a handwritten statement transferred to a rubber stamp and then stamped on the prescription.

d. A PA is required to override genetic substitution.

e. Certification is not required if a generic is not manufactured.

f. A fax copy/verbal order may be taken by the pharmacist from the physician, but the pharmacy must obtain an original printed copy and keep on file.

1203.1B SERVICE DELIVERY MODEL

For the rate and reimbursement methodology see MSM Chapter 700, Rates. For POS claims refer to the Pharmacy Manual, and for Medicaid Management Information System (MMIS) claims refer to the Nevada Medicaid and NCU Billing Manual.

1. Institutional settings

a. Medical/Surgical, Specialty, Psychiatric Hospitals, and free-standing inpatient hospice facilities – All pharmacy services are included in the daily per diem rate for inpatient services, which are billed through MMIS.

b. LTC

1. Nursing Facilities (NF) – Legend (prescription) pharmaceutical services are excluded from the daily per diem facility rate. This includes compound prescriptions and Total Parenteral Nutrition (TPN) solution and additives. Legend pharmaceuticals are billed separately directly by a licensed pharmacy through POS.

Non-legend (over the counter) pharmaceuticals are not separately reimbursable by DHCFP.

2. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) – Legend and non-legend pharmaceuticals are excluded from the facility rate. Pharmaceuticals are billed directly by a licensed pharmacy through POS.

3. Hospice services in NFs, all drugs related to the documented terminal illness and palliative, symptom relief are to be covered by the hospice and will not be reimbursed by DHCFP. Refer to MSM Chapter 3200, Hospice, for more information.

2. Outpatient Pharmaceuticals

a. Covered outpatient drugs (COD(s)) are reimbursed separately from medical services, in the following settings, in accordance with Section 1927 of the SSA.

1. Retail pharmacies (billed through POS).

2. Home Infusion Therapy (HIT)/Free Standing Infusion Clinics (billed through POS).

   a. Disposable supplies are billed separately with a 33 PT number (billed through MMIS).

   b. Refer to the Nevada Medicaid and Check Up Pharmacy Billing Manual.

3. COD(s) administered in an outpatient setting, such as a physician's office Billing Reference for Physician Administered Drugs (NVPAD).

   a. COD(s) are billed utilizing the appropriate NDC and NDC quantity (billed through MMIS.

   b. The administration of the drug is billed using the appropriate Current Procedural Terminology (CPT) code (billed through MMIS).

4. Hospital based outpatient clinics.

   a. COD(s) are billed utilizing the appropriate NDC and NDC quantity (billed through MMIS).

   b. The administration of the drug is billed using the appropriate CPT code, (billed through MMIS).

5. End Stage Renal Disease (ESRD) Facilities.

   a. Any COD(s) not included in the Prospective Payment System (PPS) Rate are billed using the appropriate NDC and NDC quantity.

   b. The administration of the drug is billed using the appropriate CPT code, (billed through MMIS).

   c. COD(s) included in the PPS Rate as documented in the CMS Manual System, Publication # 100-04, Medicare Claims Processing, Transmittal 2134 will deny if billed separately.

6. Emergency Rooms.

   a. COD(s) are billed utilizing the appropriate NDC and NDC quantity (billed through MMIS).

b. CODs are not reimbursed separately, in the following settings, in accordance with 1927(k)(2) of the SSA.

1. Ambulatory Surgical Centers (ASC). COD(s) are included in the facility rate. COD(s) may not be billed separately.

2. Outpatient facilities/clinics/Federally Qualified Health Centers (FQHCs) that are paid per encounter, cannot be reimbursed separately for CODs when drugs are included in their encounter rate.

3. Outpatient hospice reimbursement for CODs related to the documented terminal illness and palliative, symptom relief, are to be covered by the hospice and will not be reimbursed by DHCFP. Refer to MSM Chapter 3200, Hospice, for more information.

3. Disposable Medical Supplies

Please refer to MSM Chapter 1300, Durable Medical Equipment (DME), for instructions on billing and any applicable limitations for these items.

4. Unit Dose (Repackage and Re-Stock) Repackage

Nevada Medicaid provides reimbursement incentives for LTC providers who repackage non-unit dose pharmaceuticals; An additional $0.43 per claim is given on pharmaceuticals that are repackaged for unit dose dispensing. Pharmaceuticals that First Data Bank classifies as unit dose products are not covered by this policy.

This incentive is available only to pharmacies supplying long-term care inpatients. The pharmacy provider must apply to the QIO-like Vendor Pharmacy Department to enroll in this incentive program.

In accordance with the CMS, State Medicaid Director Letter (SMDL) 06-005, repackaging of pharmaceuticals must be in compliance with the Nevada State BOP. In addition, NFs must properly credit the Medicaid program for the return of unused prescription medicines upon discontinuance of the prescription or transfer, discharge, or death of a Medicaid beneficiary. This is to ensure there is no double billing of the medication.

5. Coordination of Benefits (COB)

On-line COB (cost avoidance) is part of the Nevada Medicaid POS system.

a. If Nevada Medicaid is the recipient's secondary carrier, claims for COB will be accepted.

b. Nevada Medicaid is always the payer of last resort.

c. Other coverage will be identified by the presence of other carrier information on the recipient eligibility file.

d. If the recipient shows other coverage, the claim will be denied. The POS system will return a unique client-identified carrier code identifying the other carrier, the recipient's policy number, and the carrier name in the additional message filed. It is possible that a recipient may have more than one active other carrier; in that case, the returned code will be from the first carrier, subsequent codes will be returned until fully exhausted. Providers will be required to submit this code OTHER PAYER ID (#340-7C) field as part of the override process.

e. Even if "no other insurance" is indicated on the eligibility file, the claim will be processed as a Third-Party Liability (TPL) claim if the pharmacy submits.

f. If other insurance is indicated on the eligibility file, the claim will be processed as a TPL regardless of what TPL codes the pharmacy submits.

g. In all cases, the Nevada Medicaid "allowed amount" will be used when calculating payment. In some cases, this may result in a "0" payment, when the insurance carrier pays more than the Medicaid "allowable amount."

h. In order to facilitate the TPL/COB process, Nevada Medicaid will allow providers to override "days supply limits" and/or "Drug Requires prior authorization" conditions by entering a value of "5" (exemption from prescription limits) in the PA/MC CODE field (NCPCP #416DG) if there are no PA requirements on these drugs from the primary insurer.

6. Pharmacy Billing Process

a. NCPDP Standard Billing Units

Nevada Medicaid reimburses for outpatient pharmaceuticals according to NCPDP "Billing Unit Standard Format" guidelines. The standard provides for the billing of pharmaceuticals in one of three billing units for all drug products. These units are "each," "milliliter (ml)," and "gram (g)." The following guidelines are to be used when billing Nevada Medicaid for pharmaceuticals:

Tablets, Capsules, Suppositories, Pre-filled Syringes: must be billed by "each" or by "mls." For example, if 30 tablets of Metformin are dispensed, the quantity will be 30.

Liquids, Liquid Orals, Suspensions, Solutions, Ophthalmic/Otic Solutions: must be billed by mls. For example, if 560ml of guaifenesin is dispensed, the quantity entered will be 560.

Please note:

Ounces must be converted to ml (1 ounce = 30 ml).

Liters must be converted to ml (1L = 1000 ml).

Ointments, Bulk Powders: must be billed by grams. For example, if a two-ounce tube of oxiconazole nitrate is dispensed, the quantity entered will be 60.

Please note:

Ounces must be converted to grams (1 ounce = 30g, ½ ounce = 15g). Oral Contraceptives/Therapy packs: must be billed per "each" tablet dispensed, not the number of packages. For example, Ortho Tri-Cyclen® is a 28-day dial pack, the quantity entered will be 28.

Transdermal Patches/Powder Packets: must be billed per "each" patch/packet dispensed, regardless of whether they are pre-packaged in a box or come in individual pouches/packets. For example, Catapres-TTS® comes in a box of four patches. If two of these boxes are dispensed, the quantity entered will be eight.

Inhalers and Aerosols: must be billed as either grams or ml, as specified by the manufacturer on the labeling. For example, a 90 microgram (mcg)/inh Albuterol Inhaler has a total of 17gm in the canister. If one of these is dispensed, 17 will be quantity entered.

Topical Products: must be billed as either grams or ml, as specified by the manufacturer on the labeling.

Please note: Ounces must be converted to grams or ml.

1 ounce = 30ml
1 ounce = 30g

Reconstitutables (oral, otic, ophthalmic): must be billed per ml that are/will be in the bottle after reconstitution according to the manufacturer's instructions.

Liquid Injectables (vials, ampoules): must be billed by milliliters (ml). For example, if a 10ml vial of Novolin® 70/30 is dispensed, the quantity entered will be 10.

Powdered Injectables (vials): must be billed by "each" vial given per dose. For example, if the recipient receives ampicillin 1g every six hours for one week, the quantity entered will be 1, as only one vial is used per dose (assuming a 1gm vial is used), and the number of doses entered will be 28 (four per day x seven days).

Please note: If the product is supplied with a diluent, the quantity entered is only the number of powdered vials dispensed, the diluent is not factored in.

Intravenous (IV) Solutions: must be billed in ml administered per dose. For example, if a recipient receives 250ml of Normal Saline four times per day, the quantity entered will be 250, as that is the quantity per dose.

Blood Derived Products: products may vary in potency from batch to batch. Antihemophilic products must be billed as the number of antihemophilic units dispensed (each). Prolastin® must similarly be billed as the number of milligrams dispensed (each).

Kits: defined as products with at least two different or discreet items (excluding diluents, applicators, and activation devices) in the same package, intended for dispensing as a unit. Kits carry only a single NDC. Kits are intended to be dispensed as a unit and should be billed as a unit of each kit dispensed (each).

For further information, refer to the NCPDP Billing Unit Standard Format Official Release.

b. Provider Numbers

The state National Association of Boards of Pharmacy (NABP) provider number is to be used and entered when billing online using the POS system or when using the UCF.

7. State Maximum Allowable Cost (SMAC)

a. SMAC is the upper reimbursement limit for multi-source outpatient pharmaceuticals established by DHCFP or QIO-like vendor.

1. DHCFP or the QIO-like vendor will perform ongoing market analysis to monitor pricing patterns and product availability.

2. DHCFP or the QIO-like vendor will perform monthly updates of the drugs subject to the SMAC.

b. Providers may appeal the current SMAC for a pharmaceutical product if a provider determines that a particular multi-source drug is not available at the current SMAC reimbursement.

1. The pharmacy must contact the QIO-like vendor technical call center to initiate the appeal.

2. Information needed to make a decision will include the NDC number, manufacturer, drug name, strength and price paid. A faxed copy of the actual invoice for the drug may be requested.

3. Inquiries not resolved by the technical call center are forwarded to the QIO-like vendor's SMAC Coordinator for investigation and resolution.

4. If it is determined the SMAC is negatively impacting access to care for recipients, the SMAC Coordinator has the authority to:

   a. Adjust SMAC pricing for the particular claim being appealed; and

   b. Make changes to the SMAC pricing file.

5. Appeals will be responded to within three working days of the referral to the SMAC Coordinator.

1203.1C PRIOR AUTHORIZATION PROCEDURES

1. PA requests may be done via phone, fax or via the internet. A facsimile signature stamp is acceptable on faxed PA requests.

2. PA requests must be submitted on the appropriate Prior Authorization Request form.

3. LTC drug claims are subject to PA requirements.

4. The QIO-like vendor will process the PA request within 24 hours of receipt.

   a. The requesting practitioner will be advised of the PA status (approval, denial, pending further information) within 24 hours of receipt.

   b. For PA requests in which the QIO-like vendor has pended the request for further information, the PA will deny if the practitioner does not respond to a request for further information within three working days.

5. An approved PA will be entered in the POS system prior to the dispensing of the medication. There may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).

6. The Nevada Medicaid QIO-like vendor will send all NOD denial of service letters. Reference MSM Chapter 3100 for the information on hearings.

7. Refer to the Nevada Medicaid and Check Up Pharmacy Billing Manual for more information.

1203.2 INTRAVENOUS (IV) THERAPY

For specific instructions related to billing via the POS system, refer to the Nevada Medicaid Check-Up Pharmacy Billing Manual.

A. Billing Guidelines

IV therapy is billed through the pharmacy POS system using the multi-ingredient functionality. Drug coverage edits and PA edits will be processed at the individual ingredient level.

B. LTC

1. For recipients in LTC, a daily dispensing fee of $10.17 will be applied to IV therapy claims. This dispensing fee will be multiplied by the number of days the therapy was provided.

   a. Non-Billable Items

      IV hydration therapy of standard fluids without additives (e.g., antibiotics, potassium, and heparin) and supplies associated with IV therapy, enteral nutrition and TPN administration are included in Nevada Medicaid's LTC/NF rate and may not be billed as a separate charge.

   b. Billable Items

      IV Drugs/TPN for recipients in LTC facilities may be billed as a separate charge. Refer to MSM Chapter 500, Nursing Facilities, for further information.

# 1204 HEARINGS

Please reference MSM Chapter 3100 for the Medicaid Hearings process.

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***All drugs in Appendix A may be subject to Quantity Limitations.***
***Check the Nevada Medicaid and Nevada Check Up Pharmacy Manual for a listing of the exact Quantity Limitation.***

1. DRUGS REQUIRING A PRIOR AUTHORIZATION AND/OR QUANTITY LIMITATIONS

A. Proton Pump Inhibitors (PPIs)

Therapeutic Class: Proton Pump Inhibitors
Last Reviewed by the Drug Use Review (DUR) Board: April 30, 2020

PPIs are subject to prior authorization (PA) and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

a. The recipient is not exceeding once daily dosing (quantity limit of one unit/day).

b. Requests for PPIs exceeding once daily dosing must meet one of the following:

1. The recipient has failed an appropriate duration of once daily dosing; or

2. The recipient has a diagnosis of a hypersecretory condition (e.g., Zollinger-Ellison Syndrome), esophagitis, Barrett's esophagitis, reflux esophagitis, or treatment of an ulcer caused by H. Pylori.

c. PA Guidelines:

1. PA approval will be for up to 12 months.

B. Pyrukynd® (mitapivat)

Therapeutic Drug Class: Pyruvate Kinase Activators
Last Reviewed by DUR Board: October 20, 2022

Pyrukynd® (mitapivat) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity.

1. Approval will be given if the following criteria are met and documented:

   a. Recipient is at least 18 years of age; and

   b. Recipient has a confirmed diagnosis of pyruvate kinase deficiency (PKD) as defined by the documented presence of at least two variant alleles in the PKLR gene, of which at least one was a missense variant; and

   c. Recipient is not homozygous for the c.1436G>A (p.R479H) variant; and

   d. Recipient does not have two non-missense variants (without the presence of another missense variant) in the PKLR gene; and

   e. Recipient has a baseline serum hemoglobin level <10 grams (g)/deciliter (dL) or required more than six transfusions in the prior year; and

   f. Other causes of hemolytic anemia have been ruled out (e.g., immune hemolysis, other enzyme deficiencies, vitamin/mineral deficiencies); and

   g. Recipient does not have moderate or severe hepatic impairment; and

   h. Prescriber will advise patients currently on hormonal contraceptives to use an alternative non-hormonal contraceptive method or add a barrier method of contraception during treatment; and

   i. Quantity limit is 60 tablets/30 day (max dose 100 milligrams (mgs)/day).

2. Recertification Requests:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient has shown a beneficial response to therapy compared to pre-treatment baseline in one or more of the following:

      1. Hemoglobin (Hb) response (defined as a ≥1.5g/dL increase in Hb level without transfusion over a four week or longer time period; or

      2. Transfusion reduction response (defined as a ≥33% reduction in the number of red blood cell [RBC] units transfused compared to historical transfusion burden); or

3. Recipient had an increase in Hb and/or decrease in transfusion requirement, to a lesser extent than the above, and also had an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, lactate dehydrogenase [LDH], haptoglobin).

c. Recertification will be approved for six months.

3. PA Guidelines:

a. PA will be approved for six months.

C. Agents Used for the Treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD)

Therapeutic Class: ADD/ADHD Agents
Last Reviewed by the DUR Board: April 25, 2019

Agents for the treatment of ADD/ADHD are subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria is met and documented:

a. General Criteria (Children and Adults)

1. A diagnosis of ADD/ADHD or other Food and Drug Administration (FDA) approved diagnosis.

2. Only one long-acting stimulant (amphetamine and methylphenidate products) may be used at a time.

3. A 30-day transitional overlap in therapy will be allowed.

4. Other treatable causes of ADD/ADHD have been ruled out.

b. ADD/ADHD Criteria (Children up to age 18 years)

1. The recipient is at least three years of age (short-acting stimulants) or at least six years of age (long-acting stimulants, long-acting alpha agonists, atomoxetine).

An initial evaluation or regular examination has been done within the past 12 months with the treating prescriber.

2. Exception Criteria

a. Prescriptions for ADD/ADHD medications do not require PA for children five years of age, up to 18 years of age, if the following criteria are met and documented:

1. The recipient is at least five years of age for short acting stimulants or at least six years of age for long-acting stimulants, long-acting alpha agonists, atomoxetine;

2. The medication is prescribed by a psychiatrist; and

3. An International Classification of Diseases (ICD) code for ADD with or without hyperactivity is documented on the prescription and transmitted on the claim.

3. PA Guidelines

a. PA approval will be for one year.

D. Growth Hormones

Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 28, 2022

Growth Hormones are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Approval will be given if the following criteria are met and documented:

1. Children (with open epiphyses and with remaining growth potential) must meet all the following:

a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy; and

b. The recipient has had an evaluation ruling out all other causes for short stature; and

c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids, or gonadotropic hormones.

The recipient must then meet one of the following:

1. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is at least two standard deviations below the mean or below the fifth percentile for the patient's age and gender and the bone age is <16 years for male recipients or <14 years for female recipients; or

2. The recipient has a diagnosis of Prader-Willi Syndrome; or

3. The recipient has a diagnosis of Turner Syndrome, is female and has a bone age of <14 years; or

4. The recipient has a diagnosis of chronic renal insufficiency (<75 milliliter (mL)/minute), and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

5. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and the height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

6. The recipient is a newborn infant with evidence of hypoglycemia, and has low growth hormone level (<20 nanograms (ng)/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP) 3 (no stimulation test required for infants); or

7. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender and their bone age is <16 years for male or <14 years for female.

   And recipient must meet one of the following:

   a. The recipient has failed two growth hormone stimulation tests (<10 ng/mL); or

   b. The recipient has failed one growth hormone stimulation test (<10 ng/mL) and one IGF-1 or IGFBP-3 test; or

   c. The recipient has failed one growth hormone stimulation test (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), adrenocorticotropic hormone (ACTH) or antidiuretic hormone (ADH)).

2. Adults (with closed epiphyses, and no remaining growth potential) must meet all the following:

   a. The recipient is being evaluated by an endocrinologist; and

   b. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids, or gonadotropic hormones; and

   c. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to

structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation); and

The recipient must then meet one of the following:

1. The recipient has failed two growth hormone stimulation tests (<5 ng/mL); or

2. The recipient has failed one growth hormone stimulation test (<5 ng/mL) and one IGF-1 or IGFBP-3 test; or

3. The recipient has failed one growth hormone stimulation test (<5 ng/mL) or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH), and has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.

3. Continued authorization will be given for recipients (up to age 21, with remaining growth potential) who meet all the following:

   a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age, or Turner Syndrome; and

   b. The recipient's epiphyses are open; and

   c. The recipient's growth rate on treatment is at least 2.5 cm/year; and

   d. The recipient does not have evidence of an expanding lesion or tumor formation; and

   e. The recipient has not undergone a renal transplant.

4. Continued authorization will be given for recipients (age 21 years and older, with closed epiphyses and no remaining growth potential) who meet all the following:

   a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease; and

   b. There is documentation of improvement in clinical manifestations associated with growth hormone deficiency

5. PA Guidelines

a. Initial PA will be for six months.

b. Recertification approval will be for 12 months.

b. Serostim® (somatropin)

1. Approval will be given if the following criteria are met and documented:

a. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and

b. The medication is indicated to increase lean body mass, body weight and physical endurance; and

c. The recipient is receiving and is compliant with antiretroviral therapy (ART); and

d. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kilograms (kg)/meter (m)$^2$; and

e. The recipient has experienced an adverse event, allergy, or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent; and

f. The recipient has experienced an adverse event, allergy, or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone) or the recipient has a contraindication to treatment with these agents.

2. PA Guidelines:

a. PA approval will be for 12 weeks.

c. Zorbtive® (somatropin)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of short bowel syndrome; and

b. The recipient is aged 18 years or older; and

c. The medication is being prescribed by or following a consultation with a gastroenterologist; and

d. The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. PA Guidelines

a. Initial authorization will be approved for six months.

b. Recertification requests will be approved for 12 months.

d. Somavert® (pegvisomant)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of acromegaly; and

b. The recipient is 18 years age or older; and

c. One of the following:

1. The recipient has an inadequate response to one of the following:

a. Surgery; or

b. Radiation Therapy; or

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; or

2. The recipient is not a candidate for all the following:

a. Surgery; and

b. Radiation Therapy; and

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; and

d. The recipient has tried and failed, a contraindication, or intolerance to generic octreotide (a somatostatin analogue); and

e. The medication is prescribed by or in consultation with an endocrinologist.

2. Recertification Criteria:

a. The recipient must meet the following:

1. The recipient must have a documented positive clinical response to Somavert® therapy (e.g., biochemical control; decrease or normalization of IGF-1 levels).

3. PA Guidelines:

a. Initial authorization will be approved for 12 weeks.

b. Recertification approval will be approved for 12 months.

e. Skytrofa® (lonapegsomatropin-tcgd)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is one year or age or older; and

b. Recipient's weight is >11.5kg; and

c. Recipient has growth failure secondary to growth hormone deficiency (GHD); and

d. Recipient has short stature as defined by height that is ≥2 standard deviations below the mean for chronological age; and

1. Recipient has hypothalamic-pituitary defects (e.g., major congenital malformation, tumor, or irradiation) and a deficiency of ≥1 additional pituitary hormone; or

2. Recipient had an inadequate response to growth hormone (GH) provocation tests on two separate stimulation tests as defined as a serum peak GH concentration <10 ng/mL; and

e. Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypercortisolism).

2. Recertification Criteria:

a. Recipient must continue to meet the initial criteria; and

b. Recipient has shown a beneficial response compared to pre-treatment baseline (with lonapegsomatropin-tcgd or somatropin [if used as switch maintenance]) as evidenced by greater than or equal to one of the following:

1. Improvement in height; or

2. Improvement in growth velocity.

3. PA Guidelines:

a. PA approval will be given for 12 months.

E. Over-the-Counter (OTC) Drugs

Last Reviewed by the DUR Board: N/A

OTC drugs are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. OTC drugs must be FDA approved and manufactured by pharmaceutical companies participating in the Federal Medicaid Drug Rebate Program.

   b. OTC drugs are limited to two prescription requests for medications within the same therapeutic class.

   c. Nevada Medicaid will reimburse up to the OTC Maximum Allowable Cost (MAC) listed in the OTC MAC table. Refer to the Nevada Medicaid Nevada Check Up Pharmacy Manual for details.

   d. Insulin and diabetic supplies are exempt from any PA and OTC MAC limits.

2. PA Guidelines:

   a. PA is required for more than two prescriptions within the same therapeutic class. Determinations are based on medical necessity and may require additional information.

   b. Approval will be for a one-month time limit.

F. Transdermal Fentanyl

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by the DUR Board: April 25, 2019

Transdermal fentanyl, a narcotic agonist analgesic, is indicated in the management of chronic pain in patients requiring continuous opioid analgesia for pain that cannot be managed by lesser means such as acetaminophen-opioid combinations, non-steroidal analgesics, or pro re nata (PRN) dosing with short-acting opioids. Transdermal fentanyl is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Because serious or life-threatening hypoventilation could occur, fentanyl transdermal is contraindicated in management of acute or postoperative pain, mild or intermittent pain responsive to PRN, or non-opioid therapy or in doses exceeding 25 micrograms (mcg)/hr at the initiation of opioid therapy. Therefore, patients must meet the following criteria in order to gain PA approval:

a. Patient cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics, or PRN dosing with short-acting opioid.

b. Patient requires continuous opioid administration.

c. Prescribers are required to check the Nevada State Board of Pharmacy's (BOP) Prescription Monitoring Program (PMP) prior to prescribing narcotic analgesics. Refer to the PMP website at http://bop.nv.gov/links/PMP/.

d. If transitioning from another opioid, daily morphine equivalent doses are used to calculate the appropriate fentanyl patch dose.

1. Morphine 60-134 mg/day per os (PO); initial Transdermal Fentanyl dose 25 mcg/hr.

2. Morphine 135-224 mg/day PO; initial Transdermal Fentanyl dose 50 mcg/hr.

3. Morphine 225-314 mg/day PO; initial Transdermal Fentanyl dose 75 mcg/hr.

4. Morphine 315-404 mg/day PO; initial Transdermal Fentanyl dose 100 mcg/hr.

5. Morphine 405-494 mg/day PO; initial Transdermal Fentanyl dose 125 mcg/hr.

6. Morphine 495-584 mg/day PO; initial Transdermal Fentanyl dose 150 mcg/hr.

7. Morphine 585-674 mg/day PO; initial Transdermal Fentanyl dose 175 mcg/hr.

8. Morphine 675-764 mg/day PO; initial Transdermal Fentanyl dose 200 mcg/hr.

9. Morphine 765-854 mg/day PO; initial Transdermal Fentanyl dose 225 mcg/hr.

10. Morphine 855-944 mg/day PO; initial Transdermal Fentanyl dose 250 mcg/hr.

11. Morphine 945-1034 mg/day PO; initial Transdermal Fentanyl dose 275 mcg/hr.

12. Morphine 1035-1124 mg/day PO; initial Transdermal Fentanyl dose 300 mcg/hr.

2. PA Guidelines

a. PA approval will be given for 12 months.

G. Immediate-Release Fentanyl Products

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by the DUR Board: July 28, 2022

Immediate-Release Fentanyl Products are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Approval will be given if the following criteria are met and documented:

1. Subsys® (fentanyl sublingual spray), Onsolis® (fentanyl citrate buccal film), Fentora® (fentanyl citrate buccal tablet), Lazanda® (fentanyl citrate nasal spray), Abstral® (fentanyl citrate sublingual tablet), and Actiq® (fentanyl citrate transmucosal lozenge):

2. The recipient must meet all the following:

a. The recipient is 18 years of age or older or the recipient is >16 years of age if requesting fentanyl citrate transmucosal lozenge (Actiq®); and

b. The recipient has pain resulting from a malignancy; and

c. The recipient is already receiving and is tolerant to opioid therapy; and

d. The recipient is intolerant of at least one of the following immediate-release opioids: hydrocodone, hydromorphone, morphine, or oxycodone.

b. Recertification Criteria:

1. Documentation of disease improvement and/or stabilization.

c. PA Guidelines:

1. PA approval will be for six months.

H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)
Last Reviewed by the DUR Board: January 19, 2023

This policy applies in all settings with the exception of inpatient facilities. Hematopoietics and Hematinics are subject to PAs and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. The recipient has been evaluated for adequate iron stores; and

   b. Recent laboratory results are required for PA, i.e. serum hemoglobin, within seven days of PA request; and

   c. Recipients must meet one of the following criteria for coverage:

      1. Achieve and maintain hemoglobin levels in one of the following conditions:

         a. Treatment of anemia secondary to myelosuppressive anticancer chemotherapy, Hb levels should not exceed 10 g/dL.

         b. Treatment of anemia related to zidovudine therapy in HIV-infected patients. Hb levels should not exceed 12 g/dL.

         c. Treatment of anemia secondary to end-stage renal disease (ESRD). Hb levels should not exceed 11 g/dL if on dialysis or 10 g/dL if not on dialysis.

   d. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) has adequate iron stores as demonstrated by serum ferritin ≥100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥20% (measured within the previous three months for renewal).

2. Non-Covered Indications

   a. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis.

   b. Anemia associated with the treatment of acute and chronic myelogenous leukemias (AML, CML) or erythroid cancers.

   c. Anemia of cancer not related to cancer treatment.

   d. Any anemia associated only with radiotherapy.

e. Prophylactic use to prevent chemotherapy-induced anemia.

f. Prophylactic use to reduce tumor hypoxia.

g. Patients with erythropoietin-type resistance due to neutralizing antibodies.

h. Anemia due to cancer treatment if patients have uncontrolled hypertension.

3. Recertification Requests

a. Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria identified in Section III; and

2. Previous dose was administered within the past 60 days; and

3. Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pure red cell aplasia severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in recipients with cancer, severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), etc.; and

b. Anemia Due to Myelodysplastic Syndrome (MDS):

1. Hb <12 g/dL and/or Hematocrit (Hct) <36%.

c. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis:

1. Hb <10 g/dL and/or Hct <30%.

d. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria.

e. Anemia Due to Chronic Kidney Disease (CKD) (Non-Dialysis Patients):

1. Pediatric patients: Hb <12 g/dL and/or Hct <36%.

2. Adult patients: Hb <11 g/dL and/or Hct <33%.

4. PA Guidelines

a. Prior approval will be given for a one-month period.

I. Anti-Fungal Agents

Therapeutic Class: Antifungal Agents
Last Reviewed by the DUR: October 20, 2022

Anti-Fungal Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Topical Agents (Julia® (efinaconazole), Kerydin® (tavaborole))

   a. Approval will be given if the following criteria are met and documented:

      1. Diagnosis of onychomycosis; and

      2. At least one of the following:

         a. The recipient is experiencing pain which limits normal activity; or

         b. The recipient has diabetes; or

         c. The recipient has significant peripheral vascular compromise; or

         d. The recipient's disease associated with immunosuppression; or

         e. The recipient's disease is iatrogenically induced; and

            1. An inadequate response (to an appropriate length or therapy), an adverse reaction, a contraindication to use, or a clinical reason either oral terbinafine or itraconazole cannot be used; and

            2. The recipient must have an adverse reaction or have a contraindication to ciclopirox 8% solution.

2. Oral Agents (Sporanox®, Lamisil®)

   a. Approval will be given if the following criteria are met and documented:

      1. An adequate response (to an appropriate length of therapy), an adverse reaction, a contraindication to use, or a clinical reason either oral terbinafine or itraconazole cannot be used; and

      2. The recipient must have had an adverse reaction or have a contraindication to ciclopirox 8% solution.

   b. PA Guidelines

      1. PA will be approved for 48 weeks.

3. Brexafemme® (ibrexafungerp)

   a. Approval will be given if all the following criteria is met and documented:

      1. Recipient is postmenarchal female 12 years of age or older; and

      2. Diagnosis of vulvovaginal candidiasis (VVC); and

      3. Females of reproductive potential must have negative pregnancy test; and

      4. Recipient must have an adequate trial and failure, contraindication, resistance, or intolerance of at least single dose 150 mg oral fluconazole.

      5. Quantity limit is four tablets.

   b. Recertification Requests:

      1. Coverage is not renewable.

   c. PA Guidelines:

      1. PA will be for one day.

4. Vivjoa® (oteseconazole)

   a. Approval will be given if all the following criteria are met and documented:

      1. Recipient has a diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of VVC in a 12-month period; and

      2. Recipient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); and

      3. Recipient must not have hypersensitivity to any component of the product; and

      4. Recipient is not pregnant; and

      5. Recipient is not lactating; and

      6. Recipient has tried and failed or has contraindication or intolerance to maintenance antifungal therapy with oral fluconazole for six months; and

      7. Quantity limit is 18 tablets per treatment course.

   b. Recertification Requests:

      1. Coverage is not renewable.

c. PA Guidelines:

1. PA will be for 12 weeks.

J. Benlysta® (belimumab)

Therapeutic Class: Benlysta® (belimumab)
Last Reviewed by the DUR Board: January 16, 2025

Benlysta® (belimumab) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. Initial Request:

1. The recipient has a diagnosis of active Systemic Lupus Erythematosus (SLE); and

a. The recipient must meet one of the following age requirements:

1. The recipient must be 18 years of age or older for intravenous (IV) dosage or subcutaneous dosage (pre-filled syringe or autoinjector); or

2. Pediatric recipients 5-17 years of age for IV dosage or subcutaneous dosage (autoinjector); and

b. Documentation confirms that the recipient is autoantibody positive (i.e., anti-nuclear antibody [ANA] and/or anti-double-stranded deoxyribonucleic acid [anti-dsDNA]); and

c. The recipient is currently receiving at least one standard of care treatment for active SLE that includes one or more of the following agents (unless all agents are contraindicated): antimalarials (e.g., Plaquenil® (hydroxychloroquine)), corticosteroids (e.g., prednisone), glucocorticoids, or immunosuppressants (e.g., methotrexate, Imuran™ (azathioprine), mycophenolate); and

d. The medication is prescribed by or in consultation with a rheumatologist; and

e. The recipient must not have active Central Nervous System (CNS) Lupus; and

f. The recipient must not currently be receiving treatment for a chronic infection; and

g. The recipient must not have evidence of severe renal disease.

b. Recertification Requests (the recipient must meet all the following criteria):

1. Authorization for continued use shall be reviewed at least every six months when the following criteria are met:

a. Documentation of positive clinical response to Benlysta® therapy.

2. Lupus Nephritis

a. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

1. Initial Request:

a. The recipient has a diagnosis of active Lupus Nephritis; and

b. The recipient must meet one of the following age requirements:

1. Adult recipients 18 years of age or older for IV dosage or subcutaneous dosage (pre-filled syringe or autoinjector); or

2. Five years of age or older for IV dosage

c. The recipient is currently receiving at least one standard of care treatment that includes one or more of the following agents (unless all agents are contraindicated); antimalarials (e.g., Plaquenil® (hydroxychloroquine)), corticosteroids (e.g., prednisone), glucocorticoids, or immunosuppressants (e.g., methotrexate, Imuran® (azathioprine), mycophenolate); and

d. The medication is prescribed by or in consultation with a rheumatologist or nephrologist;

e. The recipient must not have active CNS Lupus; and

f. The recipient must not currently be receiving treatment for a chronic infection

2. Recertification Requests (the recipient must meet all the following criteria):

a. Authorization for continued use shall be reviewed at least every six months when the following criteria are met:

1. Documentation of positive clinical response to Benlysta® therapy.

3. PA Guidelines

a. PA approvals will be for:

1. Initial request: six months.

K. Spinal Muscular Atrophy (SMA) Agents

Therapeutic Class: Spinal Muscular Atrophy Agents
Last Reviewed by the DUR Board: July 28, 2022

SMA agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid Check Up Pharmacy Manual for specific quantity limits.

1. Evrysdi® (risdiplam)

   a. Approval will be given if the following criteria are met and documented:

      1. Recipient has a diagnosis of SMA type I, II, or III; and

      2. Both the following:

         a. Recipient has mutation or deletion of genes in chromosome 5q resulting in one of the following:

            1. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); or

            2. Compound heterozygous mutation (e.g., deletion of survival motor neuron 1 (SMN1) exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

         b. Recipient has at least two copies of SMN2; and

      3. Recipient is not dependent on invasive ventilation or tracheostomy and non-invasive ventilation beyond use for naps and nighttime sleep; and

      4. At least one of the following exams (based on the recipient's age and motor ability) have been conducted to establish baseline motor ability:

         Note: Baseline assessments for patients <2 months of age requesting risdiplam proactively are not necessary to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

         a. Hammersmith Infant Neurological Exam (HINE) (infant to early childhood); or

         b. Hammersmith Functional Motor Scale Expanded (HFMSE); or

         c. Upper Limb Module (ULM) Test (Non ambulatory); or

         d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND); or

e. Motor Function Measure 32 (MFM-32) Scale; and

5. The medication is prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA; and

6. Recipient is not to receive concomitant chronic SMN modifying therapy for the treatment of SMA (e.g. Spinraza®); and

7. One of the following:

a. Recipient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma®); or

b. Recipient has previously received gene therapy for the treatment of SMA (e.g. Zolgensma®) and the provider attest that there has been an inadequate response to gene therapy (e.g. sustained decrease in at least one motor test score over a period of six months).

b. Recertification Requests (recipient must meet all criteria):

1. The recipient has documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

a. One of the following HINE-2 milestones:

1. Improvement or maintenance of previous improvement of at least a two-point (or maximal score) increase in ability to kick; or

2. Improvement or maintenance of previous improvement of at least a one-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp; or

3. Recipient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement); or

4. The recipient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

b. One of the following HFMSE milestones:

1. Improvement or maintenance of a previous improvement of at least a three-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

c. One of the following ULM test milestones:

1. Improvement or maintenance of a previous improvement of at least a two-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

d. One of the following CHOP INTEND milestones:

1. Improvement or maintenance of a previous improvement of at least a four-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

e. One of the following MFM-32 milestones:

1. Improvement or maintenance of a previous improvement of at least a three-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); and

2. Recipient remains not be dependent on invasive ventilation or tracheostomy and use of non-invasive ventilation beyond use for naps and nighttime sleep; and

3. The medication is prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA; and

4. Recipient is not to receive concomitant chronic SMN modifying therapy for the treatment of SMA (e.g. Spinraza®); and

5. One of the following:

a. Recipient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma®); or

b. Recipient has previously received gene therapy for the treatment of SMA (e.g. Zolgensma®) and the provider attest that there has been an inadequate response to gene therapy (e.g. sustained decrease in at least one motor test score over a period of six months).

c. PA Guidelines:

1. Initial authorization will be approved for 12 months.

2. Recertification requests will be approved for 12 months.

2. Spinraza® (nusinersen)

a. Approval will be given if the following criteria are met and documented:

1. Initial Request:

a. The recipient has a diagnosis of SMA, and

b. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA.

2. Recertification Requests (the recipient must meet all the following criteria):

a. The recipient has been on therapy for <12 months; and

b. The recipient is maintaining neurological status; and

c. The recipient is tolerating therapy; and

d. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA, or all the following:

1. The recipient has been on therapy for 12 months or more; and

2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

3. The recipient is maintaining neurological status; and

4. The recipient is tolerating therapy; and

3. PA Guidelines

a. Initial request will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

3. Zolgensma ® (onasemnogene abeparvovec-xioi)

a. Approval will be given if the following criteria are met and documented:

1. The recipient must be two years of age or younger; and

a. The recipient must have the mutation or deletion of genes in chromosome 5q in one of the following: homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); or

b. Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1, exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

1. The recipient has a diagnosis of SMA confirmed by a neurologist with expertise in the diagnosis of SMA; or

2. The recipient has a diagnosis of SMA based on the results of SMA newborn screening with three copies or less of SMN2; and

c. The recipient is not dependent on either invasive ventilation or tracheostomy or use of non-invasive ventilation beyond use of naps and nighttime sleep; and

d. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's anti-AAV9 antibody titers are ≤1:50; and

e. The recipient is not to receive concomitant SMN modifying therapy (e.g. Spinraza®); and

f. The medication is prescribed by a neurologist with expertise in the diagnosis of SMA; and

g. The recipient has never received Zolgensma® treatment in their lifetime.

b. PA Guidelines

1. PA approval is limited to once in a lifetime.

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: January 18, 2024

Immunomodulator Drugs are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. For all recipients:

      1. The recipient has had a negative tuberculin test; and

      2. The recipient does not have an active infection or a history of recurring infections; and

      3. The approval will not be given for the use of more than one biologic at a time (combination therapy); and

      4. The requested medication is being prescribed for an FDA-approved indication or the prescriber has provided clinical justification for off-label usage; and

      5. The recipient has not received live or live-attenuated vaccines within the past four weeks and will not receive live or live-attenuated vaccines during treatment with immunomodulator.

      6. Each request meets the appropriate diagnosis/agent specific criteria (b-n).

   b. Rheumatoid Arthritis (RA):

      1. The recipient has a diagnosis of moderately to severely active RA; and

      2. The recipient is 18 years of age or older; and

      3. The recipient has had a rheumatology consultation, including the date of the visit; and one of the following:

         a. The recipient has had RA for <6 months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate, hydroxychloroquine, leflunomide, minocycline, and sulfasalazine); or

         b. The recipient has had RA for ≥6 months (intermediate or long-term disease duration) and has moderate disease activity and has an inadequate response to a DMARD (methotrexate,

hydroxychloroquine, leflunomide, minocycline, or sulfasalazine); or

c. The recipient has had RA for ≥6 months (intermediate or long-term disease duration) and has high disease activity.

c. Psoriatic Arthritis:

1. The recipient has a diagnosis of moderate or severe psoriatic arthritis; and

2. The recipient is 18 years of age or older; and

3. The recipient has had a rheumatology consultation including the date of the visit or a dermatology consultation including the date of the visit; and

4. The recipient had an inadequate response or a contraindication to treatment with any one nonsteroidal anti-inflammatory (NSAID) or to any one of the following DMARDs: methotrexate, leflunomide, cyclosporine, or sulfasalazine.

d. Ankylosing Spondylitis:

1. The recipient has a diagnosis of ankylosing spondylitis; and

2. The recipient is 18 years or older; and

3. The recipient has had an inadequate response to NSAIDs; and

e. Juvenile RA/Juvenile Idiopathic Arthritis:

1. The recipient has a diagnosis of moderately or severely active juvenile RA or juvenile idiopathic arthritis; and

2. The recipient is at an appropriate age, based on the requested agent, and:

a. Abatacept: Six years of age or older.

b. Adalimumab, canakinumab, etanercept, tocilizumab: Two years of age or older.

3. And the recipient has at least five swollen joints; and

4. The recipient has three or more joints with limitation of motion and pain, tenderness, or both; and

5. The recipient has had an inadequate response to one DMARD.

f. Plaque Psoriasis:

1. The recipient has a diagnosis of chronic, moderate to severe plaque psoriasis; and

2. The recipient is at an appropriate age based on the requested agent; and

3. The agent is prescribed by a dermatologist; and

4. The recipient has failed to adequately respond to a topical agent; and

5. The recipient has failed to adequately respond to at least one oral treatment.

g. Crohn's Disease:

1. The recipient has a diagnosis of moderate to severe Crohn's Disease; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Adalimumab, infliximab: Six years of age or older.

b. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to conventional therapy (e.g., sulfasalazine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or

4. The recipient has fistulizing Crohn's Disease.

h. Ulcerative Colitis (UC):

1. The recipient has a diagnosis of moderate to severe UC; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Infliximab: Six years of age or older.

b. Humira®: Five years of age or older.

c. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to one or more of the following standard therapies:

a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

4. Zeposia® (ozanimod) for diagnosis of UC

a. Approval will be given if all the following criteria are met and documented:

1. Prescribed by or in consultation with a gastroenterologist; and

2. The recipient has a diagnosis of moderately to severely active UC; and

3. Inadequate response after a 90-day trial of one of the following conventional therapies:

a. 6-mercaptopurine

b. Aminosalicylates (e.g., mesalamine, balsalazide, olsalazine)

c. Sulfasalazine

d. Azathioprine

e. Corticosteroids (e.g., budesonide, high dose steroids, 40-60 mg of prednisone daily); and

4. The recipient has tried and failed two preferred immunomodulator therapies indicated for moderately to severely active UC.

i. Cryopyrin-Associated Periodic Syndromes (CAPS): Familial Cold Autoinflammatory Syndromes (FCAS) or Muckle-Wells Syndrome (MWS):

1. The recipient has a diagnosis of FCAS or MWS; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Canakinumab: Four years of age or older.

b. Rilonacept: 12 years of age or older.

j. CAPS: Neonatal-Onset Multisystem Inflammatory Disease (NOMID):

1. The recipient has a diagnosis of NOMID.

k. Remicade® biosimilars (infliximab-axxq, infliximab-abda, infliximab-dyyb, infliximab-qbtx).

1. Medication prescribed for FDA-approved diagnosis and patient is appropriate age per FDA labeling.

2. Prescriber has provided documentation to justify that patient is not a candidate for unbranded/generic infliximab (e.g. product-specific past intolerance or contraindication).

l. Spevigo® (spesolimab-sbzo) for generalized pustular psoriasis (GPP) flares.

1. Approval will be given if all the following criteria are met and documented:

a. The recipient is 18 years of age or older;

b. Diagnosis of GPP; and

c. Prescribed by or in consultation with a dermatologist, immunologist, or rheumatologist; and

d. The recipient does not have any of the following conditions: synovitis, acne, pustulosis, hyperostosis, osteitis (SAPHO) syndrome; erythrodermic plaque psoriasis without pustules or with pustules restricted to psoriatic plaques, or drug-triggered acute generalized exanthematous pustulosis (AGEP); and

e. The recipient is experiencing an acute GPP flare of moderate to severe intensity defined by all the following: GPP Global Assessment (GPPGA) total score of ≥3 (moderate), presence of fresh pustules (new or worsening) a GPPGA pustulation of sub score of ≥2 (mild), and ≥5% of body surface area with erythema and the presence of pustules; and

f. The recipient has not received a live virus vaccine in the last four weeks and will not receive a live virus vaccine during therapy.

2. PA approval will be 14 days.

m. Uplizna™ (inebilizumab-cdon).

1. Initial Request

a. Patient is ≥18 years; and

b. Patient has been diagnosed with neuromyelitis optica spectrum disorder (NMOSD); and

c. Patient has positive serologic test for anti-AQP4 antibodies; and

d. Patient has a history of ≥1 relapse that required rescue therapy within the year prior to treatment or ≥2 relapses that required rescue therapy in two years prior to treatment (initial request only); and

e. Patient has an Expanded Disability Status Score (EDSS) of ≤8.0 (initial request only); and

f. Medication prescribed by or on consultation with neurologist; and

g. Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; and

h. Prescriber attestation that serum immunoglobulin will be monitored at beginning, during, and after discontinuation of treatment until B-cell repletion.

2. Renewal Requests:

a. Patient must continue to meet above criteria; and

b. Documentation of positive disease response as indicated by stabilization/improvement in any of the following; neurologic symptoms as evidence by a decreased in acute relapses, stability, or improvement in EDSS, reduced hospitalizations, and/or reduction in plasma exchange treatments.

c. PA guidelines for Uplizna® initial authorization is six months approval and recertification is 12 months.

n. Refractory Atopic Dermatitis

1. Initial Request:

a. The recipient has diagnosis of refractory, moderate to severe atopic dermatitis (AD); and

b. The recipient has documented trial and failure to at least one other systemic option for AD; and

c. The recipient is at least 12 years of age (and at least 40 kg for Rinvoq®); and

d. The medication is prescribed by or in consultation with a dermatologist/allergist/immunologist/otolaryngologist.

2. PA Guidelines:

a. PA approval will be for 12 months unless otherwise stated in criteria.

M. Topical Immunomodulators

Therapeutic Class: Topical Immunomodulators
Last Reviewed by the DUR Board: July 28, 2022

Topical Immunomodulators drugs are a subject to PA and quantity limitations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. Authorization will be given if the following criteria are met and documented:

      1. Patient has a documented diagnosis of Atopic Dermatitis:

         a. Elidel® for mild to moderate, for ages ≥2 years.

         b. Eucrisa® for mild to moderate, for ages ≥3 months.

         c. Protopic® 0.03%; moderate to severe, for ages ≥2 years.

         d. Protopic® 0.1%; moderate to severe, for ages ≥16 years.

      2. The agent is not for chronic use.

      3. Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.

      4. Not recommended for use in immunocompromised patients.

2. Opzelura® (ruxolitinib)

   a. Approval will be given if all the following criteria is met and documented:

      1. The patient has a documented diagnosis of mild to moderate Atopic Dermatitis; and

      2. Recipient is 12 years of age or older; and

      3. The medication will not be used chronically; and

      4. Recipient is not immunocompromised; and

      5. Recipient has had a trial and failure, contraindication, or intolerance to two or more of the following classes:

         a. Prescription topical corticosteroids.

b. Topical calcineurin inhibitor (e.g., Elidel® (pimecrolimus) or Protopic® (tacrolimus)).

c. Topical phosphodiesterase-4 inhibitor (e.g., Eucrisa® (crisaborole)).

b. Recertification Requests:

1. Recipient must have disease improvement and/or stabilization.

c. PA Guidelines

1. PA will be approved within 12 months.

N. Psychotropic Medications for Children and Adolescents

Therapeutic Class: Psychotropic Agents
Last Reviewed by the DUR Board: July 23, 2020

Psychotropic medications for children and adolescents are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for billing information.

Authorization will be given if the following criteria are met and documented.

1. Coverage and Limitations

The Division of Health Care Financing and Policy (DHCFP) requires PA approval for children and adolescents for the psychotropic therapeutic classes below and medication combinations considered to be polypharmacy. DHCFP has adopted the following practice standards to strengthen treatment outcomes for our children and adolescents.

a. The psychotropic therapeutic classes subject to this policy are:

1. Antipsychotics

2. Antidepressants

3. Mood Stabilizers (including lithium and anticonvulsants used for behavioral health indications.)

4. Sedative hypnotics

5. Antianxiety agents

b. For all children under 18 years of age, the following must be documented in the medical record for authorization.

1. For psychotropic medications in this age group, when possible, be prescribed by or in consultation with a child psychiatrist.

2. Psychotropic medication must be part of a comprehensive treatment plan that addresses education, behavioral management, living home environment and psychotherapy.

3. Physician and/or prescriber monitoring is required while the recipient is utilizing any psychotropic medication.

a. For recipients who are in initial treatment (have not received any doses previously) or are continuing therapy but are considered unstable (has had a dose change in the last three months), medical documentation must support a monthly or more frequent visit with the physician and/or prescriber. If the recipient was discharged from

an institution on the medication, the follow-up visit(s) can be with their treating physician and/or prescriber.

b. For recipients who are considered stable in their medication therapy, medical documentation must support visits with the treating physician at least every three months.

c. Polypharmacy: Each psychotropic medication prescribed must be independently treating a specific symptom and/or diagnosis.

1. Polypharmacy (intra-class) is defined as more than one drug within the same therapeutic class within a 60-day time period.

a. PA approval is required for two or more drugs in the same therapeutic class within a 60-day period.

2. Polypharmacy (inter-class) is defined as more than one drug across different therapeutic classes within a 60-day time period.

a. PA approval is required for four or more drugs across all psychotropic therapeutic classes listed in this policy within a 60-day time period.

3. Approval for polypharmacy may be given in situations where the requested medication(s) will be used for cross tapering and situations where the recipient will be discontinuing the previously prescribed agent. A 30-day cross-taper will be allowed.

4. Approval for polypharmacy may be given for a medication to augment the effect of another psychotropic medication as long as the purpose of the polypharmacy is clearly documented in the recipient's medical record and each agent is supported by individual authorizations.

5. The recipient must have a trial of each individual medication alone. The reasons for an inadequate response must be documented in the medical record.

6. For intra-class and inter-class polypharmacy, all psychotropic medications must be utilized for a medically accepted indication as established by the FDA, and/or peer reviewed literature.

7. Polypharmacy rules will be bypassed for antidepressants, antipsychotics, anticonvulsants, and mood stabilizers, if the medication is prescribed by a board-certified child psychiatrist.

d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a PA approval and must be utilized for a medically accepted indication as established by the FDA and/or peer-reviewed literature.

e. Continuity of Care. In an effort to improve recipient safety and quality of care:

1. For recipients under 18 years of age, who have been discharged from an institutional facility, they will be allowed to remain on their discharge medication regimen for up to six months to allow the recipient time to establish outpatient mental health services. The initial PA after discharge must document the name of the discharge institution and the date of discharge.

2. For all other recipients under the age of 18, a six-month PA will be granted to cover current medication(s) when it is documented that the recipient has been started and stabilized. This will allow the recipient time to establish services if necessary and to transition to medication(s) per Nevada Medicaid policy.

2. Exceptions to Criteria for Anticonvulsants and ADD/ADHD Medications:

a. Treatment for seizure disorders with anticonvulsants are not subject to this policy. The ICD Codes for Epilepsy and/or Convulsions will bypass the PA requirement at the pharmacy point of service (POS) if the correct ICD Code is written on the prescription and transmitted on the claim. Or the PA requirement will be overridden for anticonvulsant medications when the prescriber has a provider Specialty Code of 126, neurology or 135, pediatric neurology, in the POS system.

b. The current policy for treatment of ADD/ADHD is to be followed. Refer to this Chapter's Appendix A.

O. Lidoderm 5% Patches®

Therapeutic Class: Topical, Local Anesthetics
Last Reviewed by the DUR Board: October 17, 2019

1. Coverage and Limitations

Topical Lidoderm Patches® are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Authorization will be given if one of the following criteria are met and documented:

a. If an ICD code for herpes zoster is documented on the prescription; or

b. Completion of a PA documenting a diagnosis of Post Herpetic Neuralgia/ Neuropathy.

2. PA Guidelines

a. PA approval will be for one year.

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: July 18, 2024, and January 16, 2025

Respirator and Allergy Biologics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Xolair® (omalizumab)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. All the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:

1. The recipient must be six years of age or older; and

2. The recipient must have a history of a positive skin test or radioallergosorbent (RAST) test to a perennial aeroallergen; and

3. The prescriber must be either a pulmonologist or allergist/ immunologist; and

4. The recipient must have had an inadequate response, adverse reaction, or contraindication to inhaled, corticosteroids; and

5. The recipient must have had an inadequate response, adverse reaction, or contraindication to a leukotriene receptor antagonist; and

6. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 international unit (IU)/mL and 700 IU/mL; and

7. The recipient's current weight must be recorded; and

8. The requested dose is appropriate for the recipient’s pre-treatment serum IgE and body weight (see Table 1).

2. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU):

a. The recipient is 12 years of age or older; and

b. The recipient must have had an inadequate response, adverse reaction, or contraindication to two different oral second-generation antihistamines; and

c. The recipient must have had an inadequate response, adverse reaction, or contraindication to an oral second-generation antihistamine in combination with a leukotriene receptor antagonist; and

d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist, or a rheumatologist regarding the diagnosis and treatment recommendations; and

e. One of the following:

1. The request is for initiation of therapy and the dose will be 150 mg every four weeks; or

2. The request is for initiation of therapy and the dose will be 300 mg every four weeks, and clinical rationale for starting therapy at 300 mg every four weeks has been provided (pharmacy review required); or

3. The request is for continuation of therapy and the dose will be 150 mg or 300 mg every four weeks.

3. All the following criteria must be met for diagnosis of Nasal Polyps (NP) and all the following:

a. The recipient is 18 years of age or older; and

b. The prescriber must be one of the following, or there is documentation in the recipient's medical record that a consultation regarding diagnosis and treatment recommendations was done by one of the following:

1. Allergist/Immunologist; or

2. Dermatologist; or

3. Rheumatologist; and

c. The recipient must have had an inadequate response, adverse reaction, or contraindication to at least 2 months of therapy with an intranasal corticosteroid and had inadequate response; and

d. One of the following:

1. The recipient will continue intranasal corticosteroid treatment along with omalizumab therapy; or

2. The prescriber has provided valid medical rationale for not continuing intranasal corticosteroid treatment along with omalizumab therapy; or

3. The request is for continuation of therapy and there is documentation of a positive clinical response to therapy (e.g., reduction in NP score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]

4. PA Guidelines:

a. PA approval will be for 12 months.

**Table 1: Dosing for Xolair® (omalizumab)**

| **Pre-treatment Serum IgE (IU/mL)** | **Body Weight (kg)** | | | |
|---|---|---|---|---|
| | **30-60** | **>60-70** | **>70-90** | **>90-150** |
| ≥30-100 | 150 mg | 150 mg | 150 mg | 300 mg |
| >100-200 | 300 mg | 300 mg | 300 mg | 225 mg |
| >200-300 | 300 mg | 225 mg | 225 mg | 300 mg |
| >300-400 | 225 mg | 225 mg | 300 mg | |
| >400-500 | 300 mg | 300 mg | 375 mg | |
| >500-600 | 300 mg | 375 mg | | |
| >600-700 | 375 mg | **DO NOT DOSE** | | |
| **Every 2 Weeks Dosing** | | | | |
| **Every 4 Weeks Dosing** | | | | |

b. Nucala® (mepolizumab), Cinqair® (reslizumab)

1. All the following criteria must be met and documented:

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; and

c. The recipient must be of FDA indicated appropriate age:

1. Mepolizumab: six years of age or older;

2. Reslizumab: 18 years of age or older; and

d. The prescriber must be either a pulmonologist or allergist/ immunologist; and

e. The recipient must be uncontrolled on current therapy including high dose corticosteroid and/or on a secondary asthma inhaler; and

f. There is documentation of the recipient's vaccination status; and

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks.

2. Reslizumab: 3 mg/kg via IV infusion of 20 to 50 minutes every four weeks.

3. PA Guidelines:

a. PA approval will be for 12 months.

c. Nucala® (mepolizumab) for the treatment of severe asthma

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of severe asthma; and

b. The asthma is an eosinophilic phenotype as defined by one of the following:

1. Baseline (pre-treatment) peripheral blood eosinophil level ≥150 cells/microliter (μL); or

2. Peripheral blood eosinophil levels were ≥300 cells/ μL within the past 12 months; and

c. One of the following:

1. The recipient has had at least one or more asthma exacerbations requiring systemic corticosteroid within the past 12 months; or

2. The recipient has had prior intubation for an asthma exacerbation; or

3. The recipient has had prior asthma-related hospitalization within the past 12-months; and

d. The recipient is currently being treated with one of the following (unless there is a contraindication or intolerance to these medications)

1. Both the following:

a. High dose inhaled corticosteroid (ICS) (e.g., >500 mcg fluticasone propionate equivalent/day); and

b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist [LABA], theophylline); or

2. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera® [mometasone/formoterol], Symbicort® [budesonide/formoterol]); and

e. The recipient age is ≥6 years; and

f. The medication must be prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergist/Immunologist

2. Recertification Requests (the recipient must meet all the criteria)

a. Documentation of positive clinical response to therapy (e.g. reduction in exacerbations, improvement in forced expiratory volume in one second [FEV1], decreased use of rescue medications); and

b. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both the following:

a. ICS; and

b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera® [mometasone/formoterol], Symbicort® [budesonide/formoterol]); and

c. The medication must be prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergist/Immunologist

3. PA Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

d. Nucala® (mepolizumab) for the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of EGPA; and

b. The recipient is at least 18 years of age; and

c. The recipient's disease has relapsed or is refractory to standard of care therapy (i.e. corticosteroid treatment with or without immunosuppressive therapy); and

d. The recipient is currently receiving corticosteroid therapy; and

e. The medication must be prescribed or in consultation with one of the following:

1. Pulmonologist; or

2. Rheumatologist; or

3. Allergist/Immunologist.

2. Recertification Requests (the recipient must meet the following criteria)

a. Documentation of positive clinical response to therapy (e.g. increase in remission time).

b. The medication prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist

3. PA Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

e. Nucala® (mepolizumab) for treatment of Hypereosinophilic Syndrome (HES)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is ≥12 years old; and

b. Recipient has a diagnosis of uncontrolled HES for ≥6 months defined by both of the following:

1. History of ≥2 flares over the past 12 months; and

2. Baseline (pre-treatment) blood eosinophil count ≥1,000 cells/mL; and

c. No identifiable non-hematologic secondary cause of the HES; and

d. Recipient does not have FIP1L1-PDGFRa kinase-positive HES; and

e. Recipient is currently received a stable dose of background HES therapy (e.g., episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and

f. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

2. Recertification Requests:

a. Documentation of positive clinical criteria response to therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroids requirements, and decreased eosinophil levels).

b. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

3. PA Guidelines:

a. Initial PA will be given for 12 months.

b. Recertification will be given for 12 months.

f. Nucala® (mepolizumab) for treatment of Chronic Rhinosinusitis with NP (CRSwNP)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is ≥18 years old.

b. Recipient has a diagnosis of CRSwNP; and

c. Unless contraindicated, the recipient has had an inadequate response to at least two months of treatment with an intranasal corticosteroid (initial approval only); and

d. Mepolizumab will be used as add-on medication to maintenance therapy (e.g. intranasal corticosteroid, saline nasal irrigations, systemic corticosteroids, antibiotics).

2. Recertification Requests:

a. Recipient continues to meet above criteria; and

b. Documentation of positive clinical response to Nucala® (mepolizumab).

3. PA Guidelines:

a. Initial PA will be given for 12 months.

b. Recertification approval will be given for 12 months.

g. Fasenra® (benralizumab)

1. All the following criteria must be met and documented:

a. The recipient must be six years of age or older and medication dosed per FDA based on age and weight; and

b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

c. The recipient must have a diagnosis of severe eosinophilic phenotype asthma; and

d. One of the following:

1. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months; or

2. Any prior intubation for an asthma exacerbation; or

3. Prior asthma-related hospitalization within the past 12 months.

e. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. One maximally dosed combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/ formoterol)).

f. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

2. Recertification Requests: Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. There is documentation of a positive clinical response (e.g., reduction in exacerbation).

b. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both an ICS (5, E) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. A combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol)).

c. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

3. PA Guidelines:

a. Initial PA will be for 12 months.

b. Recertification requests will be for 12 months.

h. Fasenra® (benralizumab) for treatment of EGPA

1. All the following criteria must be met and documented:

a. Recipient is at least 18 years of age; and

b. Recipient has a diagnosis of EGPA; and

c. Disease has relapsed or is refractory to standard of care therapy (i.e. corticosteroid treatment with or without immunosuppressive therapy); and

d. Recipient is currently receiving corticosteroid therapy; and

e. The medication is prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist

2. Recertification Requests:

a. Documentation of positive response to Fasenra® therapy; and

b. The medication is prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist.

3. PA Guidelines;

a. Initial and recertification will be approved for 12 months.

i. Dupixent® (dupilumab)

1. Approval will be given if the following criteria are met and documented:

a. The recipient has a diagnosis moderate of severe atopic dermatitis and all the following:

1. The medication is prescribed by or in consultation with a dermatologist or allergist/immunologist or an otolaryngologist; and

2. One of the following:

a. Trial and failure contraindication or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, triamcinolone); or

b. Trial and failure or intolerance to one of the following, unless the recipient is not a candidate for therapy (e.g. immunocompromised):

1. Elidel® (pimecrolimus) topical cream; or

2. Tacrolimus topical ointment; or

b. Diagnosis of moderate to severe asthma and all the following:

1. Recipient is six years of age or older; and

2. One of the following:

   a. The recipient is currently dependent on oral corticosteroids for the treatment of asthma:

      1. One or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.

      2. Any prior intubation for an asthma exacerbation.

      3. Prior asthma-related hospitalization within the past 12 months; or

   b. All the following:

      1. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥150 cells per μL; and

      2. The recipient has one of the following:

         a. One or more asthma exacerbations requiring systematic corticosteroid within the past 12 months.

         b. Any prior intubation for an asthma exacerbation.

         c. Prior asthma-related hospitalization within the past 12 months; and

      3. Recipient is currently being treated with one of the following (or there is a contraindication or intolerance to all these medications):

         a. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/ day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

         b. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol],

Dulera® [mometasone/formoterol], Symbicort® [budesonide/formoterol]); and

4. Prescribed by or in consultation with a Pulmonologist or allergy/immunology specialist; or

3. Recertification Requests:

a. Diagnosis of moderate to severe atopic dermatitis or severe eosinophilic asthma or oral corticosteroid-dependent asthma and all of the following:

1. Documentation of positive clinical response to Dupixent® therapy.

2. Recertification Criteria for severe eosinophilic asthma or oral corticosteroid-dependent asthma:

a. Both an ICS and asthma controller medication (e.g., leukotriene, receptor agonist, LABA, theophylline); or

b. One maximally dosed combination ICS/LABA product combination ICS/LABA product (e.g., Advair (fluticasone, propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol)

3. Prescribed by or in consultation with an allergist/immunologist/otolaryngologist/ear, nose, and throat (ENT).

c. Diagnosis of CRSwNP

1. Approval will be given if the following criteria are met and documented:

a. Recipient is at least 12 years of age or older

b. Unless contraindicated, the recipient has had an inadequate response to two months of treatment with an intranasal corticosteroid (e.g., fluticasone,

mometasone) [Document drug(s), dose, duration, and date of trial]; and

c. The medication will not be used in combination with another agent for CRSwNP; and

d. Prescribed by or in consultation with an allergist/immunologist/otolaryngologists/ENTs.

2. Recertification Requests:

a. Documentation of positive clinical response to Dupixent® therapy; and

b. Prescribed by or in consultation with an allergist/immunologist/otolaryngologists/ENTs

c. Medication will not be used in combination with another agent for CRSwNP.

d. Diagnosis of Eosinophilic Esophagitis (EoE)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is ≥1 year old; and

b. Recipient weighs ≥15 kg and with medication dosed per FDA label based on age and weight; and

c. Prescribed by or in consultation with an allergist or gastroenterologist; and

d. Recipient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor.

2. Recertification Requests:

a. Documentation of positive clinical response to Dupixent® therapy; and

b. Prescribed by or in consultation with an allergist or gastroenterologist.

3. PA Guidelines:

a. PA will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

e. Diagnosis of Prurigo Nodularis (PN)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is ≥18 years old; and

b. Prescribed by or in consultation with a dermatologist, allergist, or immunologist.

2. Recertification Requests:

a. Documentation of positive clinical response to Dupixent® therapy; and

b. Prescribed by or in consultation with a dermatologist, allergist, or immunologist.

3. PA Guidelines:

a. PA will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

f. Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)

1. Approval will be given if the following criteria are met and documented:

a. Recipient is at least 18 years of age; and

b. Recipient has confirmed diagnosis of inadequately controlled COPD with eosinophilic phenotype, defined by both of the following;

1. History of ≥2 moderate or ≥1 severe exacerbations within the past 12 months; and

2. Blood eosinophil count ≥300 cells/ μL; and

c. Inadequate response, intolerable adverse effects, or contraindications to ≥3-month trial of all of the following treatments;

1. LABA; and

2. Long-acting muscarinic antagonist/ anticholinergic (LAMA); and

3. ICS

[Note: trial of double therapy (LABA plus LAMA) permitted if ICS is contraindicated]; and

d. Recipient will continue to receive maintenance therapy concomitantly with Dupixent®; and

e. Medication prescribed by, or in consultation with, a pulmonologist or an allergist/immunologist

2. Recertification Requests:

a. Documentation of positive clinical response to Dupixent® therapy; and

b. Recipient continues to receive maintenance therapy concomitantly with Dupixent®; and

c. Medication prescribed by, or in consultation with, a pulmonologist or an allergist/immunologist.

3. PA Guidelines

a. Initial and recertification will be approved for 12 months.

j. Tezspire™ (tezepelumab-ekko)

1. Initial Request:

a. The recipient has a diagnosis of severe asthma; and

1. The medication is prescribed by or in consultation with a pulmonologist or allergist/immunologist; and

2. The recipient is ≥12 years old; and

3. The recipient is currently being treated with one of the following, unless there is a contraindication or intolerance to these medications:

a. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/day) and an additional asthma-controlled medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

b. One maximally dosed combination ICS/LABA product [e.g., Advair® (fluticasone propionate/ salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol); and

4. One of the following (initial request only):

a. At least one or more asthma exacerbations requiring systemic corticosteroid within the past 12 months; or

b. Any prior intubation for an asthma exacerbation; or

c. Prior asthma-related hospitalization within the past 12 months; and

5. Medication will not be used in combination with other monoclonal antibodies for asthma treatment.

2. Quantity limit:

a. One injection (210 mg/1.91mL) per 28 days

3. Renewal Requests:

a. The recipient continues to meet the above criteria; and

b. Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications)

4. PA Guidelines

a. Initial approval will be given for six months.

b. Recertification will be approved for 12 months.

k. Adbry™ (tralokinumab-ldrm)

1. Initial Request

a. Recipient is ≥12 years old; and

b. Recipient has a diagnosis of moderate to severe atopic dermatitis; and

c. The medication is prescribed by or in consultation with a dermatologist, allergist/immunologist, or otolaryngologist; and

d. One of the following:

1. Recipient has trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, triamcinolone); or

2. Recipient has trial and failure or intolerance to one of the following, unless the recipient is not a candidate for therapy (e.g. immunocompromised):

a. pimecrolimus topical cream; or

b. tacrolimus topical ointment

2. Renewal Requests:

a. Documentation of positive clinical response to therapy; and

b. The medication is prescribed by, or in consultation with, a dermatologist/allergist/immunologist/otolaryngologist.

3. PA Guidelines:

a. Initial and recertification will be approved for 12 months.

Q. Long-Acting Narcotics

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by DUR Board: April 28, 2016

Long-Acting Narcotics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

The current criteria for the use of fentanyl transdermal patches (Appendix A, (F.)) or oxycodone/acetaminophen ER tablets (Appendix A, (XX.)) is to be met.

For all other long-acting narcotics requests that exceed the quantity limit, the following criteria must be met and documented:

a. The recipient has a diagnosis of terminal cancer; or

b. All the following criteria must be met:

1. The recipient is 18 years of age or older; and

2. The requested agent will be used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment; and

3. There is documentation in the recipient's medical record that alternative agents (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

2. PA Guidelines

a. The PA approval will be for three months.

R. Toradol® (ketorolac tromethamine) tablets

Therapeutic Class: Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
Last Reviewed by the DUR Board: April 30, 2020

Toradol® is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Ketorolac is indicated for the short-term (up to five days) management of moderately severe acute pain that requires analgesia at the opioid level. It is not indicated for minor or chronic painful conditions. The following criteria must be met:

   a. Oral treatment must be indicated only as continuation therapy to IV/intramuscular (IM) therapy; and

   b. Oral treatment must not exceed five days; and

   c. Oral treatment must not exceed 40 mg/day.

2. PA Guidelines

   a. Initial request will be approved for up to five days.

S. Anti-Migraine Medications

Therapeutic Class: Serotonin 5-HT1 receptor agonists (triptans)
Last Reviewed by the DUR Board: July 25, 2019

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: January 27, 2022

Therapeutic Class: Ergot Derivatives
Last Reviewed by the DUR Board: July 28, 2022

Serotonin 5-HT1 receptor agonists commonly referred to as "triptans", CGRP Receptor Inhibitor medications and Ergot Derivatives or anti-migraine medications are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Serotonin 5-HT1 Receptor Agonists (triptans)

   a. An approved PA is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

      1. The recipient's current medication history documents the use of prophylactic medications for migraine headache, or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or

      2. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.

         a. Recipient's current medication history must not have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).

         b. Recipients whose current medication history indicates the use of propranolol will not be granted PA of Maxalt® (rizatriptan) 10 mg tablet or 10 mg orally disintegrating tablet.

         c. PA will not be given to patients with ischemic heart disease.

   b. PA Guidelines:

      1. Approval for exceeding the quantity limits on triptans will be provided for a two-month period.

2. The PA must be initiated by the prescriber. The approved PA must be available if requested.

2. CGRP Receptor Inhibitor Medications

a. CGRP General Criteria

1. Approval will be given if the following criteria are met and documented:

a. The recipient must have one of the following:

1. Both the following:

a. The recipient has a diagnosis of episodic migraines; and

b. The recipient has four to 14 migraine days per month, but not more than 14 headache days per month: or (for Nurtec® requests, the recipient does not have more than 18 headache days per month); or

2. All the following:

a. The recipient has a diagnosis of chronic migraines; and

b. The recipient has ≥15 headache days per month, of which at least eight must be migraine days for at least three months; and

c. The recipient has been considered for medication overuse headache (MOH) and potentially offending medication(s) have been discontinued; and

b. The recipient is 18 years of age or older; and

c. The recipient has a documented history of failure (after at least a two-month trial) or an intolerance/contraindication to at least one medication from two of the following categories:

1. Elavil® (amitriptyline) or Effexor® (venlafaxine)

2. Depakote®/Depakote® ER (divalproex) or Topamax® (topiramate)

3. One of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol; and

2. Recertification Requests:

a. The recipient must have a documented positive response to CGRP therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The recipient has had a decrease in use of acute migraine medications (e.g., NSAIDs, triptans) since the start of CGRP therapy; and

c. For chronic migraine only: The recipient continues to be monitored for MOH.

3. PA Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

b. CGRPs for Acute Migraines:

1. Ubrelvy® (ubrogepant), Nurtec® ODT (rimegepant).

a. Approval will be given if all the following criteria are met and documented:

1. Recipient must have a diagnosis of acute migraine with or without aura; and

2. Recipient is 18 years of age or older; and

3. The prescribed dose will not exceed two doses per migraine and treating no more than eight migraine episodes per 30 days; and

4. The recipient has had at least one trial and failure of a triptan agent; and

5. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

b. Recertification Requests:

1. The recipient must have a documented positive response to the CGRP therapy; and

2. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

c. PA Guidelines:

1. Initial request will be approved for six months.

2. Recertification requests will be approved for 12 months.

2. CGRPs for Episodic Cluster Headache

a. Emgality® (galcanezumab-gnlm)

1. Approval will be given if all the following criteria are met and documented

a. The recipient has a diagnosis of episodic cluster headache; and

b. The recipient has experienced at least two cluster periods lasting from seven days to 365 days, separated by pain-free periods lasting at least three months.

c. The recipient is 18 years of age or older.

d. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

2. Recertification Requests:

a. The recipient has documented positive response to Emgality® therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

3. PA Guidelines:

a. Initial request will be approved for three months.

b. Recertification requests will be approved for 12 months.

3. CGRP's Antagonists for Episodic Migraines

a. Nurtec® ODT (rimegepant).

1. Approval will be given if all criteria are met and documented:

a. The recipient is 18 years of age or older; and

b. The recipient has a documented diagnosis of episodic migraines, having 4-18 migraine days per month but not more than 18 headache days per month; and

c. Two of the following:

1. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or has a contraindication to both Elavil® (amitriptyline) and Effexor® (venlafaxine); or

2. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote® ER (divalproex) or Topamax® (topiramate); or has a contraindication to both Depakote® /Depakote® ER (divalproex) and Topamax® (topiramate); or

3. The recipient has a history of failure (after at least a two-month trial) or intolerance to one of the following beta blockers:

a. Atenolol; or

b. Propranolol; or

c. Nadolol; or

d. Timolol; or

e. Metoprolol; and

2. PA Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

4. Ergot Derivatives

a. Brand D.H.E. 45 (dihydroergotamine mesylate) injection, generic dihydroergotamine mesylate injection, brand Migranal nasal spray, or generic dihydroergotamine mesylate nasal spray or Trudhesa®.

1. Approval will be given if all criteria are met and documented:

   a. The recipient has a diagnosis of headaches with or without aura; and

   b. The medication will be used for the acute treatment of migraine; and

   c. The recipient is 18 years of age or older; and

   d. One of the following:

      1. The recipient has tried and failed or has intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan); or

      2. The recipient has contraindication to all triptans; and

   e. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist; and

   f. If the recipient has more than four headache days per month, they must meet at least one of the following:

      1. The recipient is currently being treated with Elavil® (amitriptyline) or Effexor® (venlafaxine) unless there is a contraindication or intolerance to these medications; or

      2. The recipient is currently being treated with Depakote®/Depakote® ER (divalproex sodium) or Topamax® (topiramate) unless there is a contraindication or intolerance to these medications; or

      3. The recipient is currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications; and

2. Recertification Requests:

a. The recipient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and

b. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. PA Guidelines:

a. Initial request will be approved for three months.

b. Recertification requests will be approved for 12 months.

b. Brand D.H.E. 45 injection or generic dihydroergotamine mesylate injection

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of cluster headache; and

b. The recipient is 18 years of age or older; and

c. The recipient has had a trial and failure, contraindication, or intolerance to sumatriptan injection; and

d. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

2. Recertification Requests:

a. The recipient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. PA Guidelines:

a. Initial authorization will be approved for three months.

b. Recertification requests will be approved for three months.

T. Tobacco Cessation Products

Therapeutic Class: Tobacco Cessation Agents
Last Reviewed by the DUR Board: April 30, 2020

Smoking cessation products, including patches, gums, lozenges, and inhalers (based on the recipients' route of choice), are subject to quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

U. Short-Acting Bronchodilators

Therapeutic Class: Beta Adrenergic Agents
Last Reviewed by the DUR Board: January 24, 2019

Short-Acting Bronchodilators are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. This criteria applies to, but is not limited to, the following list:

| | | |
|---|---|---|
| Proventil® HFA | ProAir® HFA | ProAir RespiClick® |
| Ventolin® HFA | Albuterol Nebulizer | Nebulizer Solution |

a. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

1. Quantity Limits:

a. Albuterol Metered Dose Inhalers (MDI): two units per month.

b. Albuterol Nebulizer Solution: three bottles of 20 ml each or 125 nebulizer units per month.

2. In order to exceed the quantity limit, a recipient must meet all of the following:

a. The recipient must have a diagnosis of asthma; and

b. The recipient has been assessed for causes of asthma and external triggers have been removed or reduced where possible.

3. For recipients 18 years of age or younger the following criteria must be met:

a. The recipient has a diagnosis of asthma; and

b. The recipient requires an additional inhaler unit for school or equivalent program.

b. PA Guidelines

1. PA approval will be for 12 months.

2. Xopenex® (levalbuterol)

a. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

1. Authorization only for recipients experiencing side effects on one other beta-adrenergic agent of any formulation.

2. Authorization for patients whose cardiovascular status is considered to be in severe deteriorating condition..

V. Anti-Insomnia Agents (Sedative Hypnotics)

Therapeutic Class: Anxiolytics, Sedatives and Hypnotics
Last Reviewed by the DUR Board: September 3, 2015

See Section N of this Appendix for criteria for Sedatives and Hypnotics when prescribed for a psychotropic indication.

Sedatives Hypnotics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented.

a. An FDA approved ICD diagnosis code, such as insomnia, is documented on the prescription and transmitted on the claim; or

b. A PA with an FDA approved diagnosis, such as insomnia, is submitted.

W. Doxepin Topical

Therapeutic Class: Other Topical Anti-Pruritic
Last Reviewed by DUR Board: October 22, 2020

Doxepin Topical is subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for billing information.

1. Authorization will be given if the following criteria are met and documented:

   a. The recipient has a documented diagnosis of pruritus with atopic dermatitis or lichen simplex chronicus; and

   b. The recipient is 18 years of age or older; and

   c. Treatment must not exceed eight days.

2. PA Guidelines:

   a. PA approval will be given for eight days.

X. Antiemetics

Therapeutic Class: Antiemetics, (Serotonin Receptor Antagonists (5 HT3 Antiemetics))
Last Reviewed by the DUR Board: October 28, 2010
Therapeutic Class: Antiemetic (Cannabinoid Antiemetics)
Last Reviewed by DUR Board: October 18, 2018

Antiemetics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

An approved PA is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

1. Serotonin Receptor Antagonists (5 HT3 Antiemetics)

   a. Coverage and Limitations

      1. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses; or

      2. The recipient is receiving chemotherapy treatments more often than once a week; or

      3. The recipient has a diagnosis of Acquired Immune Deficiency Syndrome (AIDS), associated nausea and vomiting; or

      4. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.

   b. PA Guidelines

      1. A PA to override the quantity limits to allow for a 30-day fill for these drugs may be effective for up to six months.

2. Cannabinoid Antiemetics

   a. Coverage and Limitations

      1. Approval will be given if all the following criteria are met and documented:

   b. Nabilone

      1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

2. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

c. Dronabinol

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

c. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or

2. The recipient has been diagnosed with AIDS and has anorexia associated with weight loss; and the recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

a. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

3. PA Guidelines

a. PA approval will be for one year.

Y. Synagis® (palivizumab)

Therapeutic Class: Antiviral Monoclonal Antibodies
Last Reviewed by the DUR Board: January 22, 2015

Synagis® (palivizumab) injections are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

For consideration outside these guidelines, a PA may also be submitted with supporting medical necessity documentation.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. Recipients younger than 12 months of age at the start of respiratory syncytial virus (RSV) season must meet one of the following criteria:

1. The recipient was born at 28 weeks, six days of gestation or earlier; or

2. The recipient has a diagnosis of chronic lung disease (CLD) of prematurity; or

3. The recipient has hemodynamically significant congenital heart disease; or

4. The recipient has congenital abnormalities of the airways or neuromuscular disease; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has clinical evidence of CLD and/or nutritional compromise.

b. Recipients younger than two years of age at the start of RSV season must meet one of the following criteria:

1. The recipient has a diagnosis of CLD of prematurity; and

a. The recipient has required medical therapy (e.g., bronchodilator, diuretics, oxygen, corticosteroids) within six months to the start of RSV season; or

2. The recipient has had a cardiac transplant; or

3. The recipient is severely immunocompromised (solid organ or hematopoietic stem cell transplant, chemotherapy, or other conditions) during the RSV season; or

4. The recipient has had a cardiopulmonary bypass and continues to require prophylaxis after surgery or at the conclusion of extracorporeal membrane oxygenation; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has had manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable) or weight for length less than the tenth percentile.

2. PA Guidelines

a. PA approval will be up to five doses per RSV season for recipients meeting criteria.

Z. Opioids, Opioid Containing Cough Preparations, Opioids Prescribed to Under Age 18

Therapeutic Class: Opioids, Last reviewed by the DUR Board: July 26, 2018
Opioid Containing Cough Preparations Last reviewed by the DUR Board: July 26, 2018
Opioids Prescribed to Under Age 18: Last Reviewed by the DUR Board: October 18, 2018

Opioids, Opioid Containing Cough Preparations, and Opioids Prescribed to Under Age 18 are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Opioids

1. Coverage and Limitations

   a. Opioids will be covered without PA:

      1. For initial prescriptions of seven days or less; and

      2. For a total of 13 seven-day prescriptions in any rolling 12-month period; and

      3. For prescriptions of 60 mg morphine equivalents or less per day.

   b. Recipients currently on chronic opioid medications will not be subject to the seven-day requirement for an opioid(s) they have been receiving in the past 45 days.

   c. PA Criteria: To exceed the number of seven-day prescriptions, or to exceed the seven-day limit, or to exceed the 60 mg morphine equivalents or less per day:

      1. All of the following criteria must be met and documented:

         a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and

         b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.); and

         c. The lowest effective dose is being requested; and

         d. A pain contract is on file.

   d. Exceptions to this policy:

      1. Recipients with cancer/malignancy related pain; or

      2. Recipients who are post-surgery with an anticipated prolonged recovery (>3 months); or

3. Recipients receiving palliative care; or

4. Recipients residing in a long-term care facility; or

5. Recipients receiving treatment for HIV/AIDS; or

6. Prescriptions written by or in consultation with a pain specialist.

2. PA Guidelines

a. PA approval will be for one year.

3. Opioid Containing Cough Preparations

a. The recipient must be 18 years of age or older.

b. PA approval will be for six months.

c. For references purposes, codeine and tramadol for children PA criteria can also be found within this chapter in Section TTT.

4. Opioids Prescribed to Under Age 18

a. Short Acting Opioids will be covered without PA for:

1. Initial prescription of three days or less; and

2. A total of 13 three-day prescriptions in any rolling 12-month period; and

3. Prescriptions of 60 morphine milligram equivalents (MME) or less per day.

b. Recipients currently on chronic opioid medications will not be subject to the three-day requirement for an opioid(s) they have been receiving in the past 45 days.

c. To exceed the number of three-day prescriptions, or to exceed the three-day limit, or to exceed the 60 MME or less per day:

1. All of the following criteria must be met and documented:

a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and

b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, chiropractic treatment, etc.); and

c. The lowest effective dose is being prescribed; and

d. A pain contract is on file.

d. Exceptions:

1. Recipients with cancer/malignancy related pain, recipients who are post-surgery with an anticipated prolonged recovery (>3 months), recipients residing in a long-term care facility, recipients receiving treatment for HIV/AIDS, hospice, palliative care or end-of-life care.

2. Prescriptions written by or in consultation with a pain specialist.

e. PA Guidelines

1. PA approval will be for three months.

AA. Savella® (milnacipran)

Therapeutic Class: Fibromyalgia Agents: Serotonin-Norepinephrine Reuptake Inhibitor (SNRI)
Last Reviewed by DUR Board: July 23, 2020

Savella® (milnacipran) is subject to PA.

1. Approval will be given if all of the following criteria are met and documented:

    a. The recipient has a diagnosis of Fibromyalgia:

        1. If an ICD code for Myalgia and Myositis unspecified is documented on the prescription; or

        2. Completion of a PA documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.

BB. Substance Abuse Agents

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: July 23, 2020

Buprenorphine/Naloxone and Buprenorphine are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Buprenorphine/Naloxone and Buprenorphine

1. Approval will be given if all the following criteria are met and documented:

a. PA approval will be required for all prescriptions over 24 mg.

b. Requires diagnosis of opioid dependence.

2. PA Guidelines

a. PA approval will be for 12 months.

b. Lucemyra™ (lofexidine)

1. Approval will be given if all of the following criteria are met and documented:

a. The recipient has a diagnosis of opioid withdrawal with symptoms due to abrupt opioid discontinuation; and

b. The requested quantity must not exceed 2.88 mg/day for up to 14 days.

2. PA Guidelines

a. PA approval will be for 14 days.

c. Vivitrol® (naltrexone)

1. Coverage and Limitations: Approval will be given if the following criteria are met and documented:

a. The drug is being used for an FDA approved indication; and

b. The drug must be delivered directly to the prescriber’s office; and

c. The drug is only to be administered once per month; and

d. Routine urine screening and monitoring is recommended.

2. PA Guidelines

a. PA approvals will be for six months.

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: January 19, 2023

MS Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient has a diagnosis of MS.

2. Ampyra® (dalfampridine)

    a. Approval will be given if all the following criteria are met and documented:

        1. The recipient must have a diagnosis of MS; and

        2. The medication is being used to improve the recipient's walking speed; and

        3. The medication is being prescribed by or in consultation with a neurologist; and

        4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and

        5. The recipient does not have moderate to severe renal dysfunction (creatinine clearance (CrCL) <50 ml/min); and

        6. The recipient does not have a history of seizures; and

        7. The recipient is not currently pregnant or attempting to conceive.

    b. PA Guidelines

        1. Initial PA approval will be for three months.

        2. Request for continuation of therapy will be approved for one year.

3. Relapsing Forms of MS Agents:

    a. Approval will be given if all the following criteria are met and documented:

        1. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS (RRMS), secondary-progressive MS (SPMS) with relapses).

    b. Lemtrada® (alemtuzumab)

1. Approval will be given if all the following criteria are met and documented:

   a. The recipient must have a diagnosis of a relapsing form of MS; and one of the following:

      1. Both the following:

         a. The recipient has not been previously treated with alemtuzumab; and

         b. The recipient has had failure after a trial of at least four weeks; a contraindication, or intolerance to two of the following disease-modifying therapies for MS:

            1. Aubagio® (teriflunomide)

            2. Avonex® (interferon beta-1a)

            3. Betaseron® (interferon beta-1b)

            4. Copaxone®/Glatopa® (glatiramer acetate)

            5. Extavia® (interferon beta-1b)

            6. Gilenya® (fingolimod)

            7. Mavenclad® (cladribine)

            8. Mayzent® (siponimod)

            9. Ocrevus® (ocrelizumab)

            10. Plegridy® (peginterferon beta-1a)

            11. Rebif® (interferon beta-1a)

            12. Tecfidera® (dimethyl fumarate)

            13. Tysabri® (natalizumab); or

            14. Zinbryta™ (daclizumab)

         c. Both the following:

            1. The recipient has previously received treatment with alemtuzumab; and

            2. The recipient has had at least 12 months elapsed or will have elapsed since the most

recent treatment course with alemtuzumab; and

2. The medication will not be used in combination with another disease-modifying therapy for MS.

2. PA Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

c. Mavenclad® (cladribine)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of a relapsing form of MS (e.g., RRMS, SPMS with relapses); and one of the following:

1. Both the following:

a. The recipient has not been previously treated with cladribine; and

b. The recipient has had failure after a trial of at least four weeks; contraindication, or intolerance to two of the following disease-modifying therapies for MS:

1. Aubagio® (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone®/Glatopa® (glatiramer acetate)

5. Extavia® (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Lemtrada® (alemtuzumab)

8. Mayzent® (siponimod)

9. Ocrevus® (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif® (interferon beta-1a)

12. Tecfidera® (dimethyl fumarate)

13. Tysabri® (natalizumab); or

14. Zinbryta™ (daclizumab)

2. Both the following:

a. The recipient has previously received treatment with cladribine; and

b. The recipient has not already received the FDA-recommended lifetime limit of two treatment courses (or four treatment cycles total) of cladribine; and

b. The medication will not be used in combination with another disease-modifying therapy for MS.

2. PA Guidelines

a. PA approval will be for one month.

d. Ocrevus® (ocrelizumab)

1. Approval will be given if all the following criteria are met and documented:

a. Recipient is at least 18 years of age (unless otherwise specified); and

b. Recipient has been screened for the presence of HBV prior to initiating treatment and does not have active disease (i.e., positive Hepatitis B surface antigen (HBsAg) and anti-HBV tests); and

c. Recipient has had baseline serum immunoglobulins assessed; and

2. Universal Criteria

a. Recipient will not receive live or live-attenuated vaccines while on therapy or within four weeks prior to initiation of treatment; and

b. Recipient does not have an active infection; and

3. MS

a. Recipient must have a confirmed diagnosis of MS as documented by laboratory report (i.e., magnetic resonance imagining (MRI)); and

b. Must be used as single agent therapy; and

1. Recipient has a diagnosis of relapsing form of MS [i.e., RRMS, active SPMS, or clinically isolated syndrome (CIS)]; or

2. Recipient has a diagnosis of primary progressive MS (PPMS); and

a. Recipient is <65 years; and

b. Recipient has an EDSS score of ≤6.5.

2. Recertification Requests (the recipient must meet all criteria):

a. Recipient continues to meet the universal and other indication-specific relevant criteria identified in section III; and

b. Recipient has not received a dose of ocrelizumab within the past five months; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy malignancy, hypogammaglobulinemia, immune-mediated colitis, etc.; and

d. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities, or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].

1. Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥1 relapse, ≥2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

e. PPMS

1. Recipient continues to ambulatory, defined as an EDSS score of <7.5.

3. PA Guidelines

a. Initial PA approval will be 12 months.

b. Recertification approval will be for 12 months.

e. Zeposia® (ozanimod)

1. Approval will be given if all the following criteria is met and documented:

a. The recipient has a documented diagnosis of a relapsing form of MS (e.g., RRMS, SPMS with relapses); and

b. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least one of the following disease-modifying therapies for MS:

a. Avonex® (interferon beta-1a)

b. Betaseron® (interferon beta-1b)

c. Copaxone®/Glatopa® (glatiramer acetate)

d. Tecfidera® (dimethyl fumarate); and

c. The medication is prescribed by or in consultation with a neurologist.

2. Recertification Criteria (the recipient must meet all criteria):

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. The medication is prescribed by or in consultation with a neurologist.

3. PA Guidelines:

a. PA approval will be for 12 months.

b. Recertification approval will be for 12 months.

f. Ponvory® (ponesimod)

1. Approval will be given if all the following criteria are met and documented:

a. Recipient has a diagnosis of a relapsing form of MS (e.g., RRMS; active SPMS, or CIS); and

b. Recipient will not be initiating therapy after previous treatment with alemtuzumab; and

c. Ponesimod will be prescribed by, or in consultation with, neurologist; and

d. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least one of the following disease-modifying therapies for MS;

a. Avonex® (interferon beta-1a); or

b. Betaseron® (interferon beta-1b); or

c. Copaxone®/Glatopa® (glatiramer acetate); or

d. Tysabri® (natalizumab); or

e. Tecfidera® (dimethyl fumarate); or

f. Aubagio® (teriflunomide); or

g. Gilenya® (fingolimod)

2. Recertification Requests:

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. Ponesimod will be prescribed by, or in consultation with, a neurologist.

3. PA Guidelines:

a. PA approval will be given for 12 months.

4. PPMS Agents:

a. Ocrevus® (ocrelizumab)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of PPMS; and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta® (belimumab), Arzerra® (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

2. Recertification Requests (the recipient must meet all criteria):

a. Documentation of a positive clinical response to Ocrevus® therapy; and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

3. The medication must not be used in combination with another B-cell target therapy (e.g., Rituxan® (rituximab), Benlysta® (belimumab), Arzerra® (ofatumumab)); and

a. The medication must not be used with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

4. PA Guidelines

a. PA approval will be for 12 months.

b. Recertification approval will be for 12 months.

DD. Hormones and Hormone Modifiers

Therapeutic Class: Androgenic Agents
Last Reviewed by the DUR Board: October 20, 2022

1. Topical Androgens

a. Approval will be given if all the following criteria are met and documented:

1. Recipient is male; and

2. The medication is used for FDA-approved indication:

a. Primary (congenital or acquired); or

b. Secondary (congenital or acquired) hypogonadism; and

3. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used; and

4. Recipient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen >4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) >19; and

5. Recipient does not have a hematocrit >50%; and

6. Recipient does not have untreated severe obstructive sleep apnea; and

7. Recipient does not have uncontrolled or poorly controlled heart failure.

b. Diagnosis of Gender Dysphoria:

1. Approval will be given if the following criteria are met and documented:

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

2. Xyosted™ (testosterone enanthate)

a. Approval will be given if the following criteria are met and documented:

1. Diagnosis of Hypogonadism (e.g., testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

2. The recipient is male at birth; and

3. One of the following:

a. Two pre-treatment serum total testosterone levels <300 ng/dL (< 10.4 nanomole (nmol)/L) or less than the reference range for the lab; or both of the following:

1. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV, liver disorder, diabetes, obesity); and

2. One pre-treatment calculated free or bioavailable testosterone level <5 ng/dL (<0.17 nmol/L) or less than the reference range for the lab; or

b. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome).

b. Diagnosis of Gender Dysphoria

1. Approval will be given if the following criteria are met and documented:

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual

c. PA Guidelines:

1. PA approval with a diagnosis of hypogonadism will be given for one year.

2. PA approval with a diagnosis of gender dysphoria will be given for six months for recipients new to testosterone therapy; or

a. PA approval will be given to recipients continuing testosterone therapy without a current authorization on file for 12 months.

3. Oral Testosterone Products

a. Hypogonadism:

1. Approval will be given if the following criteria are met and documented:

a. The recipient is >18 years of age; and

b. Recipient is male; and

c. Recipient has a diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); and

d. Recipient has history of failure, contraindication, or intolerance to both testosterone cypionate and testosterone enanthate injection; and

e. Recipient has signs/symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes); and

f. Recipient does not have "age-related hypogonadism" or another hypogonadal condition not associated with structural or genetic etiologies; and

g. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (initial approval only); and

h. Recipient is only receiving one androgen or anabolic agent; and

i. Recipient does not have current or history of breast cancer; and

j. Recipient does not have a HCT >50%; and

k. Recipient does not have uncontrolled hypertension or heart failure; and

l. Recipient does not have uncontrolled obstructive sleep apnea; and

m. Medication is prescribed by or in consultation with an endocrinologist or urologist.

b. Diagnosis of Gender Dysphoria:

1. Approval will be given if the following criteria are met and documented:

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

c. Recertification Requests:

1. Recipient must continue to meet above criteria; and

2. Recipient must have disease improvement and/or stabilization.

d. PA Guidelines:

1. PA approval will be for 12 months.

EE. Colchicine (Colcrys®)

Therapeutic Class: Antigout Agents
Last Reviewed by the DUR Board: January 28, 2016

Colchicine (Colcrys®) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. Colchicine Tablets

1. The recipient has a diagnosis of acute gout (does not require prophylaxis) and the recipient must meet all of the following:

a. The recipient is 16 years of age or older; and

b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID (indomethacin, naproxen, ibuprofen, sulindac, or ketoprofen); and

c. The recipient has had an inadequate response, adverse reaction or contraindication to a corticosteroid (oral or intra-articular).

2. For prophylaxis of chronic gout:

a. The recipient is 16 years of age or older and must meet one of the following:

1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat), or probenecid; or

2. There is documentation that the recipient will be treated with colchicine monotherapy and the recipient must meet all of the following:

a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).

3. For Familial Mediterranean Fever (FMF):

   a. The recipient is four years of age or older.

4. Requests exceeding the quantity limit may be approved for colchicine tablets if all the following are met and documented:

   a. The recipient is 12 years of age or older; and

   b. The recipient has a diagnosis of FMF; and

   c. The recipient's dose is ≤2.4 mg daily (120 tablets/30 days); and

   d. Medical necessity must be provided and documented in the recipient's medical record that the recipient had an inadequate response to 1.8 mg daily (90 tablets/30 days).

b. Colchicine Capsules

1. For Prophylaxis of chronic gout:

   a. The recipient is 18 years of age or older and the recipient must meet one of the following:

      1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat), or probenecid; or

      2. There is documentation that the recipient will be treated with colchicine monotherapy, and the recipient must meet all of the following:

         a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

         b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).

2. PA Guidelines

c. PA approval will be given based on diagnosis.

1. For FMF and chronic gout: one year.

2. For acute gout: two months.

FF. Thrombin Inhibitors

Therapeutic Class: Thrombin Inhibitors
Last Reviewed by the DUR Board: January 22, 2015

Thrombin Inhibitors are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. A diagnosis code associated with the FDA approved indication(s) is documented on the prescription and transmitted on the claim; and

b. There are no contraindications to prescribing this medication; or

c. An approved PA documenting the recipient meeting all the criteria above (1.) (a.-b.).

2. PA Guidelines

a. PA approval will be for up to one year.

GG. Antihemophilic Agents

Therapeutic Class: Antihemophilic Agents
Last Reviewed by the DUR Board: July 26, 2018

Antihemophilic Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

a. The medication being prescribed must be for an FDA approved indication; or

b. One of the following:

1. The diagnosis is supported as a use of American Hospital Formulary Service Drug Information (AHFS DI); or

2. The diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “effective” or “evidence favors efficacy” (see DRUGDEX Efficacy Rating and PA Approval Status table); or

4. Diagnosis is supported in any other section of DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal; and

a. One of the following:

1. The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

   a. AHFS Compendium;

   b. Thomson Reuters (Healthcare) Micromedex/ DRUGDEX (not Drug Points) Compendium;

   c. Elsevier Gold Standard's Clinical Pharmacology Compendium;

   d. National Comprehensive Cancer Network Drugs and Biologics Compendium; and

c. The dispensing provider will monitor the amount of product a recipient has left to avoid over-stock; and

d. The prescriber is a specialist in treating hemophilia; and

e. A new PA will be required for any dose adjustment in excess of 5% (increase or decrease).

2. PA Guidelines

   a. PA approval will be for 12 months.

HH. Anti-Hepatitis Agents

Therapeutic Class: Anti-Hepatitis Agents
Last Reviewed by the DUR Board: January 18, 2024

Anti-Hepatitis Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Epclusa® (sofosbuvir/velpatasvir)

   a. Approval will be given if all the following criteria are met and documented:

      1. The recipient is not receiving Epclusa® (sofosbuvir and velpatasvir) in combination with another hepatitis C virus (HCV) direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

      2. The medication must be prescribed by or in consultation with one of the following:

         a. Hepatologist

         b. Gastroenterologist

         c. Infectious Disease Specialist

         d. HIV Specialist (certified through the American Academy of HIV Medicine)

   b. Genotype 1, 2, 3, 4, 5, or 6 without decompensated liver disease

      1. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

      2. The recipient must not have decompensated liver disease; and

      3. Epclusa® must be used alone; and

      4. The request is FDA approved for recipient weight and age; and

      5. PA approval will be for 12 weeks.

   c. Genotype 1, 2, 3, 4, 5, or 6 with decompensated liver disease

      1. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

      2. The recipient has decompensated liver disease; and

3. Epclusa® is being used in combination with Ribavirin®; and

4. The request is FDA approved for recipient weight and age; and

5. PA approval will be for 24 weeks.

d. Genotype 1, 2, 3, 4, 5, or 6 with Ribavirin® intolerance/ineligible or prior Sovaldi® (sofosbuvir) or NS5A-based treatment failure.

1. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has decompensated liver disease; and

a. One of the following:

1. The recipient is Ribavirin® intolerant or ineligible; or

2. Both of the following:

a. The recipient has had prior failure (defined as viral relapse, breakthrough while on therapy, or is a non-responder to therapy) to Sovaldi® or NS5A-based treatment; and

b. Epclusa® is used in combination with Ribavirin®.

3. PA approval will be for 24 weeks.

2. Harvoni® (ledipasvir/sofosbuvir)

a. Approval will be given if the following criteria are met and documented:

1. The recipient is not receiving Harvoni® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

2. The medication must be prescribed by or in consultation with one of the following:

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV ribonucleic acid (RNA) is <6 million IU/mL

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

a. The recipient does not have cirrhosis; and

b. The recipient is treatment naïve; and

c. Medical records documenting pre-treatment HCV RNA <6 million IU/mL must be submitted; and

d. PA approval will be for eight weeks.

c. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is ≥6 million IU/mL

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. The recipient is treatment naïve; and

4. Medical records documenting pre-treatment HCV RNA ≥6 million IU/mL must be submitted; and

5. PA approval will be for 12 weeks.

d. Genotype 1, treatment naïve, with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient is treatment naïve; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. PA approval will be for 12 weeks.

e. Genotype 1, treatment experienced, without cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. One of the following:

a. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin® or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin®; or

b. Both of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) except in combination with Olysio® (simeprevir); and

2. The medication is used in combination with Ribavirin®.

4. PA approval will be for 12 weeks.

f. Genotype 1, Ribavirin® eligible, treatment experienced, and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin® or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin®; and

4. The medication is used in combination with Ribavirin®; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. PA approval will be for 12 weeks.

g. Genotype 1, Ribavirin® ineligible, treatment experienced. and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin® or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin®; and

4. The recipient is Ribavirin® ineligible; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. PA approval will be for 24 weeks.

h. Genotype 1, 4, 5 or 6 with decompensated cirrhosis or post-liver transplant

1. The recipient has a documented diagnosis of chronic HCV genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); or

b. Both of the following:

1. The recipient is a liver transplant recipient; and

2. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

3. The medication is used in combination with Ribavirin®; and

4. PA approval will be for 12 weeks.

i. Genotype 1,4, 5, or 6 with decompensated cirrhosis, Ribavirin® ineligible or prior failure of Sovaldi® or NS5A based regimen

1. The recipient has a documented diagnosis of chronic HCV genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); and

3. One of the following:

a. The recipient is Ribavirin® ineligible; or

b. Both of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

2. The medication is used in combination with Ribavirin®; and

4. PA approval will be for 24 weeks.

j. Genotype 4, treatment naïve or treatment experienced (peginterferon plus Ribavirin®)

1. The recipient has a documented diagnosis of chronic HCV genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. One of the following:

1. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin® and is without cirrhosis; or

2. Both of the following:

a. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin® and has compensated cirrhosis (Child-Pugh class A); and

b. The medication is used in combination with Ribavirin®.

3. PA approval will be for 12 weeks.

k. Genotype 5 or 6, treatment naïve or treatment experienced (peginterferon plus Ribavirin®)

1. The recipient has a documented diagnosis of chronic HCV genotype 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin®; and

3. PA approval will be for 12 weeks.

3. Mavyret® (glecaprevir/pibrentasvir)

a. Approval will be given if the following criteria are met and documented:

1. The recipient is not receiving Mavyret® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir)); and

2. The medication must be prescribed by or in consultation with one of the following:

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, 2, 3, 4, 5, or 6, treatment naïve without cirrhosis

1. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. PA approval will be for 12 weeks.

c. Genotype 1, 2, 3, 4, 5, or 6, treatment naïve, with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient has compensated cirrhosis (Child-Pugh class A); and

4. PA approval will be for eight weeks.

d. Genotype 1, treatment experienced (prior failure to an NS3/4A protease inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. PA approval will be for 12 weeks.

e. Genotype 1, treatment experienced (prior failure to an NS5A inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. PA approval will be for 16 weeks.

f. Genotype 3, treatment experienced (interferon or Sovaldi® based regimen), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin®, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. PA approval will be for 16 weeks.

g. Genotype 1, 2, 4, 5, or 6, treatment experienced (interferon or Sovaldi® based regimen), without cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin®, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without cirrhosis; and

5. PA approval will be for eight weeks.

h. Genotype 1, 2, 4, 5, or 6, treatment experienced (interferon or Sovaldi® based regimen), with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1, 2, 4, 5, or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin®, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek®

(telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient has compensated cirrhosis (e.g., Child-Pugh class A); and

5. PA approval will be for 12 weeks.

4. Sovaldi® (sofosbuvir)

a. Approval will be given if the following criteria are met and documented:

1. The medication must be prescribed by or in consultation with one of the following:

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1 or 4 without decompensated liver disease

1. The recipient has a documented diagnosis of chronic HCV genotype 1 or 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with peginterferon alfa and Ribavirin®; and

3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

4. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

5. PA approval will be for 12 weeks.

c. Genotype 3 without decompensated liver disease

1. The recipient has a documented diagnosis of chronic HCV genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient must be 18 years of age or older; or

3. Both of the following:

a. The recipient has a documented diagnosis of chronic HCV genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is <12 years of age; and

4. The medication is used in combination with Ribavirin®; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. PA approval will be for 24 weeks.

d. Genotype 2 without decompensated liver disease

1. The recipient has a documented diagnosis of chronic HCV genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient must be 18 years of age or older; or

3. Both of the following:

a. The recipient has a documented diagnosis of chronic HCV genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is <12 years of age; and

4. The medication is used in combination with Ribavirin®; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. PA approval will be for 12 weeks.

e. Genotype 1 without cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. PA approval will be for 12 weeks.

f. Genotype 1 with cirrhosis

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient has cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. PA approval will be for 12 weeks.

g. Genotype 1

1. The recipient has a documented diagnosis of chronic HCV genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin®.

5. PA approval will be for 12 weeks.

h. Genotype 3

1. The recipient has a documented diagnosis of chronic HCV genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has cirrhosis (compensated or decompensated) and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin®.

5. PA approval will be for 12 weeks.

5. Viekira Pak® (ombitasvir, paritaprevir, ritonavir tablets, dasabuvir tablets)

a. Genotype 1a or Mixed Genotype 1 Infection without cirrhosis and without liver transplant

1. Approval will be given if all criteria are met and documented:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic HCV genotype 1a or mixed genotype 1 infection; and

b. The recipient is without cirrhosis; and

c. The medication is used in combination with Ribavirin®; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hepatologist

2. Gastroenterologist

3. Infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)).

2. PA Guidelines:

a. PA will be for 12 weeks.

b. Genotype 1a or Mixed Genotype Infection with cirrhosis and without liver transplant

1. Approval will be given if all criteria are met and documented:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic HCV genotype 1a or mixed genotype 1 infection; and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient has cirrhosis; and

c. The medication is being used in combination with Ribavirin®; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hematologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir)).

2. PA Guidelines:

a. PA approval will be for 24 weeks.

c. Genotype 1b without liver transplant

1. Approval will be given if all criteria are met and documented:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic HCV genotype 1b; and

b. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

c. The medication is prescribed by or in consultation with one of the following:

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

d. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

e. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir)).

2. PA Guidelines:

a. PA approval will be for 12 weeks.

d. Genotype 1 (regardless of sub genotype) – Liver Transplant Recipient

1. Approval will be given if all criteria are met and documented:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic HCV genotype 1; and

b. Documentation confirming the recipient is a liver transplant recipient; and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting the recipient's normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score ≤F2); and

d. The medication is used in combination with Ribavirin®; and

e. Prescribed by or in consultation with one of the following:

1. Hepatologist

2. Gastroenterologist

3. Infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/ sofosbuvir), Sovaldi® (sofosbuvir)).

2. PA Guidelines:

a. PA approval will be for 24 weeks.

6. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

a. Approval will be given if all criteria are met and documented:

1. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

2. The recipient is not receiving Vosevi® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Zepatier® (elbasvir/grazoprevir)); and

3. The medication must be prescribed by or in consultation with one of the following:

   a. Hepatologist

   b. Gastroenterologist

   c. Infectious Disease Specialist

   d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, 2, 3, 4, 5, or 6 without decompensated cirrhosis, prior relapse to NS5A based regimen

1. Approval will be given if all criteria are met and documented:

   a. The recipient has a documented diagnosis of chronic HCV (submission of medical records e.g., chart notes, laboratory values); and

   b. The recipient is a previous relapse to an NS5A based regimen (e.g., Daklinza® (daclatasvir), Epclusa® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Technivie® (ombitasvir/ paritaprevir/ ritonavir), Viekira® (ombitasvir/ paritaprevir/ ritonavir/ dasabuvir), Zepatier® (elbasvir/grazoprevir); and

   c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score ≤F2); and

2. PA Guidelines:

   a. PA approval will be for 12 weeks.

3. Genotype 1a, without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor.

   a. Approval will be given if all criteria are met and documented:

1. The recipient has a documented diagnosis of chronic HCV genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. PA Guidelines:

1. PA approval will be for 12 weeks.

4. Genotype 3 without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor.

a. Approval will be given if all criteria are met and documented:

1. The recipient has a documented diagnosis of chronic HCV genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. PA Guidelines:

1. PA approval will be for 12 weeks.

7. Zepatier® (elbasvir/grazoprevir)

a. Approval will be given if all criteria are met and documented:

1. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and

2. The recipient is not receiving Zepatier® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

3. The medication must be prescribed by or in consultation with one of the following:

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1a, treatment naïve, or Peg-IFN/RBV experienced, or Peg-IFN/RBV/protease inhibitor experienced, without NS5A polymorphisms:

1. Approval will be given if all criteria met and documented:

a. The recipient has a documented diagnosis of chronic HCV genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

b. One of the following:

1. The recipient is treatment naïve; or

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin® treatment; or

3. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin® plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir); and

c. Both of the following:

1. The recipient has been tested for the presence of NS5A resistance associated polymorphisms; and

2. The recipient has baseline NS5A resistance associated polymorphisms (e.g., polymorphisms at amino acid positions 28, 30, 31, or 93); and

d. The medication is used in combination with Ribavirin®; and

2. PA Guidelines:

a. PA approval will be for 16 weeks.

3. Genotype 1b, treatment naïve, or Peg-IFN/RBV experienced, or Peg-IFN/RBV/protease inhibitor experienced

a. Approval will be given if all criteria are met and documented:

1. The recipient has a documented diagnosis of chronic HCV genotype 1b (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has had prior failure to peginterferon alfa plus Ribavirin® treatment; or

c. Both of the following:

1. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin® plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir or telaprevir); and

2. The medication is used in combination with Ribavirin®; and

b. PA Guidelines:

1. PA approval will be for 12 weeks.

4. Genotype 4, treatment naïve

a. Approval will be given if all criteria are met and documented:

1. The recipient has a documented diagnosis of chronic HCV genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

b. PA Guidelines:

1. PA approval will be for 12 weeks.

5. Genotype 4, Peg-IFN/RBV experienced

a. Approval will be given if all criteria are met and documented:

1. The recipient has a documented diagnosis of chronic HCV genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin®; and

3. The medication is used in combination with Ribavirin®; and

b. PA Guidelines:

1. PA approval will be for 16 weeks.

II. Daliresp® (roflumilast) and Ohtuvayre™ (ensifentrine)

Therapeutic Class: Phosphodiesterase-4 Inhibitors or combination.
Last Reviewed by the DUR Board: April 17, 2025

Daliresp® (roflumilast) and Ohtuvayre™ (ensifentrine) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting anticholinergic agent;

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting beta (β) agonist;

c. The recipient has experienced an inadequate response, adverse event or has a contraindication to an inhaled corticosteroid;

d. The recipient has a diagnosis of COPD; and

e. The recipient has a history of COPD exacerbations.

2. Contraindication

a. Daliresp® (roflumilast) may not be approved for a recipient with a diagnosis of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

3. Caution

a. Prescriber attestation that Ohtuvayre™ (ensifentrine) will be used with caution in recipients with hepatic impairment.

4. PA Guidelines

a. PA approval will be for one year.

JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed by DUR Board: April 22, 2021

Hereditary Angioedema (HAE) agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Cinryze® (C1 esterase inhibitor), Haegarda® (C1 esterase inhibitor), Orladeyo® (berotralstat) or Takhzyro® (lanadelumab-flyo)

   a. Approval will be given if all the following criteria are met and documented:

      1. The recipient has a diagnosis of HAE; and

      2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

         a. C1-INh antigenic level below the lower limit of normal; or

         b. C1-INh functional level below the lower limit of normal; and

            1. The medication is being prescribed by or in consultation with an allergist or immunologist.

      3. The medication is being used as prophylaxis against attacks; and

   b. PA Guidelines:

      1. PA approval will be approved for 12 months.

2. Cinryze® (C1 esterase inhibitor), Firazyr® (icatibant), Ruconest® (C1 esterase inhibitor)

   Note: off label use

   a. Approval will be given if all the following criteria are met and documented:

      1. The recipient has a diagnosis of HAE; and

      2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

         a. C1-INh antigenic level below the lower limit of normal; or

         b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

4. The medication is not used in combination with other approved treatment for acute HAE attacks; and

5. The medication is prescribed by or in consultation with an allergist or immunologist.

b. PA Guidelines:

1. PA approval will be approved for 12 months.

3. Kalbitor® (ecallantide)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis of HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the lower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

4. The recipient is 12 years of age or older; and

5. The medication is not used in combination with other approved treatments for acute HAE attacks; and

6. The medication is prescribed by or in consultation with an allergist or immunologist.

b. PA Guidelines:

1. PA approval will be approved for 12 months.

4. Berinert® (C1 esterase inhibitor)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the lower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is not used in combination with other approved treatments for acute HAE attacks; and

4. The medication is being prescribed by or in consultation with an allergist or immunologist; and

5. The medication is being used to treat acute HAE attacks and

6. One of the following:

a. The recipient has trial and failure, contraindication, or intolerance to Ruconest®; or

b. The recipient is 12 years of age or younger and there is documentation that the recipient has history of laryngeal attacks.

b. PA Guidelines:

1. PA approval will be approved for 12 months.

KK. Incretin Mimetics

Therapeutic Class: Incretin Mimetics
Last Reviewed by the DUR Board: April 17, 2025
Previously reviewed by the DUR Board: July 18, 2024

Incretin Mimetics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all criteria are met and documented:

   a. Initial Request:

      1. Medication being prescribed for one of the following:

         a. Adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (T2DM); or

         b. Reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in recipients with type 2 diabetes and established cardiovascular disease; and

      2. Documentation of A1C lab result within past 180 days; and

      3. Recipient does not have history of pancreatitis; and

      4. Recipient does not have type 1 diabetes mellitus; and

      5. Medication is not being prescribed for weight loss in absence of T2DM indication; and

      6. Medication prescribed at FDA-approved dose for T2DM indication; and

      7. Recipient is appropriate age per FDA label.

   b. Renewal Requests:

      1. Recipient continues to meet above criteria; and

      2. Documentation of positive response from therapy.

2. PA Guidelines

   a. PA approval will be for one year.

3. Exception criteria:

a. Wegovy® (semaglutide)

1. Approval will be given if the following criteria are met and documented:

a. Medication is being prescribed for risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

b. Recipient must be 18 years of age or older; and

c. Documentation that patient has a body mass index (BMI) ≥27 $kg/m^2$; and

d. Established cardiovascular (CV) disease as evidenced by at least one of the following criteria:

1. prior myocardial infarction;

2. prior ischemic or hemorrhagic stroke;

3. symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) <0.85 (at rest), or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; or

4. Recipient has established CV disease verified by specialist and the specialist has provided documentation to confirm medication is being prescribed to reduce the recipient's specific CV risk;

e. Wegovy® must be prescribed by, or in consultation with, a cardiologist or vascular specialist; and

f. Recipient must not have type 1 or type 2 diabetes. Recipients with type 1 or type 2 diabetes must have appropriate diabetic care with an alternative therapy as this indication is specific to non-diabetic patients; and

g. Recipient must not have any contraindications for use of Wegovy®; and

h. Recipient must not be utilizing another glucagon-like peptide (GLP-1) therapy; and

i. Documentation that recipient has received individualized healthy lifestyle counseling; and

j. Provider attestation that in addition to Wegovy® the provider will maintain standard of care treatment for the recipient's established CV disease; and

b. Zepbound® (tirzepatide)

1. Approval will be given if the following criteria are met and documented:

a. Initial request:

1. The recipient must be 18 years of age or older; and

2. Medication is being prescribed for moderate to severe obstructive sleep apnea (OSA) in adults with obesity, with OSA defined by one of the following [submission of records required]:

a. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study from a certified or accredited sleep disorder facility; or

b. Both of the following:

1. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study from a certified or accredited sleep disorder facility; and

2. One of the following signs/symptoms are present:

a. Daytime sleepiness; or

b. Nonrestorative sleep; or

c. Fatigue; or

d. Insomnia; or

e. Waking up with breath holding, gasping, or choking; or

f. Habitual snoring noted by a bed partner or other observer; or

g. Observed apnea; or

c. Both of the following:

1. The recipient is not an appropriate candidate for a facility sleep study due to immobility, safety, or critical illness; and

2. Zepbound® is being prescribed by, or in consultation with, a board-certified sleep specialist or pulmonologist for a diagnosis of moderate to severe OSA; and

3. All of the following:

a. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP), unless there is rationale from provider as to why treatment is not indicated; and

1. Documentation that the recipient has a body mass index (BMI) >30 kg/m2; and

2. The recipient must not have type 1 or type 2 diabetes. Recipients with type 1 or type 2 diabetes must have appropriate diabetic care with an alternative therapy as this indication is specific to non-diabetic patients; and

3. The recipient must not have any contraindications for use of Zepbound®; and

4. Provider attestation that this medication will be used in combination with a reduced calorie diet and increased physical activity.

b. Recertification request:

1. Documentation of positive clinical response to therapy; and

2. The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP), unless there is rationale from provider as to why treatment is not indicated.

c. PA Guidelines:

1. Initial PA approval will be for six months.

2. Recertification approval will be for six months and requires achievement of 2.4 mg once weekly maintenance dose shown to reduce the risk of major cardiovascular events following titration according to package labeling or prescriber must provide reasoning why the 2.4 mg once weekly maintenance dose is not appropriate.

LL. Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: April 17, 2025

Cystic Fibrosis (CF) Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given for a single agent concomitantly if the following criteria are met and documented:

   a. Kalydeco® (ivacaftor)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient is age appropriate according to the FDA-approved package labeling; and

         b. The recipient has a diagnosis of CF; and

         c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the gene mutations listed in the FDA-approved package insert; and

         d. The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a CF care center.

      2. Recertification Requests (the recipient must meet all the following criteria)

         a. Documentation of a positive clinical response to Kalydeco® therapy.

      3. PA Guidelines:

         a. Initial request will be approved for 12 months.

         b. Recertification requests will be for 12 months.

   b. Orkambi® (lumacaftor/ivacaftor)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient has a diagnosis of CF; and

         b. The recipient is age appropriate according to the FDA-approved package labeling; and

c. The recipient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene; and

d. The requested dose is two tablets every 12 hours; or

e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. PA Guidelines:

a. PA approvals will be for one year.

c. Symdeko® (tezacaftor/ivacaftor)

1. Approval will be given if the following criteria are met and documented:

a. Initial Request:

1. The recipient is age appropriate according to the FDA-approved package labeling; and

2. The recipient has a documented diagnosis of CF; and

3. The medication must be prescribed by or in consultation with either a Pulmonologist or a specialist associated with a CF care center.

4. One of the following:

a. The recipient is homozygous for the F508del mutation as detected by an FDA cleared CF mutation test or Clinical Laboratory Improvement Amendments (CLIA) approved facility; or

b. The recipient has one of the FDA approved package insert listed mutations on at least one allele in the CFTR gene as detected by FDA cleared CF mutation test or CLIA approved facility.

b. Recertification Requests (the recipient must meet the following criteria):

1. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

2. PA Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

d. Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

1. Approval will be given if the following criteria are met and documented:

a. The recipient is age appropriate according to the FDA-approved package labeling; and

b. The recipient has a documented diagnosis of CF; and

c. The recipient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data as detected by an FDA cleared CF mutation test, or a test performed at a CLIA approved facility; and

d. The medication is prescribed by or in consultation with either a Pulmonologist or a specialist affiliated with a CF care center.

2. Recertification Requests:

a. The recipient must have documentation of a positive clinical response to Trikafta® therapy (e.g. improvement in lung function [percent predicted FEV1 {PPFEV1}] or decreased number of pulmonary exacerbations)

3. PA Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

e. Alyftrek™ (vanzacaftor/tezacaftor/deutivacaftor tablets)

1. Initial request:

a. The recipient is age-appropriate according to the FDA-approved package labeling; and

b. The recipient has a document diagnosis of CF; and

c. The recipient has at least one F508del mutation or another responsive mutation in the CTFR gene as detected by FDA-cleared CF mutation test or CLIA-approved facility; and

d. The recipient does not have moderate or severe hepatic impairment (Child-Pugh class B or C); and

e. Prescriber attestation that liver function tests are being monitored per FDA package-insert (i.e., prior to initiating therapy, every month for the first six months, every three months for next 12 months, then at least annually); and

f. The mediation is prescribed by, or in consultation with, a pulmonologist or a specialist affiliated with a CF care center.

2. Renewal requests:

a. Documentation of positive response to therapy; and

b. The medication is prescribed by, or in consultation with, a pulmonologist or a specialist affiliated with a CF care center.

MM. Gimoti® (metoclopramide)

Therapeutic Class: Gastrointestinal Prokinetic Agents
Last Reviewed by the DUR Board: October 26, 2021

Gastrointestinal Prokinetic Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria are met and documented:

    a. The recipient has a diagnosis of acute diabetic gastroparesis; and

    b. The recipient is 18 years of age or older; and

    c. The recipient does not have any of the following:

        1. History of signs or symptoms of tardive dyskinesia (TD); or

        2. History of a dystonic reaction to metoclopramide; or

        3. Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation); or

        4. Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma; or

        5. Diagnosis of epilepsy or any other seizure disorder; or

        6. Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm); or

        7. Moderate or severe renal impairment (CrCL <60 mL/minute); or

        8. Moderate or severe hepatic impairment (Child-Pugh B or C); and

    d. One of the following:

        1. The recipient has had an adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., IM) metoclopramide; or

        2. The recipient is not a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications)

2. Recertification Requests:

    a. Recipient continues to meet all initial authorization criteria; and

b. At least two weeks have passed (i.e., drug holiday) since completion of a previous course or metoclopramide treatment of any dosage form; and

c. Recipient demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); and

d. Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention)

3. PA Guidelines:

a. PA approval will be for two months

b. Recertification requests will be approved for two months

NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors
Last Reviewed by the DUR Board: April 22, 2021

Platelet Inhibitors are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Authorization will be given if the following criteria are met and documented:

   a. Brilinta® (ticagrelor)

      1. The recipient has a diagnosis of Acute Coronary Syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

      2. The recipient does not have an active pathological bleed or history of intracranial hemorrhage; and

      3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and

      4. One of the following:

         a. The recipient has been started and stabilized on the requested medication; or

         b. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

         c. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

   b. Effient® (prasugrel)

      1. The recipient has a diagnosis of ACS (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

      2. The recipient does not have an active pathological bleed or history of transient ischemic attack or cerebral vascular accident (CVA); and

      3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and

      4. The recipient has a history of percutaneous coronary intervention; and

      5. One of the following:

a. The recipient has been started and stabilized on the requested medication; or

b. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

c. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

2. PA Guidelines

a. PA approval will be for 12 months.

OO. Voydeya™ (danicopan)

Therapeutic Class: Oral Complement Factor D Inhibitor
Last Reviewed by the DUR Board: January 16, 2025

Voydeya™ (danicopan) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial Request:

1. Recipient ≥18 years old; and

2. Recipient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry testing; and

3. Recipient has received a stable dose of C5 inhibitor therapy (ravulizumab-cwvz [Ultomiris®] or eculizumab [Soliris®]) for ≥6 months prior to starting Voydeya™; and

4. Voydeya™ will be used as add-on therapy to eculizumab (Soliris®) or ravulizumab-cwvz (Ultomiris®); and

5. Recipient has clinically significant extravascular hemolysis (EVH) while on Soliris® or Ultomiris® as evidenced by both of the following:

a. Hb ≤9.5 g/dL; and

b. Absolute reticulocyte count ≥120 x $10^9$/L; and

6. Medication prescribed by or in consultation with Hematologist; and

7. Recipient has documented vaccinations for Neisseria meningitidis (N. meningitidis) and Streptococcus pneumoniae (S. pneumoniae) ≥2 weeks prior to initiating therapy; and

8. Recipient does not have any of the following:

a. Severe hepatic impairment (Child-Pugh class C); or]

b. Unresolved serious infection caused by encapsulated bacteria (including N. meningitides, S. pneumoniae, or Haemophilus influenzae type b (HIB))

b. Recertification Requests (the recipient must meet all of the following criteria):

1. Voydeya™ being used as add-on therapy to eculizumab (Soliris®) or ravulizumab-cwvz (Ultomiris®); and

2. Medication prescribed by or in consultation with Hematologist; and

3. Recipient has demonstrated positive response to therapy (e.g., decreased requirement of RBC transfusions, Hb stabilization or improvement LDH reduction, symptom improvement or stabilization, reduction in thrombotic events); and

4. Recipient does not have any treatment restricting adverse effects (e.g., encapsulated bacterial infection, clinically significant or symptomatic hepatic enzyme elevations)

c. Quantity Limit: 200 mg three times daily.

PP. Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations

Therapeutic Class: GnRH Antagonist and Combinations
Last Reviewed by DUR Board: July 27, 2023

GnRH Antagonist and Combinations are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Orilissa® (elagolix)

   a. Approval will be given if all criteria are met and documented:

      1. The recipient has a diagnosis of moderate to severe pain associated with endometriosis; and

      2. One of the following:

         a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

            1. Danazol; or

            2. Combination (estrogen/progesterone) oral contraceptive; or

            3. Progestins; or

         b. The recipient has had surgical ablation to prevent occurrence.

      3. For Orilissa® 200 mg request only, the treatment will not exceed six months.

   b. Recertification Requests (All criteria must be met and documented):

      1. The recipient has documented improvement in pain associated with endometriosis improvement in dysmenorrhea and non-menstrual pelvic pain); and

      2. Treatment duration has not exceeded a total of 24 months; and

      3. The request is for Orilissa® 150 mg.

   c. PA Guidelines:

      1. PA approval will be for six months.

      2. Recertification approval will be for six months.

2. Oriahnn® (elagolix, estradiol, and norethindrone)

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and

2. One of the following:

a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

1. Danazol; or

2. Combination (estrogen/progesterone) oral contraceptive; or

3. Progestins; or

b. The recipient has had surgical ablation to prevent occurrence.

b. Recertification Requests:

1. The recipient has documented improvement in menstrual bleeding; and

2. Treatment duration will not exceed a total of 24 months.

c. PA Guidelines:

1. PA approval will be for six months.

2. Recertification approval will be for six months.

3. Myfembree®

a. Approval will be given if the two criteria below have been met and documented:

1. The recipient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and

2. One of the following has occurred:

a. The recipient has a documented history of inadequate control response following a trial of at least three months or the recipient has a documented history of intolerance or contraindication to:

1. Danazol;

2. Combination (estrogen/progesterone) oral contraceptive;

3. Progestins;

b. The recipient has had a surgical ablation to prevent occurrence.

b. Recertification Requests (All criteria must be met and documented):

1. The recipient has documented improvement in menstrual bleeding; and

2. Treatment duration will not exceed a total of 24 months.

c. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of moderate to severe pain associated with endometriosis; and

2. One of the following has occurred:

a. The recipient has a documented history of inadequate pain control response following a trial of at least three months or the recipient has a documented history of intolerance or contraindication to:

1. Danazol;

2. Combination (estrogen/progesterone) oral contraceptive; or

3. Progestins;

b. The recipient has had surgical ablation to prevent occurrence.

d. Recertification Requests (All criteria must be met and documented):

1. The recipient has documented improvement in pain associated with endometriosis (improvement in dysmenorrhea and non-menstrual pelvic pain); and

2. Treatment duration will not exceed a total of 24 months.

4. PA Guidelines

a. PA approval will be for six months.

QQ. Spravato™ (esketamine)

Therapeutic Class: Miscellaneous Anti-Depressant
Last Reviewed by the DUR Board: January 16, 2025

Spravato™ (esketamine) is subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. Initial approval will be given if the following criteria are met and documented:

      1. The recipient is 18 years of age or older; and

      2. Recipient must have a diagnosis of one of the following:

         a. Treatment resistance depression as evidence of failure of two antidepressants; or

         b. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior; and

      3. Medication must be administered under the direct supervision of a healthcare provider with post-administration observation; and

      4. Treatment must be in conjunction with an oral antidepressant if being prescribed for depressive symptoms in adults with MDD with acute suicidal ideation or behavior; and

      5. The medication must be prescribed by or in consultation with a psychiatrist; and

      6. The recipient must not have an aneurism or arteriovenous (AV) malformation.

   b. Approval will not be given for recipients who are currently pregnant or lactating and breastfeeding.

2. Recertification Requests:

   a. In addition to the PA criteria listed above (initial approval), the recipient must also have a positive clinical response to the medication treatment.

3. PA Guidelines

   a. Initial PA approval will be given for four weeks.

b. Recertification authorization approval will be given for six months.

RR. Omontys® (peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)
Last Reviewed by DUR Board: October 25, 2012

Omontys® (peginesatide) is subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of anemia secondary to chronic kidney disease;

   b. The recipient must be over 18 years of age;

   c. The recipient is receiving dialysis;

   d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);

   e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and

   f. The target hemoglobin level will not exceed 11 g/dL.

2. PA Guidelines

   a. PA approval will be for one month.

SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: January 19, 2023

Colony Stimulating Factors are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The requested agent is being used for an FDA-approved indication.

b. The requests for a diagnosis of nonmyeloid malignancy must meet one of the following criteria:

1. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of ≥20%; or

2. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age >65 years, absolute neutrophil count (ANC) <100 cells/μL or the expected duration of neutropenia is >10 days); or

3. The recipient has experienced a prior episode of febrile neutropenia, and the requested drug will be used as secondary prophylaxis.

2. PA Guidelines

a. PA approval will be for one month.

TT. Auvi-Q® (epinephrine injection device)

Therapeutic Class: Anaphylaxis-Self Injectable Epinephrine
Last Reviewed by the DUR Board: January 23, 2014

Auvi-Q® (Epinephrine Injection Device) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient or recipient's caregiver is unable to read or comprehend written directions.

2. PA Guidelines

   a. Initial PA approval will be for one year.

   b. Recertification approval will be for one year.

UU. Alzheimer's Disease Agents

Therapeutic Class: Alzheimer's Disease Agents
Last Reviewed by DUR Board: October 26, 2021

Alzheimer's Disease Agents is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Aduhelm® (aducanumab-avwa)

   a. Approval will be given if the following criteria are met and documented:

      1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

         a. Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one the following;

            1. Diagnosis of mild cognitive impairment due to Alzheimer's disease; or

            2. Diagnosis of probable Alzheimer's disease dementia; and

         b. All of the following:

            1. Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4; and

            2. Repeatable Battery for the Assessment of Neuropsychological (RBANS) score ≤85; and

            3. Mini-Mental State Examination score of 24-30; or

            4. Montreal Cognitive Assessment (MoCA) of 17 or above; and

      2. Documentation of beta-amyloid protein disposition, as evidenced by one of the following:

         a. Positive amyloid positron emission tomography (PET) scan; or

         b. Both of the following:

            1. Attestation that the patient does not have access to amyloid PET scanning; and

2. Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., AB42 level, AB42:AB40 ratio); and

3. All of the following:

a. Recipient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less); and

b. Recipient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment; and

c. Recipient had no history of relevant brain hemorrhage, bleeding disorder, and cerebrovascular abnormalities in last six months; and

4. A baseline brain MRI has been completed within 12 months prior to initiating treatment to rule out other causes (e.g., stroke, small vessel disease, tumor); and

5. Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA) (ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H)) and recipient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; and

6. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist, or other expert in the disease state.

b. Recertification Requests:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting recipients benefitting from therapy as defined by both of the following:

a. Based on NIA-AA criteria, one of the following:

1. Recipient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease; or

2. Recipient continues to have a diagnosis of probable disease dementia; and

b. All of the following:

1. CDR-G score of 0.5 of CDR-SB score of 0.5-4; and

2. RBANS score ≤85; and

a. Mini-Mental State Examination (MMSE) score of 24-30; and

c. Recipient has a follow-up brain MRI that has been completed after the initiation of therapy to show one of the following:

1. Both of the following:

a. <10 new incident microhemorrhages; and

b. Two or less focal areas of superficial siderosis; or

2. If 10 or more new incident microhemorrhages or >2 focal areas of superficial siderosis are present then both of the following:

a. Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances); and

b. Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H); and

c. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist.

c. PA Guidelines:

1. PA approval will be for six months.

2. Recertification requests will be approved for six months.

2. Leqembi® (lecanemab-irmb)

a. Approval will be given if the following criteria are met and documented:

1. Recipient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia as evidenced by all of the following:

a. CDR-G score of 0.5 to 1

b. Memory Box score ≥0.5

c. MMSE score 22 to 30

d. Objective evidence of cognitive impairment at screening

e. PET scan or CSF assessment of amyloid beta (1-42) is positive for amyloid beta plaque; and

2. Prescriber attests that other conditions causing similar symptoms have been ruled out (e.g., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, normal pressure hydrocephalus); and

3. Prescribed by a neurologist, geriatrician, geriatric psychiatrist, or other expert in the treatment of AD.

4. Recipient does not have risk factors for intracerebral hemorrhage (e.g., prior cerebral hemorrhage >1 cm in greatest diameter, more than for microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease); and

5. Recipient has not had a stroke, TIA, or seizure in the last 12 months; and

6. Recipient has not demonstrated clinically significant and unstable psychiatric illness in the last six months; and

7. Recipient does not have a history of alcohol or substance abuse within the last 12 months; and

8. Recipient is not currently taking an anticoagulant or antiplatelet agent (with the exception of aspirin 325 mg/day or less); and

9. Brain MRI has been obtained within 12 months prior to treatment initiation; and

10. Baseline disease severity has been assessed using an objective measure/tool (e.g., MMSE, AD Assessment Scale-Cognitive Subscale [ADAS-Cog-13], AD Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], CDR-SB).

b. Recertification Requests:

1. Recipient must continue to meet the above criteria; and

2. Scoring on an objective measure/tool (e.g., ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB) demonstrates improvement, stability, or slowing in cognitive and/or functional impairment; and

3. Recipient has not progressed to moderate or severe AD; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions); and

5. Recipient has undergone MRI prior to the 5th, 7th, and 14th infusions to monitor for ARIA-E or ARIA-H.

c. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

VV. Medications for the Treatment of Acne

Therapeutic Class: Acne Agents
Last Reviewed by the DUR Board: July 24, 2014

Acne agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   No PA necessary for recipients up to 21 years of age.

   Approval will be given if the following criteria are met and documented:

   a. The recipient is age 21 years of age or older; and

   b. The recipient has a diagnosis of moderate to severe acne (Grade III or higher).

2. PA Guidelines

   a. PA approval will be for one year.

WW. Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome (IBS) Agents, Opioid-Induced Constipation Agents
Last Reviewed by the DUR Board: July 18, 2024

Functional Gastrointestinal Disorder Agents are subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Chronic Constipation Agents

   a. Approval will be given if all the following criteria are met and documented:

      1. The requested drug must be FDA approved for the recipient's age; and

      2. Must have a diagnosis of one of the following:

         a. CIC; or

         b. Function Constipation (FC) in pediatric recipients (Linzess® only)

      3. Recipient has trial and failure, contraindication or intolerance to either lactulose or polyethylene glycol (MiraLAX®); and

      4. Recipient has trial and failure, contraindication or intolerance to at least one stimulant laxative, such as sennosides (Ex-Lax®, Senokot®), bisacodyl (Dulcolax®) or cascara sagrada; and

      5. The maximum allowable doses for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2 mg, once daily

         d. Trulance® (plecanatide): 2 mg, once daily

      6. The maximum allowable dose for FC indication is as follows:

         a. Linzess® (linaclotide) 72 mcg, once daily

   b. PA Guidelines

      1. PA approval will be for one year.

2. IBS Agents

a. Coverage and Limitations

1. Approval will be given if the following criteria are met and documented:

a. The recipient is 18 years of age or older; and

b. The requested agent is being prescribed based on FDA approved guidelines; and

1. For requests for a diagnosis of IBS with Constipation (IBS-C):

a. For requests for Amitiza® (lubiprostone), the recipient must be female.

b. The requested dose is appropriate based on indication and age.

1. Linzess® (linaclotide): 290 µg daily.

2. Amitiza® (lubiprostone): 16 µg daily.

3. Trulance® (plecanatide): 3 µg daily.

2. For requests for a diagnosis of IBS with Diarrhea (IBS-D):

a. The medication is being prescribed by or in consultation with a gastroenterologist; and

b. The requested dose is appropriate based on indication and age.

1. Lotronex® (alosetron): 0.5 mg twice daily or 1 mg twice daily.

2. Viberzi® (eluxadoline): 75 mg twice daily or 100 mg twice daily.

3. Xifaxan® (rifaximin): 550 mg three times a day for 14 days.

b. PA Guidelines

1. PA approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

c. Zelnorm® (tegaserod)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of IBS-C; and

b. The recipient is female; and

c. The recipient is <65 years of age; and

d. The recipient has had trial and failure, contraindication, or intolerance to one of the following:

1. Lactulose; or

2. Polyethylene glycol.

2. Reauthorization Requests (the recipient must meet all criteria):

a. Documentation of positive clinical response to Zelnorm® therapy.

3. PA Guidelines

a. Initial PA approval will be for six weeks.

b. Recertification approval will be 12 months.

3. Opioid-Induced Constipation Agents

a. Approval will be given if all the following criteria are met and documented:

1. The recipient is 18 years of age or older; and

2. The requested medication is being used for an FDA approved indication; and

3. The recipient must meet the following criteria:

a. There is documentation in the recipient's medical record of an inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative drug classes:

1. Bulk forming laxatives;

2. Osmotic laxatives;

3. Saline laxatives;

4. Stimulant laxatives.

4. And requests for methylnaltrexone bromide that exceed the quantity limit must meet all the following criteria:

a. The recipient has opioid-induced constipation in advanced illness, is receiving palliative care, and is not enrolled in DHCFP's hospice program; and

b. The requested dose is 0.15 mg/kg; and

c. The recipient's current weight is >114 kg.

b. PA Guidelines

1. PA approval will be for one year.

XX. Xartemis® XR (oxycodone and acetaminophen)

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: January 22, 2015

Xartemis® XR (oxycodone and acetaminophen) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient is 18 years or older; and

   b. A diagnosis code of Acute Pain is documented on the prescription and transmitted on the claim; or

   c. An approved PA documenting the recipient meeting the following criteria:

      1. The recipient is 18 years or older; and

      2. A diagnosis code of Acute Pain is documented on the PA form.

2. PA Guidelines

   a. More than two fills of a quantity of 60 each, within six months requires an approved PA documenting the reason to exceed the prescribing limit.

   b. PA approval will be for six months.

YY. GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: April 26, 2018

GnRH Analogs are subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. This PA criteria only applies to recipients who are under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:

1. The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and

a. The requested dose and frequency are based on FDA-approved guidelines; and

b. The medication is being prescribed by or in consultation with a pediatric endocrinologist; and

c. There is an onset of secondary sex characteristics before age eight years (females) or nine years (males); and

d. The recipient is currently <11 years of age (females) or <12 years of age (males).

2. The recipient has a diagnosis of gender dysphoria, formerly known as gender identity disorder; and

a. The medication is being prescribed for suppression of puberty; and

b. The provider indicates a demonstrable knowledge what gonadotropins medically can and cannot do and their social benefits and risks; and

c. One of the following:

1. A documented real-life experience (living as the other gender) for at least three months prior to the administration of gonadotropin; or

2. A period of psychotherapy for a duration specified by the mental health professional after the initial evaluation (usually a minimum of three months).

d. The member must meet the definition of gender dysphoria (see definition below):

1. Gender Dysphoria:

a. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).

b. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

c. The disturbance is not concurrent with a physical intersex condition.

d. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

e. The transsexual identity has been present persistently for at least two years.

f. The disorder is not a symptom of another mental disorder or a chromosomal abnormality.

3. The recipient has a diagnosis of endometriosis, and

a. The requested dose and frequency are based on FDA-approved guidelines; and

b. The recipient has had an inadequate response, adverse reaction, or contraindication to an NSAID; and

c. The recipient has had an inadequate response, adverse reaction, or contraindication to a hormonal contraceptive.

4. The recipient has a diagnosis of uterine leiomyomata (fibroids), and

a. The requested dose and frequency are based on FDA-approved guidelines; and

b. The recipient is symptomatic; and

c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rational why surgical intervention is not required.

5. The recipient has a diagnosis of prostate cancer, and

a. The requested dose and frequency are based on FDA-approved guidelines.

2. PA Guidelines

a. PA approval will be given for an appropriate length of therapy based on the diagnosis unless the prescriber indicates a shorter duration of approval.

1. CPP: One year, or until the member reaches the age of 11 years (female) or 12 years (male).

2. Endometriosis: One year.

3. Uterine Leiomyomata (fibroids): One month or until the time of the documented surgery (maximum of three months).

4. Prostate Cancer: One year.

ZZ. Human immunodeficiency virus (HIV) Agents
Therapeutic Drug Class: HIV Agents
Last Reviewed by the DUR Board: April 28, 2022

HIV agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Cabenuva® (cabotegravir, rilpivirine) and Vocabria® (cabotegravir).

      1. All of the following:

         a. Diagnosis of HIV-1 infection; and

         b. Recipient is currently virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least six months; and

         c. Recipient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine; and

         d. Prescribed by or in consultation with a clinician with HIV expertise; and

         e. Will not be used concurrently with other ART medications; or

      2. The agent is used for continuation of prior therapy.

   b. PA Guidelines:

      1. PA approval will be given in 12 months.

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: January 18, 2024

Narcolepsy Agents are subject to PAs and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Provigil® (modafinil) and Nuvigil® (armodafinil)

    a. Approval will be given if the following criteria are met and documented:

        1. The recipient has a diagnosis of narcolepsy; or

            a. Obstructive Sleep Apnea (OSA); or

            b. Excessive sleepiness associated with shift work disorder.

    b. For treatment of OSA:

        1. Approval will be given if all the following criteria are met and documented:

            a. The recipient must have a diagnosis of OSA defined by one of the following:

                1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study unless the prescriber provides justification confirming that a sleep study would not be feasible; or

                2. Both the following:

                    a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

                    b. One of the following signs/symptoms are present:

                        1. Daytime sleepiness; or

                        2. Nonrestorative sleep; or

                        3. Fatigue; or

                        4. Insomnia; or

5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP)); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

c. Recertification Requests:

1. Documentation of positive clinical response to therapy.

2. For OSA: The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP).

d. PA Guidelines:

1. PA approval will be given for 12 months.

2. Sunosi® (solriamfetol)

a. For treatment of Narcolepsy

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has had trial and failure, contraindication, or intolerance to both of the following:

1. modafinil; and

2. armodafinil.

2. Recertification Requests:

a. Documentation of positive clinical response to Sunosi® therapy.

3. PA Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

b. For treatment of OSA

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of OSA defined by one of the following:

1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); or

2. Both the following:

a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. One of the following signs/symptoms are present:

1. Daytime sleepiness; or

2. Nonrestorative sleep; or

3. Fatigue; or

4. Insomnia; or

5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

d. The recipient has had a trial and failure, contraindication, or intolerance to both of the following:

1. Modafinil; and

2. Armodafinil.

2. Recertification Requests (recipient must meet all the criteria)

a. Documentation of positive clinical response to therapy; and

b. The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP)

3. PA Guidelines

a. Initial request will be approved for six months.

b. Recertification requests will be approved for six months.

3. Wakix® (pitolisant)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a documented diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. The recipient is 18 years of age and older.

b. Recertification Requests:

1. The recipient must have documentation of positive clinical response to Wakix® therapy.

c. PA Guidelines:

1. Initial request will be approved for six months.

2. Recertification requests will be approved for 12 months.

4. Xywav® (calcium, magnesium, potassium, and sodium oxybates), Xyrem® (sodium oxybate), Lumryz® (sodium oxybate ER)

a. Narcolepsy with Cataplexy (Narcolepsy Type 1).

1. Approval will be given if the following criteria are met and documented:

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has present symptoms of cataplexy; and

c. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

d. The medication is prescribed by or in consultation with either a Neurologist, a psychiatrist, or a Sleep Medicine Specialist.

e. Patient is FDA approved age for agent (≥7 years old Xywav®, Xyrem®; ≥18 years old Lumryz®).

2. Recertification Requests:

a. The recipient has documentation demonstrating a reduction in the frequency of cataplexy attacks associate with therapy; or

b. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. PA Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

b. Narcolepsy without Cataplexy (Narcolepsy Type 2)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient symptoms of cataplexy are absent; and

c. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

d. The recipient has trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to generic modafinil or generic armodafinil and Sunosi®; and

e. One of the following:

1. The recipient has trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant; or

2. The recipient has history of or potential for substance use disorder; and

f. The medication is prescribed by or in consultation with either a Neurologist, a psychiatrist, or a Sleep Medicine Specialist.

g. Patient is FDA approved age for agent (≥7 years old Xywav®, Xyrem®; ≥18 years old Lumryz®).

2. Recertification Requests:

a. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. PA Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

c. Idiopathic Hypersomnia (Xywav® only)

1. Approval will be given if the following criteria are met and documented:

a. Diagnosis of idiopathic hypersomnia with all of the following:

1. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; and

2. The absence of cataplexy; and

3. Fewer than two sleep onset REM periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques, or no SOREMPs if the REM sleep latency on the preceding polysomnogram was <15 minutes; and

4. One of the following:

a. A mean sleep latency of ≤8 minutes; or

b. Total 24-hour sleep time ≥660 minutes; and

5. Other causes of sleepiness have been ruled out; and

6. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist; and

7. Patient is ≥18 years old.

2. Recertification Requests:

a. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. PA Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

BBB. Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine)

Therapeutic Class: Nonsteroidal Anti-inflammatory Drug/Anti-ulcer Agent Combinations
Last Reviewed by the DUR Board: April 23, 2015

Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine) are subject to PAs and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The drug is being used for an FDA approved indication; and

b. The recipient's medical records documents one of the following risk factors for developing an NSAID-related ulcer:

1. Previous history of a major gastrointestinal bleed, perforation, or obstruction; or

2. Previous history of a peptic ulcer, hemorrhagic gastritis, hemorrhagic gastropathy or erosive esophagitis; or

3. Concomitant therapy for an anticoagulant or antiplatelet agent (including aspirin) or chronic oral corticosteroids; or

4. The recipient has had gastric bypass surgery (Roux-en-Y gastric bypass); and

c. The recipient is intolerant to a COX-2 inhibitor or has had a gastric or duodenal ulcer while taking a COX-2 inhibitor; and

d. The recipient has experienced an NSAID-associated ulcer in the past while taking a single-entity PPI or prostaglandin agent concomitantly with an NSAID or the recipient is intolerant to both PPIs and prostaglandin agents; and

e. The recipient's medical records document an inadequate response or adverse reaction with concurrent therapy of an equivalent dose of the individual components.

2. PA Guidelines

a. PA approvals will be for one year.

CCC. Rayos® (prednisone delayed release)

Therapeutic Class: Corticosteroid, Systemic
Last Reviewed by the DUR Board: April 23, 2015

Rayos® (prednisone delayed release) is subject to PAs based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

   Approval will be given if all the following criteria are met and documented:

   a. The requested drug is being used for an FDA approved indication; and

   b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate–release tablets.

2. PA Guidelines

   a. PA approvals will be:

      1. Initial therapy: three months.

      2. Recertification: one year.

DDD. Corlanor® (ivabradine)

Therapeutic Class: Cardiovascular Agent
Last Reviewed by the DUR Board: September 3, 2015

Corlanor® (ivabradine) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. A diagnosis of chronic heart failure; and

   b. A left ventricular ejection fraction (LVEF) $\leq$35%; and

   c. A resting heart rate $\geq$70 bpm; and

   d. The recipient is $\geq$18 years of age; and

   e. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted regarding the diagnosis and treatment recommendations; and

   f. The recipient is in a normal sinus rhythm; and

   g. The recipient is on a maximally tolerated dose of a beta-blocker or the recipient has a contraindication to beta-blocker use.

2. PA Guidelines

   a. The extent of PA approvals will be based on the appropriate use for the individual agents.

EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: Antilipemic Agent, PCSK9 Inhibitors
Last Reviewed by the DUR Board: July 23, 2020

Anti-lipidemic Agents – PCSK9 Inhibitors are subject to PA and quantity limitation based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria are met and document:

   a. Initial Request:

      1. The recipient has an FDA-approved diagnosis; and

      2. The requested medication was prescribed by or in consultation with a cardiologist or lipid specialist; and

      3. The requested medication will be used as an adjunct to a low-fat diet and exercise; and

      4. For the treatment of homozygous familial hypercholesterolemia:

         a. With Praluent® (alirocumab)

            1. The recipient is 18 years of age or older; or

         b. With Repatha® (evolocumab)

            1. The recipient is 13 years of age or older.

      5. And the recipient must meet one of the following (a, b, c, or d):

         a. The recipient has had an inadequate response to high intensity statin therapy defined as all of the following:

            1. The recipient has received therapy with atorvastatin $\geq$40 mg or rosuvastatin $\geq$20 mg for at least the past three months; and

            2. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

            3. The low-density lipoprotein cholesterol (LDL-C) after therapy for at least the past three months was $\geq$100 mg/dL heterozygous familial hypercholesterolemia (HeFH) for $\geq$70 mg/dL (clinical atherosclerotic cardiovascular disease); and

            4. The statin therapy will be continued with PCSK-9 therapy.

b. Or the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:

1. The recipient has an intolerance or contraindication to high intensity statin therapy; and

2. The recipient has received therapy with:

a. atorvastatin 10 to 20 mg; or

b. rosuvastatin 5 to 10 mg; or

c. simvastatin >20 mg; or

d. pravastatin >40 mg; or

e. lovastatin 40 mg; or

f. fluvastatin XL 80 mg; or

g. fluvastatin 40 mg twice daily; or

h. pitavastatin >2 mg

for at least the past three months; and

3. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

4. The LDL-C after therapy for at least the past three months was $\geq$100 mg/dL HeFH or $\geq$70 mg/dL (clinical atherosclerotic cardiovascular disease); and

5. Statin therapy will be continued with PCSK-9 therapy.

c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.

d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.

2. Recertification Requests (The recipient must meet all criteria (a-d))

a. The recipient has been adherent with PCSK-9 inhibitor therapy; and

b. The recipient has been adherent with statin therapy, or the recipient has a labeled contraindication to statin therapy; and

c. The recipient is continuing a low-fat diet and exercise regimen; and

d. The recipient has achieved a reduction in LDL-C level.

3. PA Guidelines

a. Initial authorization will be approved for six months.

b. Recertification approval will be approved for 12 months.

FFF. Long-Acting Injectable (LAI) Antipsychotics

Therapeutic Class: Second Generation (Atypical) Antipsychotic
Last Reviewed by the DUR Board: July 28, 2022

LAI antipsychotic drugs are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. General for all LAIs:

   a. Treatment-naïve patients require documentation confirming tolerance to the oral formulation prior to transitioning to the LAI.

2. Invega Trinza® (paliperidone palmitate)

   a. Approval will be given if the following criteria are met and documented.

      1. The recipient has a diagnosis of schizophrenia; and

      2. The recipient has been stabilized on once-monthly paliperidone palmitate injection (Invega Sustenna®) for at least four months with the two most recent doses of the once-monthly injection being the same strength; and

      3. The recipient is 18 years of age or older; and

      4. The requested dose is one injection every three months.

   b. PA Guidelines

      1. PA approvals will be for 12 months.

3. Invega Hafyera® (paliperidone palmitate)

   a. Approval will be given if the following criteria are met and documented.

      1. The recipient has a diagnosis of schizophrenia; and

      2. The recipient has been stabilized on once-monthly paliperidone palmitate extended-release (PP1M) injectable suspension (Invega Sustenna®) for at least four months, the two most recent doses of the once-monthly injection being the same strength or one dose of three-month IM paliperidone (Invega Trinza®); and

      3. Patient is 18 years of age or older; and

      4. The requested dose is one injection every six months.

   b. Recertification Requests:

1. Documentation confirming a positive response from therapy.

c. PA Guidelines:

1. PA approvals will be for 12 months.

GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: January 27, 2017
Previously reviewed: January 28, 2016

Medications for recipients on hospice are subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. For recipients 21 years of age or older:

      1. The prescriber has verified the recipient is enrolled in the hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care; and

      4. The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient; and

      5. The requested medication is not providing a curative or long-term prophylactic therapy.

   b. For recipients 20 years of age or younger:

      1. The prescriber has verified the recipient is enrolled in a hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care.

      4. Medically necessary curative medications for this age group are covered by DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. PA Guidelines

   a. PA approval will be for three months.

HHH. Ileal Bile Acid Transporter (IBAT) Inhibitor (D7F)

Therapeutic Drug Class: IBAT Inhibitor (D7F)
Last Reviewed by the DUR Board: July 28, 2022

IBAT inhibitor (D7F) drugs are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Bylvay® (odevixibat)

   a. Approval will be given if the following criteria are met and documented:

      1. Recipient is three months of age or older; and

      2. Recipient is diagnosed with progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; and

      3. Recipient has elevated serum bile acid concentration; and

      4. Recipient experiences persistent moderate to severe pruritus; and

      5. Recipient does not have any of the following:

         a. Positive test for the ABCB11 gene variant that predicts complete absence of the bile salt export pump (BSEP) protein; and

         b. Prior hepatic decompensation event; and

         c. Another concomitant liver disease; and

         d. An international normalized ratio (INR) >1.4; and

         e. Significant portal hypertension; and

         f. An alanine aminotransferase (ALT) or total bilirubin (TB) level more than 10 times the upper limit of normal (ULN); and

         g. Medical history or ongoing chronic diarrhea; and

         h. Decompensated cirrhosis; and

         i. Significant portal hypertension; and

      6. Bylvay® is prescribed by or in consultation with a specialist (e.g. gastroenterologist, hepatologist, dermatologist).

   b. Recertification Requests:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite vitamin A, D, E, K supplementation; elevated liver function tests [ALT, TB, direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension

c. PA Guidelines:

1. PA approval will be given for 12 months

2. Livmarli® (maralixibat)

a. Approval will be given if all the following criteria are met and documented:

1. Recipient is one year of age or older; and

2. Recipient is diagnosed with Alagille syndrome; and

3. Recipient experiences persistent moderate to severe pruritus; and

4. Recipient does not have any of the following:

a. Chronic diarrhea requiring ongoing IV fluid or nutritional intervention; and

b. Prior hepatic decompensation event; and

c. Significant portal hypertension; and

d. Decompensated cirrhosis; and

e. Another concomitant liver disease; and

5. Maralixibat is prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist, dermatologist); and

6. Patient has failed an adequate trial, or is intolerant to, or has a contraindication to at least one pruritus treatment (e.g., ursodeoxycholic acid [ursodiol], cholestyramine, rifampin, naloxone, naltrexone, antihistamine).

b. Recertification Requests:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet the above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite Vitamin A, D, E, K supplementation; elevated liver function tests [ALT, aspartate aminotransferase (AST), TB, DB]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension.

c. PA Guidelines:

1. PA approval will be given for six months.

2. Recertification will be given for 12 months.

III. Hetlioz® (tasimelteon)

Therapeutic Class: Sedative Hypnotic
Last Reviewed by the DUR Board: April 28, 2022

Hetlioz® (tasimelteon) is subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. For treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

1. Approval will be given if all following criteria are met and documented:

a. The recipient has a diagnosis of Non-24 disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome); and

b. The medication is being prescribed by or in consultation with a sleep specialist; and

c. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least three months of therapy) to a therapeutic dose of melatonin.

2. Recertification Requests:

a. Documentation of positive clinical response to therapy.

3. PA Guidelines:

a. Initial PA will be approved for six months.

b. Recertification will be approved for 12 months.

b. For the treatment for nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of SMS; and

b. The recipient is at least 16 years of age and older (3 through 15 years of age for LQ suspension); and

c. The recipient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking); and

d. Prescribed by a neurologist or a specialist in sleep disorder; and

e. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least three months of therapy) to a therapeutic dose of melatonin.

2. Recertification Requests:

a. Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality).

3. PA Guidelines:

a. Initial PA will be approved after six months.

b. Recertification will be approved after 12 months.

JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotensin II Receptor Blocker
Last Reviewed by the DUR Board: October 26, 2021

Entresto® (sacubitril/valsartan) is subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of chronic heart failure New York Heart Association (NYHA) Class II to IV; and

   b. The recipient has reduced LVEF; and

   c. The recipient is one year of age or older; and

   d. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted; and

   e. The recipient has had a trial of an angiotensin converting enzyme (ACE) or an angiotensin receptor blocker (ARB) for at least four weeks prior to the initiation of therapy; and

   f. The recipient will not concurrently receive an ACE inhibitor; and

   g. The recipient is on an individualized dose of a beta blocker, or the recipient has a contraindication to beta blocker use; and

   h. Entresto® will be given twice daily with a maximum dose of 97/103 mg.

2. PA Guidelines:

   a. PA approval will be for one year.

KKK. Neurokinin-1 Antagonists and Combinations

Therapeutic Class: Neurokinin-1 Antagonists and Combinations
Last Reviewed by the DUR Board: April 28, 2016

Neurokinin-1 antagonists and combinations are subject to PA and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   For requests to exceed the quantity limits approval will be given if all the following criteria are met and documented:

   a. The requested medication is being used for an FDA-approved indication; and

   b. The requested medication is being prescribed by an oncologist or in consultation with an oncologist; and

   c. The recipient must meet one of the following criteria:

      1. The recipient is 18 years of age or older; or

      2. The recipient is 12 years of age or older, the requested medication is aprepitant (Emend®) and the recipient is diagnosed with nausea and vomiting caused by chemotherapy; and

   d. It is a medical necessity for the recipient to exceed the quantity limit (e.g., duration of chemotherapy cycle).

2. PA Guidelines

   a. PA approval will be for six months.

LLL. Voquezna® Dual Pak® (vonoprazan and amoxicillin), Voquezna® Triple Pak® (vonoprazan, amoxicillin, and clarithromycin)

Therapeutic Drug Class: Qualified Infection Disease Product
Last Reviewed by DUR Board: October 20, 2022

Voquezna® Dual Pak® (vonoprazan and amoxicillin), Voquezna® Triple Pak® (vonoprazan, amoxicillin, and clarithromycin) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Recipient is 18 years or age or older; and

   b. Recipient has a confirmed diagnosis of Helicobacter pylori (H. pylori) infection; and

   c. Recipient must not have hypersensitivity or cross-hypersensitivity to any component or drug class of the product (e.g., penicillins, cephalosporins, macrolides); and

   d. Treatment will not be used concurrently with rilpivirine-containing products; and

   e. For vonoprazan/amoxicillin/clarithromycin requests (Voquezna® Triple Pak®), the patient does not have a history or hepatic dysfunction or cholestatic jaundice associated with prior use of clarithromycin; and

   f. For vonoprazan/amoxicillin/clarithromycin (Voquezna® Triple Pak®), the patient does not have ventricular cardiac arrythmia, prolongation of the QT interval, or proarrhythmic condition (e.g., uncorrected hypokalemia or hypomagnesemia); and

   g. Recipient must have an adequate trial and failure of, or relevant medical reason for not using, PPI-based H. pylori treatment regimen; and

   h. Baseline renal and hepatic function laboratory tests have been obtained; and

   i. Quantity limit of 14-day supply.

2. Recertification Requests:

   a. Coverage is not renewable.

3. PA Guidelines:

   a. PA will be given for 14 days.

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: DMD Agents
Last Reviewed by the DUR Board: July 18, 2024

DMD agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Exondys 51® (eteplirsen)

   a. Approval will be given if all the following criteria are met and documented:

      1. Initial Request:

         a. The recipient has a diagnosis of DMD; and

         b. There is documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping; and

         c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

         d. The prescribed dose does not exceed 30 mgs per kg of body weight once weekly.

      2. Recertification Requests (the recipient must meet all the following criteria).

         a. The recipient has been on therapy for <12 months; and

         b. The recipient has experienced clinically significant benefit; and

         c. The recipient is tolerating therapy; and

         d. The prescribed dose will not exceed 30mgs per kg of body weight once weekly; and

         e. The medication is prescribed by or in consultation with a neurologist who has experience treating children, or all the following:

            1. The recipient has been on therapy for 12 months or more; and

            2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

            3. The recipient has experienced clinically significant benefit; and

4. The recipient is tolerating therapy; and

5. The prescribed dose will not exceed 30 mgs per kg of body weight once weekly; and

6. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

b. PA Guidelines

1. Initial authorization will be approved for six months.

2. Recertification requests will be approved for 12 months.

2. Emflaza® (deflazacort)

a. Approval will be given if all the following criteria are met and documented:

1. Initial Request:

a. The recipient must have a diagnosis of DMD; and

b. The recipient must be five years of age or older; and

c. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:

1. Documentation of a confirmed mutation of the dystrophin gene; or

2. Muscle biopsy confirming an absence of dystrophin protein; and

d. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and

e. The recipient has had at least a three-month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and

The dose will not exceed 0.9 mgs per kg of body weight once daily.

b. Recertification Requests (the recipient must meet all the following criteria):

1. Documentation of positive clinical response to Emflaza® therapy (e.g., improvement or preservation of muscle strength); and

2. The dose will not exceed 0.9 mgs per kg of body weight once daily.

c. PA Guidelines:

1. Initial PA approval will be approved for 12 months.

2. Recertification requests will be approved for 12 months.

3. Vyondys 53® (golodirsen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting the following:

a. The recipient has a diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

3. The dose will not exceed 30 mgs per kg of body weight infused once weekly.

b. Recertification Requests (recipient must meet all criteria):

1. One of the following:

a. All the following:

1. The recipient has been on therapy for <12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 mgs per kg of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a neurologist who has experience treating children; or

b. All the following:

1. The recipient has been on therapy for 12 months or more; and

2. The recipient experienced a benefit from therapy (e.g. disease amelioration compared to untreated patients); and

3. The recipient is tolerating therapy; and

4. Dose will not exceed 30 mgs per kg of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a neurologist who has experience in treating children.

c. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification requests will be approved for 12 months.

4. Viltepso® (viltolarsen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. The recipient has a diagnosis of DMD; and

b. The recipient has documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; and

3. Dose will not exceed 80 mgs per kg of body weight infused once weekly.

b. Recertification Requests (recipient must meet all criteria):

1. One of the following:

a. All of the following:

1. The recipient has been on therapy for <12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 80 mgs per kg of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; or

b. All of the following:

1. The recipient has been on therapy for 12 months or more; and

2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

3. The recipient is tolerating therapy; and

4. Dose will not exceed 80 mgs per kg of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a Neurologist who has experience treating children.

c. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification requests will be approved for 12 months.

5. Amondys 45® (casimersen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. Diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 to exon 45 skipping; and

2. Prescribed by or in consultation with a neurologist who has experience treating children; and

3. Dose will not exceed 30 mgs per kg of body weight infused once weekly.

b. Recertification Requests (recipient must meet all criteria):

1. The recipient is tolerating therapy; and

2. Dose will not exceed 30 mgs per kg of body weight infused weekly; and

3. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

c. PA Guidelines:

1. PA will be approved for six months.

2. Recertification requests will be approved for 12 months.

6. Elevidys™ (delandistrogene moxeparvovec-rokl)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting the following:

a. The recipient has a diagnosis of DMD; and

b. The recipient has confirmed mutation of the DMD gene; and

c. The recipient does not have any deletion in exon 8 and/or exon 9 in the DMD gene; and

d. The recipient must have a baseline anti-AAVrh74 total binding antibody titer of <1,400 as measured by enzyme-linked immunosorbent assay (ELISA).

2. Age four and older; and

3. Prescribed by or in consultation with pediatric neuromuscular specialist with advanced knowledge in treating DMD; and

4. The recipient is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen); and

5. The recipient does not have an active infection, including clinically important localized infections; and

6. The recipient has been on a stable dose of corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); and

7. The recipient's troponin-I levels will be monitored at baseline and subsequently as clinically indicated; and

8. The recipient will have liver function assessed prior to and following therapy for at least three months as indicated; and

9. The recipient is receiving physical and/or occupational therapy; and

10. The recipient has never previously received Elevidys™ treatment in their lifetime.

b. Recertification Requests:

1. Coverage not renewable.

7. Amagree® (vamorolone)

a. Approval will be given if all the following criteria are met and documented:

1. Initial Request:

a. Recipient is ≥2 years of age; and

b. Diagnosis of DMD confirmed by genetic analysis (e.g., dystrophin deletion, duplication mutation) or muscle biopsy documenting absent dystrophin; and

c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

d. The recipient has had at least one of the following (initial request only):

1. At least six month trial and failure of prednisone (prednisolone or equivalent dose) at dose of 0.75 mg/kg/day; or

2. Documented history of intolerable adverse events, hypersensitivity, or contraindication to prednisone (prednisolone or equivalent dose); and

e. Medication dosed per FDA-label based on recipient weight (up to a maximum daily dosage of 300 mg for patients weighing more than 50 kg); and

2. Renewal Requests:

a. Recipient continues to meet above criteria; and

b. Documentation of positive clinical response to therapy.

b. Recertification Requests:

1. Initial and recertification is 12 months.

8. Duvyzat® (givinostat)

a. Approval will be given if all the following criteria are met and documented;

1. Initial Request:

   a. Recipient is ≥6 years of age; and

   b. Diagnosis of DMD confirmed by genetic analysis (e.g., dystrophin deletion, duplication mutation) or muscle biopsy documenting absent dystrophin; and

   c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

   d. The requested medication will be used in combination with a corticosteroid (i.e., prednisone) unless contraindicated or not tolerated; and

   e. Platelets are ≥150 x $10^9$/L prior to initiation (initial request only); and

   f. Medication dosed per FDA-label based on recipient body weight (maximum dose of 53.2 mg twice daily).

2. Renewal Requests:

   a. Recipient continues to meet above criteria; and

   b. Recipient has not experienced any treatment-restricting adverse effects (e.g., hematological changes such as thrombocytopenia or other signs of myelosuppression, hypertriglyceridemia, severe-gastrointestinal disturbances, and/or QTc prolongation); and

   c. Documentation of positive clinical response to therapy.

b. PA Guidelines:

1. Initial and recertification approval will be 12 months.

NNN. Qutenza® (capsaicin)

Therapeutic Class: Topical Neuropathic Pain Agents
Last Reviewed by the DUR Board: January 27, 2022

Qutenza® (capsaicin) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria is met and documented:

   a. The recipient has a diagnosis of neuropathic pain associated with postherpetic neuralgia; or

   b. The recipient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet; and

   c. The recipient has a history of failure or intolerance to over-the-counter capsaicin.

2. Recertification Requests (recipient must meet all criteria):

   a. At least three months have transpired since the last Qutenza® application/administration; and

   b. The recipient experienced pain relief with a prior course of therapy; and

   c. The recipient is experiencing a return of neuropathic pain.

3. PA Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification requests will be approved for three months.

OOO. Movement Disorder Agents

Therapeutic Class: Movement Disorder Agents
Last Reviewed by the DUR Board: January 16, 2025

Movement Disorder Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Austedo® (deutetrabenazine)

   a. For treatment of Chorea Associated with Huntington's Disease.

      1. Approval will be given if all the following criteria are met and documented:

         a. The recipient must have a diagnosis of chorea associated with Huntington's disease; and

         b. The recipient must be 18 years of age or older; and

         c. The medication is prescribed by or in consultation with a neurologist; and

      2. Recertification criteria:

         a. Documentation of positive clinical response to therapy.

      3. PA Guidelines

         a. Initial PA approval will be for 12 months.

   b. For the treatment of Tardive Dyskinesia (TD).

      1. Approval will be given if all the following criteria are met and documented:

         a. The recipient must have a confirmed diagnosis of TD; and

         b. The recipient must be 18 years of age or older; and

         c. The medication is prescribed by or in consultation with a neurologist or psychiatrist; and

         d. One of the following:

            1. Persistent symptoms of TD despite a trial dose reduction, tapering or discontinuation of the offending medication; or

            2. The recipient is not a candidate for trial dose reduction, tapering or discontinuation of the offending medication.

2. Recertification Requests:

a. Documentation of positive clinical response to therapy

3. PA Guidelines

a. Initial PA approval will be for three months.

2. Ingrezza® (valbenazine)

a. Approval will be given if the following criteria are met and documented:

1. For the treatment of TD

a. Initial Request:

1. The recipient must have a diagnosis of severe TD;

2. The recipient must be 18 years of age or older; and

3. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and

4. One of the following:

a. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or

b. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.

2. For the treatment of Chorea Associated with Huntington's Disease

a. Initial Request:

1. The recipient must have a diagnosis of chorea associated with Huntington's disease; and

2. The recipient must be 18 years of age or older; and

3. The medication is prescribed by or in consultation with a neurologist

b. Recertification Requests:

1. Documentation of positive clinical response to therapy.

c. PA Guidelines:

1. Initial authorization will be approved for three months (TD indication) or 12 months (Chorea associated with Huntington's Disease).

2. Recertification will be approved for 12 months.

PPP. Brineura® (cerliponase alfa)

Therapeutic Class: Brineura® (cerliponase alfa)
Last Reviewed by the DUR Board: October 19, 2017

Brineura® (cerliponase alfa) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial Request:

1. The recipient must have a diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis Type 2 (CLN2) also known as tripeptidyl peptidase 1 (TPP1) deficiency; and

2. The diagnosis must be confirmed by TPP1 enzyme detected by a dried blood spot test and CLN2 genotype analysis; and

3. The recipient must be three years of age or older; and

4. The drug must be prescribed by or in consultation with a neurologist with expertise in the diagnosis of CLN2; and

5. The drug must be administered by, or under the direction of, a physician knowledgeable in intraventricular administration; and

6. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

7. The recipient must not have a ventriculoperitoneal shunt.

b. Recertification Requests (the recipient must meet all of the following criteria):

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

b. The recipient must not have a ventriculoperitoneal shunt; and

c. Documentation of positive clinical response to Brineura®, (e.g., improvement in walking or crawling, or no evidence of disease progression).

c. PA Guidelines

1. Initial PA approval will be for four months.

QQQ. Vuity® (pilocarpine) 1.25% Ophthalmic Solution

Therapeutic Class: Ophthalmic Agents, Intraocular Pressure (IOP)-Modifying

Last Reviewed by the DUR Board: April 28, 2022

Vuity® (pilocarpine) 1.25% Ophthalmic Solution is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient has a diagnosis of presbyopia; and

    b. The medication prescribed by or in consultation with an ophthalmologist or optometrist; and

    c. The recipient is unable to use corrective lenses (e.g., eyeglasses or contact lenses) confirmed by medical records (e.g., chart notes); and

    d. Vuity will not be prescribed concurrently with any ophthalmic pilocarpine formulations.

2. Recertification Requests:

    a. Documentation or positive clinical response to therapy (e.g., improvement in near vision in low light conditions without loss of distance vision); and

    b. Prescribed by or in consultation with an ophthalmologist or optometrist.

3. PA Guidelines:

    a. Initial authorization will be approved for one month.

    b. Recertification will be approved for six months.

RRR. Livtencity® (maribavir)

Therapeutic Drug Class: Antivirals
Last Reviewed by DUR Board: October 20, 2022

Livtencity® (maribavir) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Recipient is ≥12 years of age; and

   b. Recipient must weigh >35 kg; and

   c. Recipient of a hematopoietic stem cell or solid organ transplant; and

   d. Recipient has documented cytomegalovirus (CMV) infection in whole blood or plasma (screening value ≥2,730 IU/mL in whole blood or ≥910 IU/mL in plasma) in two consecutive assessments separated by ≥1 day; and

   e. Recipient has current CMV infection that is refractory (documented failure to achieve >1 log10 decrease in CMV DNA level in whole blood or plasma after ≥14 days treatment) to anti-CMV treatment agents (ganciclovir, valganciclovir, cidofovir, or foscarnet), even with documented genetic mutations associated with resistance; and

   f. Maribavir will not be coadministered with ganciclovir or valganciclovir; and

   g. Recipient will be monitored for clinically important drug interactions that could result in decreased therapeutic effect of maribavir.

2. Recertification Requests:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient must have disease improvement and/or stabilization or improvement in the slope of decline (>1 log10 decrease in CMV DNA level in whole blood or plasma after 14 days or longer treatment); and

   c. Recipient has not experienced any treatment-restricting adverse effects (e.g., dysgeusia, diarrhea, nausea, and recurrence of underlying disease); and

   d. Recipient is not a non-responder (resistant) to maribavir.

3. PA Guidelines:

   a. PA will be approved for six months.

SSS. Anti-Parkinson's Agents

Therapeutic Class: Anti-Parkinson's Agents
Last Reviewed by the DUR Board: October 20, 2022

Anti-Parkinson's Agents is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Xadago® (safinamide)

   a. Approval will be given if all the following criteria are met and documented:

      1. The recipient must have a diagnosis of Parkinson's disease: and

      2. The recipient must be five years of age or older; and

      3. Documented continued Levodopa and/or other dopaminergic treatments; and

      4. Recipient reports >1.5 hours per day "off" episodes ("off" episodes refer to "end-of-dose wearing off" and unpredictable "on/off" episodes); and

      5. Recipient must not also be taking any of the following drugs: other MAO inhibitors (MAOIs) or other drugs that are potent inhibitors of MAOI (e.g., linezolid), opioid drugs (e.g., tramadol, meperidine, and related derivatives), SNRIs, tri- or tetra-cyclic or triazolopyridine antidepressants (TCAs), cyclobenzaprine, methylphenidate, amphetamine and their derivatives, St. John's wort or dextromethorphan; and

      6. The recipient must not have severe hepatic impairment (e.g., Child-Pugh C).

   b. Recertification Requests:

      1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

         a. Documentation of positive clinical response to Xadago® therapy; and

         b. Documented continued Levodopa and/or other dopaminergic treatments.

   c. PA Guidelines:

      1. Initial PA approval will be for three months.

2. Kynmobi® (apomorphine)

a. Approval will be given if the following criteria are met and documented:

1. Recipient is 18 years of age or older; and

2. Recipient has a documented diagnosis of Parkinson's disease (PD); and

3. Recipient is experiencing "off" episodes of PD at least two hours per day on average; and

4. Recipient is on a stable levodopa-based therapy; and

5. Recipients will not be on a concomitant 5HT3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and

6. Recipient will be prescribed a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide) for initial therapy; and

7. Recipient does not have a major psychotic disorder.

b. Recertification Requests:

1. Recipient must continue to meet the initial criteria above; and

2. Recipient has demonstrated a beneficial response to therapy (e.g., decrease in frequency and duration from baseline in motor fluctuations ["off" episodes]); and

3. Recipient is absent of unacceptable toxicity from the drug (e.g., nausea or vomiting, oral mucosal irritation or stomatitis, decreased impulse control, syncope or hypotension, hallucinations or psychotic-like behavior, QTc prolongation, fibrotic complications, priapism, retinal atrophy or degeneration, excessive daytime sleepiness including falling asleep during activities that require active participation).

c. PA Guidelines:

1. PA will be approved for 12 months.

TTT. Codeine and Tramadol for Children

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: October 19, 2017

Codeine, codeine with acetaminophen and tramadol, tramadol with acetaminophen is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Codeine, codeine with acetaminophen

1. All of the following criteria must be met:

a. The recipient must be 12 years of age or older; and

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI >30 kg/m$^2$), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy.

b. Tramadol, tramadol with acetaminophen

1. All the following criteria must be met:

a. The recipient must be 12 years of age or older; and

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI >30 kg/m$^2$), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy; and

e. The prescribed dose does not exceed 200 mg/day and does not exceed a five-day supply.

2. Tramadol ER will not be approved for children under 18 years of age and will be rejected at point of sale.

c. PA Guidelines

1. Codeine, codeine with acetaminophen

    a. PA approval will be given for the lowest effective dose for the shortest period of time requested.

        1. PA will be given for a one-month time period.

2. Tramadol, tramadol with acetaminophen

    a. PA approval will be given for the lowest effective dose for the shortest period of time requested.

    b. PA will be given for a one-month time period.

UUU. High Dollar Claim

Last Reviewed by the DUR Board: April 26, 2018

A High Dollar Claim is defined as a single point-of-sale claim that exceeds $10,000. A High Dollar Claim is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits. If other PA criteria exist, it will supersede this criteria.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. One of the following:

1. The medication is being prescribed for an FDA approved indication; or

2. One of the following:

a. Diagnosis is supported as a use of AHFS-DI; or

b. Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “Effective” or “Evidence Favors Efficacy” (see DRUGDEX Efficacy Rating and PA Approval Status table); or

4. Diagnosis is supported in any other section in DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

b. And one of the following:

1. The dosage/quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

   a. AHFS Compendium.

   b. Thomson Reuters (Healthcare) Micromedex/DRUGDEX (not Drug Points) Compendium.

   c. Elsevier Gold Standard Clinical Pharmacology Compendium.

   d. National Comprehensive Cancer Network Drugs and Biologics Compendium.

c. Excluded:

   1. Hemostatic coagulation factors used for the treatment of hemophilia are excluded from this criteria.

d. PA Guidelines

   1. PA approval will be for 12 months.

VVV. Cuvrior® (trientine tetrahydrochloride)

Therapeutic Drug Class: Copper Chelator
Last Reviewed by DUR Board: October 20, 2022

Cuvrior® (trientine tetrahydrochloride) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given once the following criteria are met and documented:

   a. Recipient is 18 years of age or older; and

   b. Recipient has Wilson's Disease (defined by a prior or current Leipzig score of ≥4); and

   c. Recipient is being treated with penicillamine for ≥1 year at a stable dose and regimen for ≥4 months, and recipient is tolerating penicillamine and adequately controlled (e.g., serum non-ceruloplasmin copper [NCC] level between ≥25 and ≤150 mcg/L or 24-hour urinary copper excretion [UCE] of between levels ≥100 and ≤900 mcg/24 hours); and

   d. Penicillamine will be discontinued before initiating Cuvrior®; and

   e. Recipient will not concurrently use another formulation of trientine (e.g., Syprine®, generics); and

   f. Prescribed by or in consultation with a hepatologist or neurologist; and

   g. Quantity limit is 300 tablets/30 days (max daily dose 3,000 mg).

2. Recertification Requests:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient has evidence of effectiveness of therapy (e.g., as assessed by serum NCC level between ≥25 and ≤150 mcg/L or 24-hour UCE levels ≥100 and ≤900 mcg/24 hours); and

   c. Recipient does not exhibit clinical manifestations of advancement of Wilson's Disease from baseline (e.g., jaundice, edema, ascites, esophageal varices, liver failure, CNS symptoms); and

   d. Recipient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity reactions, copper deficiency, iron deficiency).

3. PA Guidelines:

   a. PA will be approved for six months.

WWW. Botulinum Toxin

Therapeutic Class: Neurotoxic Protein
Last reviewed by the DUR Board: July 26, 2018

Botulinum toxins are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Policy

   Botulinum toxin injections are a Nevada Medicaid covered benefit for certain spastic conditions including, but not limited to cerebral palsy, stroke, head trauma, spinal cord injuries, and multiple sclerosis. The injections may reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and ambulation, to allow improved range of motion, to permit better physical therapy, and provide adequate perineal hygiene.

2. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. It is expected that physicians be familiar with and experienced in the use of botulinum toxin products and utilize FDA-approved product labeling, compendia, and peer-reviewed scientific literature to select the appropriate drug and dose regimen for each recipient condition. A complete list of covered indications can be found within the "Provider Type 20, 24, and 77 Billing Guide" applicable to botulinum toxins.

   b. Documentation must be provided that the recipient has been unresponsive to conventional methods of treatment (e.g., medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions); and

   c. If maximum dose is reached and positive clinical response is not established, treatment must be discontinued; and

   d. Documentation of medical necessity is required for treatment more frequent than every 90 days; and

   e. Coverage will be approved for one injection per site. A site is defined as including muscles of a single contiguous body part, such as a single limb, eyelid, face, or neck.

   f. Coverage will not be provided for injections given for cosmetic or for investigational purposes.

3. Recertification Requests (the recipient must meet all the following criteria):

a. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

1. Documentation of a positive clinical response to Botulinum Toxin therapy.

4. PA Guidelines

a. PA approval will be for six months.

XXX. Compounded Medications

Last Reviewed by the DUR Board: January 24, 2019

Compounded medications are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and

b. The therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery; and

c. If any prescription ingredients require PA and/or step therapy, all drug specific criteria must also be met; and

d. The compounded medication must not be used for cosmetic purpose; and

e. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (drugs withdrawn from the market due to safety or effectiveness); and

f. The recipient has tried and failed therapy or had an intolerance to at least two FDA-approved, commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

1. The recipient has a contraindication to commercially available products; or

2. One or no other therapeutic alternatives are commercially available; or

3. Compound medication is prepared in a different dosage form for a recipient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does not meet this criteria); or

4. The recipient has an allergy or sensitivity to inactive ingredients (e.g., dyes, preservatives, sugars, etc.) that are found in commercially available products.

2. PA Guidelines

a. PA approval will be for six months unless the provider requests for a shorter length of therapy.

YYY. Antibiotics

Last Reviewed by the DUR Board: July 26, 2018

Antibiotic medications are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

The outpatient antibiotic class criteria apply to the following:

| **Third Generation Cephalosporins** | **Fluoroquinolones** | **Oxazolidinones** |
|---|---|---|
| cefixime | ciprofloxacin | tedizolid |
| cefdinir | levofloxacin | linezolid |
| cefpodoxime | delafloxacin | |
| ceftibuten | moxifloxacin | |
| cefditoren | ofloxacin | |

If applicable, reference current Infectious Disease Society of America (IDSA) (or equivalent organization) guidelines to support the use of the following:

1. Coverage and Limitations for Third Generation Cephalosporins and Fluoroquinolones

   Approval will be given if the following criteria are met and documented:

   a. Culture and sensitivity-proven susceptibilities and resistance to other agents suggest the requested drug is necessary.

2. Coverage and Limitations for Oxazolidinones

   a. Sivextro® (tedizolid)

      Approval will be given if the following criteria are met and documented:

      1. Recipient has diagnosis of Acute Bacterial Skin and Skin Structure Infection; and

      2. Infection is caused by methicillin-resistant *Staphylococcus aureus* (MRSA); and

      3. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to:

trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, vancomycin, daptomycin, telavancin, clindamycin); or

4. Recipient started treatment with IV antibiotic(s) in the hospital and requires continued outpatient therapy.

b. Zyvox® (linezolid)

Approval will be given if the following criteria are met and documented:

1. Recipient has a diagnosis of vancomycin-resistant *enterococcus* (VRE) *faecium* infection or diagnosis of MRSA infection; and

2. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, tetracycline, clindamycin); or

3. Recipient started treatment with IV antibiotic(s) in the hospital and requires continued outpatient therapy.

3. Exception Criteria (applies to antibiotic medications)

a. Prescribed by an infectious disease specialist or by an emergency department provider; or

b. Ceftriaxone prescribed as first line treatment for gonorrhea, pelvic inflammatory disease, epididymo-orchitis and as an alternative to benzylpenicillin to treat meningitis for those with a severe penicillin allergy; or

c. If cefixime is prescribed for gonococcal infection where ceftriaxone is unavailable; or

d. The recipient resides in one of the following:

1. Acute Care

2. Long-term Acute Care (LTAC)

3. Skilled Nursing Facility (SNF)

4. PA Guidelines

a. PA approval will be for a single course.

ZZZ. Oral Oncology Agents

Therapeutic Class: Oral Oncology Agents
Last Reviewed by the DUR Board: January 24, 2019

Oral oncology agents are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations (this criteria only applies if other product-specific criteria is not available in MSM Chapter 1200 – Prescribed Drugs)

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis that is indicated in the FDA approved package insert or listed in nationally recognized compendia, for the determination of medically accepted indications; and

   b. If the oral oncology medication is not indicated as a first line agent, either in the FDA approved package insert or nationally recognized compendia, then documentation of previous therapies tried and failed is required; and

   c. The medication is prescribed by or in consultation with an oncologist or hematologist; and

   d. The recipient does not have any contraindications to the requested oral oncology medication; and

   e. The requested quantity and dosing regimen falls within the manufacturer's published dosing guidelines or nationally recognized compendia and is appropriate for the recipient's age; and

   f. The medication must be used in combination with other chemotherapeutic or adjuvant agents according to the FDA-approved prescribing information; and

   g. One of the following:

      1. If an FDA-approved companion diagnostic test for the requested agent exists, then documentation that the test was performed to confirm the diagnosis is required; or

      2. If a test with adequate ability to confirm a disease mutation exists, then documentation that the test was performed to confirm the diagnosis is required.

2. Recertification Requests

   a. Documentation of a positive clinical response to oral oncology treatment.

3. PA Guidelines

a. PA approval will be for 12 months.

AAAA. Pulmonary Arterial Hypertension Agents

Therapeutic Class: Pulmonary Arterial Hypertension Agents
Reviewed by the DUR Board: January 24, 2019

Pulmonary arterial hypertension (PAH) agents are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The recipient has a documented diagnosis of PAH; or

b. The recipient has one of the following ICD-10 diagnosis codes submitted on the pharmacy claim:

| ICD-10 | Description |
|---|---|
| 127.20 | Pulmonary Hypertension, Unspecified |
| 127.21 | Secondary PAH |
| 127.22 | Pulmonary Hypertension Due to Left Heart Disease |
| 127.23 | Pulmonary Hypertension Due to Lung Diseases and Hypoxia |
| 127.9 | Pulmonary Heart Disease, Unspecified |

2. PA Guidelines

a. PA approval will be for 12 months.

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: April 22, 2021

Anticonvulsants are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Cannabinoid

   a. Epidiolex® (cannabidiol)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient has a diagnosis of Lennox-Gastaut syndrome, Dravet Syndrome or Tuberous Sclerosis Complex (TSC); and

         b. The recipient is one years of age or older; and

         c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and

         d. The drug is prescribed by or in consultation with a neurologist; and

         e. The total dose does not exceed 20 mg/kg/day (10 mg/kg twice daily) for LGS/DS or 25 mg/kg/day (12.5 mg/kg twice daily)

         f. The medication will be used as adjunctive therapy in recipients with uncontrolled seizure management (the recipient has taken one or more antiepileptic drugs and has chart notes confirming persistent seizure events after titration of current anti-seizure regiment to highest tolerated doses).

      2. Recertification Requests

         a. Documentation of a positive clinical response to Epidiolex® therapy; and

         b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.

      3. PA Guidelines

         a. Initial PA will be for three months.

         b. Recertification approval will be for 12 months.

4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.

2. Nayzilam® (midazolam)

a. Approval will be given if the following criteria are met and documented:

1. The recipient has a diagnosis of acute intermittent seizures; and

2. The recipient is at least 12 years of age; and

3. The medication is prescribed by or in consultation with a Neurologist; and

4. The dose must not exceed two sprays per seizure cluster, no more than one episode every three days and treat no more than five episodes per month.

b. Recertification Requests

1. Documentation of positive clinical response to Nayzilam® therapy.

c. PA Guidelines

1. Initial PA will be for six months.

2. Recertification approval will be for 12 months.

3. Valtoco® (diazepam)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years or older; and

3. The medication is prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern; and

4. The medication is prescribed by or in consultation with a neurologist; and

5. The quantity must not exceed five episodes per month.

b. PA Guidelines:

1. Documentation of positive clinical response to Valtoco® therapy.

c. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

4. Fintepla® (fenfluramine)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a documented diagnosis of seizures associated with Dravet Syndrome; and

2. The recipient is two years of age or older; and

3. The medication is prescribed by or in consultation with a neurologist.

b. Recertification Requests:

1. The recipient has documentation of positive clinical response to Fintepla® therapy.

c. PA Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

5. Ztalmy® (ganaxolone)

a. Approval will be given if the following criteria are met and documented:

1. Recipient is ≥2 years of age; and

2. Recipient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing; and

3. Recipient has tried and/or is concomitantly receiving ≥2 other anticonvulsant medications; and

4. Ganaxolone is prescribed by or in consultation with a neurologist.

b. Dosage Limits

1. Max Daily Dose is 1,800 mg

c. Recertification Requests:

1. Recipient must continue to meet the above criteria; and

2. Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline; and

3. Recipient has not experienced any treatment-restricting adverse effects (e.g., somnolence, pyrexia, suicidal thoughts, or behavior).

d. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for 12 months.

CCCC. Amvuttra® (vutrisiran)

Therapeutic Drug Class: Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B)
Last Reviewed by DUR Board: October 20, 2022

Amvuttra® (vutrisiran) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity.

1. Approval will be given if the following criteria are met and documented:

    a. Recipient is ≥18 years of age; and

    b. Recipient will receive supplementation with vitamin A as the recommended daily allowance during vutrisiran therapy; and

    c. Vutrisiran must not be used in combination with other TTR reducing agents (e.g., inotersen [Tegsedi®], tafamidis [Vyndamax®, Vyndaqel®], patisiran [Onpattro®]); and

    d. Recipient has a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis/familial amyloidotic polyneuropathy (FAP) as documented by amyloid deposition on tissue biopsy and identification of a pathogenic TTR variant using molecular genetic testing; and

    e. Polyneuropathy is demonstrated by ≥2 of the following criteria:

        1. Subjective patient symptoms are suggestive of neuropathy; or

        2. Abnormal nerve conduction studies are consistent with polyneuropathy; or

        3. Abnormal neurological examination is suggestive of neuropathy; and

    f. Recipient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; and

    g. Baseline strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council [MRC] muscle strength); and

    h. Recipient has not had an orthotopic liver transplant (OLT); and

    i. Quantity limit is one syringe every three months.

2. Recertification Requests:

    a. Recipient continues to meet the above criteria; and

b. Recipient is absent of unacceptable toxicity from the drug. Examples of unacceptable toxicity include ocular symptoms related to hypovitaminosis A, etc.; and

c. Recipient has experienced disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in greater than or equal to one of the following:

1. Signs and symptoms of neuropathy; or

2. MRC muscle strength.

d. Recertification will be approved for six months.

3. PA Guidelines:

a. PA will be approved for six months.

DDDD.Oxervate® (cenegermin-bkbj)

Therapeutic Drug Class: Ophthalmic Human Nerve Growth Factor (Q25)
Last Reviewed by DUR Board: October 20, 2022

Oxervate® (cenegermin-bkbj) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity.

1. Approval will be given if the following criteria are met and documented:

    a. Recipient must be ≥2 years of age; and

    b. Recipient must have a diagnosis of moderate to severe (stage two or stage three) neurotrophic keratitis (NK); and

    c. Prescribed by or in consultation with an ophthalmologist; and

    d. Prescriber attestation that patient or caregiver has been counseled on proper administration technique; and

    e. Quantity Limit of eight kits per affected eye per lifetime.

2. Renewal Criteria:

    a. Coverage not renewable.

3. PA Guidelines:

    a. PA will be approved for eight weeks.

EEEE. Penicillamine

Therapeutic Class: Antirheumatics
Last reviewed by DUR Board: January 19, 2023

Penicillamine is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Wilson's Disease

    a. Approval will be given if the following criteria are met and documented:

        1. Recipient has diagnosis of Wilson's Disease; and

        2. Medication prescribed by or in consultation with gastroenterologist, hepatologist, rheumatologist, or liver transplant physician.

    2. Recertification Requests:

        a. Recipient continues to meet above criteria; and

        b. Recipient has demonstrated positive clinical response to therapy.

    3. PA Guidelines:

        a. Initial approval will be given for 12 months.

        b. Recertification approval will be given for 12 months.

2. Cystinuria

    a. Approval will be given if the following criteria are met and documented:

        1. Recipient has diagnosis of cystinuria; and

        2. Recipient has a history of failure, contraindication, or intolerance to conservative treatment measures (e.g., use of urinary alkalinization such as potassium citrate, high fluid intake, sodium, and protein restriction) [initial criteria only]; and

        3. Medication is prescribed by or in consultation with nephrologist or urologist.

    b. Recertification Requests:

        1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. PA Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

3. RA

a. Approval will be given if the following criteria are met and documented:

1. Recipient has diagnosis of severe, active RA; and

2. Recipient has contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate, leflunomide, or azathioprine) [initial criteria only].

3. Medication is prescribed by or in consultation with a rheumatologist.

b. Recertification Requests:

1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. PA Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

FFFF. Rayaldee® (calcifediol)

Therapeutic Class: Vitamins
Last reviewed by DUR Board: January 19, 2023

Rayaldee® (calcifediol) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Rayaldee® (calcifediol)

   a. Approval will be given if the following criteria are met and documented:

      1. Recipient is ≥18 years of age; and

      2. Recipient has a diagnosis of secondary hyperparathyroidism (HPT); and

      3. Recipient has both of the following:

         a. serum total 25-hydroxyvitamin D level <30 ng/mL; and

         b. serum corrected total calcium below 9.8 mg/d; and

      4. Recipient has CKD Stage 3 or 4

      5. Recipient does not have CKD Stage 5 or end stage renal disease (ESRD) on dialysis

      6. Recipient has a history of failure, contraindication, or intolerance to adequate trial of all of the following:

         a. Calcitriol

         b. Doxercalciferol

         c. Paricalcitol

      7. Medication is prescribed by or in consultation with nephrologist or endocrinologist.

   b. Recertification Requests:

      1. Recipient has demonstrated positive response to treatment as defined by increase in serum total 25-hydroxyvitamin D level and/or decrease in intact parathyroid hormone (iPTH).

      2. Medication is prescribed by or in consultation with nephrologist or endocrinologist.

c. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be approved for six months.

GGGG. Relyvrio® (sodium phenylbutyrate/taurursodiol)

Therapeutic Class: Amyotrophic Lateral Sclerosis (ALS)
Last reviewed by DUR Board: October 19, 2023

Relyvrio® (sodium phenylbutyrate/taurursodiol) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Relyvrio® (sodium phenylbutyrate/taurursodiol)

   a. Approval will be given if the following criteria are met and documented:

      1. The recipient is ≥18 years of age; and

      2. The recipient has a diagnosis of ALS based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

      3. The recipient must have an adequate trial of riluzole for ≥8 weeks or contraindication to therapy; and

      4. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R)); and

      5. The recipient does not require permanent assisted ventilation; and

      6. Therapy prescribed by or in consultation with neurologist; and

   b. Recertification Requests:

      1. The recipient must continue to meet the above criteria; and

      2. The recipient must have disease stabilization or improvement in the slope of decline as demonstrated on an objective measure/tool (e.g., ALSFRS-R); and

      3. The recipient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure).

   a. PA Guidelines:

      1. Initial approval will be given for six months.

      2. Recertification will be approved for six months.

2. Qalsody™ (tofersen)

   a. Approval will be given if the following criteria are met and documented:

1. The recipient is 18 years of age or older; and

2. The recipient has a diagnosis of ALS based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

3. The recipient has a baseline measure of plasma neurofilament light chain (NfL) and

4. Prescribed by or in consultation with a neurologist; and

5. The recipient has the presence of a superoxide dismutase 1 (SOD1) gene mutation; and

6. Dosing is in accordance with FDA approved labeling.

b. Recertification Requests:

1. Prescribed by or in consultation with a neurologist; and

2. The recipient must have stabilization or improvement in plasma NfL compared to baseline; and

4. The recipient has responded to therapy compared to pretreatment baseline with disease stability or mild progression (recipient has not experienced rapid disease progression while on therapy); and

5. Dosing is in accordance with FDA approved labeling.

c. PA Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

HHHH. Verkazia® (cyclosporine)

Therapeutic Class: Ophthalmic Anti-Inflammatory Agents
Last Reviewed by DUR Board: April 20, 2023

Verkazia® (cyclosporine) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented

    a. Recipient is ≥4 years old; and

    b. Recipient has a diagnosis of vernal keratoconjunctivitis; and

    c. Prescriber attestation that disease severity is moderate to severe; and

    d. Recipient has had a disease flare within the past one year; and

    e. Recipient is not using another immunomodulator via the ophthalmic route (e.g., other formulations of cyclosporine, tacrolimus, pimecrolimus).

2. Dosage Limits

    a. Max daily dose of four vials

3. Recertification Requests:

    a. Recipient must continue to meet the above criteria; and

    b. Prescriber attestation that recipient has had disease improvement and/or stabilization (e.g., improvement on corneal fluorescein staining (CFS), decrease in number of flares, improvement in symptoms); and

    c. Recipient has not experienced any treatment-restricting adverse effects (e.g., eye pain, infection).

4. PA Guidelines:

    a. Initial approval will be given for 12 months.

    b. Recertification will be given for 12 months.

IIII. Strensiq® (asfotase alfa)

Therapeutic Class: Hypophosphatasia (HPP) Agents
Last Reviewed by DUR Board: July 27, 2023

HPP are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Approval will be given if all criteria are met and documented:

   A recipient has a diagnosis of either perinatal/infantile or juvenile-onset HPP demonstrated by all of the following:

   a. The recipient was 18 years of age or younger at onset;

   b. The recipient experienced clinical manifestations of HPP (e.g., vitamin B6-responsive seizures, chest deformity, severe hypercalcemia, bowing of the long bones, failure to thrive);

   c. The recipient obtained radiographic imaging to support diagnosis of HPP;

   d. Genetic testing has been completed documenting tissue non-specific alkaline phosphatase (ALP) gene mutation; and

   e. There has been reduced activity of unfractionated serum ALP;

   f. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

   g. The requested quantity is within FDA-labeled dosing requirement based on the recipient's weight.

2. Recertification Requests:

   a. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

   b. The requested quantity is within FDA-labeled dosing based on the recipient's weight.

3. PA Guidelines:

   a. Initial PA will be for six months.

   b. Recertification approval will be for 12 months.

JJJJ. Tzield® (teplizumab-mzwv)

Therapeutic Class: Disease Modifying Agents for Type 1 Diabetes
Last Reviewed by DUR Board: July 27, 2023

Disease Modifying Agents for Type 1 Diabetes are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Approval will be given if all criteria are met and documented:

   a. The recipient is at least eight years of age;

   b. The recipient has a diagnosis of stage 2 type 1 diabetes, confirmed by:

      1. Documenting at least two positive pancreatic islet cell autoantibodies (e.g., glutamic acid decarboxylase 65 [GAD65], insulin autoantibody [IAA), insulinoma-associated antigen 2 autoantibody [IA-2A], zinc transporter 8 autoantibody [ZnT8A], islet cell autoantibody [ICA], and

      2. Documenting dysglycemia without overt hyperglycemia using an oral glucose tolerance test (an alternative method of diagnosis dysglycemia without overt hyperglycemia may be used if an oral glucose tolerance test is not available); and

   c. Prescriber has attested to the absence of acute Epstein-Barr virus (EBV) and CMV infection through laboratory or clinical evidence; and

   d. Prescriber has confirmed the absence of an active serious infection or chronic active infection, excluding localized skin infection;

   e. The recipient has received all age-appropriate vaccines, with live vaccines administered at least eight weeks before treatment, and inactivated vaccines and mRNA vaccines administered at least two weeks before treatment;

   f. The recipient is not pregnant or planning to become pregnant during the 14-day treatment course; and

   g. It has been prescribed by or in consultation with an adult or pediatric endocrinologist.

2. Quantity Limitations:

   a. 24 vials per 14-day course of therapy.

   b. Maximum one treatment course per lifetime.

   c. Coverage not renewable.

KKKK. Vyjuvek™ (beremagene geperpavec-svdt)

Therapeutic Class: dystrophic epidermolysis bullosa (DEB)
Last reviewed by DUR Board: October 19, 2023

Vyjuvek™ (beremagene geperpavec-svdt) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is six months of age or older; and

    b. The recipient has not received a skin graft within the past three months; and

    c. The recipient has a genetically confirmed diagnosis of DEB with mutation in the COL7A1 gene; and

    d. Prescribed by or in consultation with pediatric dermatologist or other specialist with advanced knowledge of treating DEB; and

    e. The recipient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

2. Recertification Requests:

    a. The recipient must continue to meet the above criteria; and

    b. The recipient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reaction resulting in discontinuation of therapy; and

    c. The recipient must have disease response as defined by improvement (healing) of treated wound(s); and

    d. The recipient requires continued treatment for new and/or existing open wounds.

3. PA Guidelines:

    a. Initial approval will be given for six months.

    b. Recertification will be approved for six months.

LLLL. Hemgenix® (etranacogene dezaparvovec-drlb)

Therapeutic Class: hemophilia B;
Last reviewed by DUR Board: October 19, 2023

Hemgenix® (etranacogene dezaparvovec-drlb) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is at least 18 years of age; and

    b. Prescribed by or in consultation with a hematologist; and

    c. The recipient has a diagnosis of moderately severe or severe congenital factor IX deficiency (e.g., pre-treatment factor IX ≤2%), as confirmed by blood coagulation testing; and

    d. The recipient has one or more of the following:

        1. Currently uses factor IX prophylaxis therapy; or

        2. Current or historical life-threatening hemorrhage; or

    e. Repeated, serious spontaneous bleeding episodes; and

    f. The recipient has been recently tested (within two weeks prior to administration of Hemgenix® and found negative for factor IX inhibitors; and

    g. The recipient does not have active hepatitis B and/or hepatitis C infection; and

    h. The recipient does not have uncontrolled HIV infection; and

    i. Liver health assessments including enzyme testing [ALT, AST, ALP and total bilirubin] and hepatic ultrasound and elastography have been performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and

    j. The recipient has not received previous gene therapy for Hemophilia B; and

    k. Prescriber attestation that factor IX activity will be monitored periodically per package insert (e.g., weekly for three months) post-administration.

2. Recertification Requests:

    a. Coverage not renewable.

3. PA Guidelines:

a. Limited to one treatment per lifetime.

MMMM.Roctavian™ (valoctocogene roxaparvovec-rvox)

Therapeutic Class: hemophilia A
Last reviewed by DUR Board: October 19, 2023

Roctavian™ (valoctocogene roxaparvovec-rvox) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is at least 18 years of age; and

    b. Prescribed by or in consultation with a hematologist; and

    c. The recipient has a diagnosis of severe congenital factor VIII deficiency (e.g., pre-treatment factor VIII activity <1 IU/dL), as confirmed by blood coagulation testing; and

    d. The recipient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; and

    e. The recipient does not have an active infection, either acute (e.g., acute respiratory infection or acute hepatitis) or uncontrolled chronic (e.g., chronic active hepatitis B); and

    f. The recipient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; and

    g. The recipient has not received prior hemophilia adeno-associated virus (AAV)-vector-based gene therapy; and

    h. The recipient is AAV serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA compliant test; and

    i. The recipient has been tested and found negative for active factor VIII inhibitors (e.g., results from a Bethesda assay or Bethesda assay with Nijmegen modification of under 0.6 Bethesda Units (BU) on two consecutive occasions ≥1 week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba); and

    j. Prescriber attestation that factor VIII activity will be monitored periodically post-administration; and

        1. The recipients with factor VIII activity levels >5 IU/dL should discontinue routine prophylactic exogenous factor VIII; or

        2. If factor VIII activity levels decrease and/or if bleeding is not controlled, assess presence of factor VIII inhibitors, and assess the need for hemostatic prophylaxis.

2. Recertification Requests:

   a. Coverage not renewable.

3. PA Guidelines:

   a. Limited to one treatment per lifetime.

NNNN. Evkeeza™ (evinacumab-dgnb)

Therapeutic Class: Antihyperlipidemic – Angiopoietin-like protein 3 (ANGPTL3)
Last reviewed by DUR Board: October 19, 2023

Evkeeza™ (evinacumab-dgnb) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is at least five years of age; and

    b. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

    c. The recipient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) by any of the following:

        1. Documented DNA test for functional mutation(s) in low density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality; or

        2. Untreated LDL cholesterol (LDL-C) levels >500 mg/dL or treated LDL-C ≥300 mg/dL; and

            a. Cutaneous or tendon xanthoma before age 10 year; or

            b. Untreated LDL-C levels in both parents consistent with heterozygous familial hypercholesterolemia (HeFH); and

    d. The recipient does not have HeFH; and

    e. Baseline LDL-C, total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment; and

    f. The recipient has been receiving stable background lipid lowering therapy for ≥4 weeks; and

    g. Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PKSK (inhibitors, lomitapide, LDL apheresis; and

    h. The recipient has tried and failed at least a three-month trial of adherent therapy with ezetimibe used in combination with the highest available or maximally tolerated dose of atorvastatin or rosuvastatin, unless contraindication to statin or ezetimibe; and

i. The recipient has tried and failed at least a three-month trial of adherent therapy with combination therapy consisting of the highest available or maximally tolerated dose of atorvastatin or rosuvastatin, ezetimibe, and a PCSK9 inhibitor indicated for HoFH (i.e., evolocumab), unless contraindicated; and

j. Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL-C is ≥100 mg/dL or ≥70 mg/dL for recipients with clinical atherosclerotic cardiovascular disease; and

k. Female recipients must have a negative pregnancy test and have been counselled to use effective contraception during treatment.

2. Recertification Requests

a. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

b. The recipient has had a documented reduction in LDL-C when compared to the initial baseline labs; and

c. The recipient continues to adhere to diet and background lipid lowering therapy (e.g., statin, ezetimibe, PCSK9 inhibitor).

3. PA Guidelines:

a. Initial approval will be given for three months.

b. Recertification will be approved for six months.

OOOO. Joenja® (leniolisib)

Therapeutic Class: activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)
Last reviewed by DUR Board: October 19, 2023

Joenja® (leniolisib) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is at least 12 years of age; and

    b. The recipient weighs at least 45 kg; and

    c. The recipient has a diagnosis of APDS confirmed genetic mutation of either the PIK3CD or PIK3R1 gene; and

    d. Prescribed by or in consultation with immunologist; and

    e. The recipient has nodal and/or extra-nodal lymphoproliferation, with the presence of ≥1 measurable nodal lesion as confirmed by prescriber attestation of palpable diagnosis (and/or on computed tomography (CT) or MRI; and

    f. The recipient has clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sinopulmonary infections, organ dysfunction [e.g., lung, liver]); and

    g. Pregnancy status will be confirmed in female recipients of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment; and

    h. The recipient is not on concurrent immunosuppressive therapy (e.g., mammalian target of rapamycin (mTOR) inhibitors, B-cell depleters, glucocorticoids [doses >25 mg/day of prednisone equivalent.

2. Recertification Requests:

    a. The recipient must continue to meet the above criteria; and

    b. The recipient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells, decrease in disease-related hospitalizations); and

    c. The recipient has not experienced any treatment-restricting adverse effects (e.g., severe neutropenia: ANC <500 cells/μL).

3. PA Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

PPPP. Daybue™ (trofinetide)

Therapeutic Class: Rett syndrome
Last reviewed by DUR Board: October 19, 2023

Daybue™ (trofinetide) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. The recipient is two years of age or older; and

   b. The recipient has a diagnosis of typical Rett Syndrome, and a documented MECP2 gene mutation confirmed by genetic testing; and

   c. Prescribed by or in consultation with neurologist, geneticist, or developmental pediatrician; and

   d. Prescriber has assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression-Improvement [CGI-I] score, Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale); and

   e. The recipient does not have progressive weight loss prior to initiation of therapy; and

   f. The recipient does not have moderate or severe renal impairment (e.g., estimated glomerular filtration rate (eGFR) <45 mL/min/1.73m$^2$).

2. Recertification Requests:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced on objective measure or tool (e.g., Rett Syndrome Behavior Questionnaire [RSBQ], CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor scale); and

   c. The recipient has not experienced any treatment-restricting adverse effects (e.g., severe diarrhea or dehydration, significant weight loss).

3. PA Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

QQQQ. Elfabrio® (pegunigalsidase alfa-iwxj)

Therapeutic Class: treats Fabry disease
Last reviewed by DUR Board: October 19, 2023

Elfabrio® (pegunigalsidase alfa-iwxj) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is 18 years of age or older; and

    b. The recipient has a documented diagnosis of Fabry disease (α -galactosidase A [α-Gal A] deficiency) with biochemical/genetic confirmation by one of the following:

        1. α-Gal-A activity in plasma, isolated leukocytes, and/or cultured cells (males only); or

        2. Detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing; and

    c. Prescribed by or in consultation with a neurologist, geneticist, or other specialist with advanced knowledge in treating Fabry disease; and

    d. The recipient must have a baseline value for plasma GL-3 and/or GL-3 inclusions, plasma or urinary globotriaosylceramide (Gb3/GL-3); or plasma globotriaosylsphingosine (lyso- Gb3); and

    e. Recipient must not be taking migalastat (Galafold®) or agalsidase beta (Fabrazyme®) during pegunigalsidase alfa-iwxj (Elfabrio®) therapy; and

    f. Medication is dosed per FDA labeling of 1 mg/kg (based on actual body weight) administered by IV infusion every two weeks.

2. Recertification Requests:

    a. Recipient must continue to meet the above criteria; and

    b. Recipient must have experienced a disease response with treatment as defined by a reduction or stabilization in ≥1 of the following, as compared to pre-treatment baseline:

        1. plasma GL-3 and/or GL-3 inclusions

        2. plasma or urinary Gb3/GL-3

        3. plasma lyso-Gb3; or

c. The recipient must have experienced a disease response with treatment as defined by an improvement or stabilization in the rate of decline of the eGFR; and

d. The recipient has not experienced unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, glomerulonephritis).

3. PA Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be approved for 12 months.

RRRR. Xiaflex® (collagenase clostridium histolyticum)

Therapeutic Class: treats Dupuytren's contracture and Peyronie's disease
Last reviewed by DUR Board: October 19, 2023

Xiaflex® (collagenase clostridium histolyticum) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Dupuytren's Contracture:

    a. Approval will be given if the following criteria are met and documented:

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Dupuytren's contracture with a palpable cord; and

        3. The recipient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days; and

        4. Documentation that the flexion deformity is causing functional limitations; and

        5. Treatment is administered no sooner than four-week interval (up to three cycles in total).

    b. Recertification Requests:

        1. Recipient continues to meet the above criteria.

    c. PA Guidelines:

        1. One treatment cycle.

2. Peyronie's Disease (PD)

    a. Approval will be given if the following criteria are met and documented:

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Peyronie's disease (PD) with a palpable plaque; and

        3. The recipient has curvature deformity of at least 30 degrees and <90 degrees at the start of therapy and stable disease defined by symptoms (i.e. penile curvature and pain) for at least six months (initial request only); and

4. Xiaflex® is not being used for sexual or erectile dysfunction associated with PD; and

5. Must be used in conjunction with penile modeling procedure; and

6. Treatment is administered no sooner than 6-week intervals (up to 4 cycles in total).

b. Recertification Requests:

1. The recipient continues to meet above criteria; and

2. Curvature deformity remains >15 degrees (curvature <15 degrees does not warrant subsequent treatment cycle).

c. PA Guidelines:

1. One treatment cycle.

SSSS. Skyclarys® (omaveloxolone)

Therapeutic Class: Friedreich ataxia
Last reviewed by DUR Board: October 19, 2023

Skyclarys® (omaveloxolone) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. The Recipient is at least 16 years of age; and

   b. The recipient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; and

   c. The recipient by or in consultation with neurologist, geneticist, or other specialist with advanced knowledge in treating Friedreich's ataxia; and

   d. The recipient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates); and

   e. The recipient has baseline Modified Friedreich's Ataxia Rating Scale (mFARS) score $\geq$20 and $\leq$80; and

   f. The recipient B-Type Natriuretic Peptide (BNP) is $\leq$200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; and

   g. Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:

      1. Liver function (ALT, AST, bilirubin); and

      2. Lipid parameter.

   h. The recipient does not have severe hepatic impairment (Child-Pugh C); and

   i. The recipient has the ability to swallow capsules; and

   j. The recipient of reproductive potential has been advised to use non-hormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation.

2. Recertification Requests:

   a. The recipient must continue to meet the above criteria; and

b. The recipient must have disease improvement as defined by stabilization or slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; and

c. The recipient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction).

3. PA Guidelines:

a. Initial approval will be given for 12 months.

b. Recertification will be approved for 12 months.

TTTT. Voxzogo™ (vosoritide)

Therapeutic Class: Treatment of achondroplasia

Last reviewed by DUR Board: January 18, 2024

Voxzogo™ (vosoritide) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Voxzogo™ (vosoritide)

   a. Initial Requests:

      1. Patient <18 years of age; and

      2. Patient has diagnosis of confirmed achondroplasia based on one of the following:

         a. Submission of records documenting:

            1. Clinical manifestations of achondroplasia (e.g. proximal shortening of arms, large head, narrow chest, short fingers) and radiographic (e.g., ilia and horizontal acetabula, narrow sacrosciatic notch, proximal radiolucency of the femurs, generalized metaphyseal abnormality, decreasing interpedicular distance caudally); and

            2. Radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia, and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphysis, and short and narrow chest); or

         b. Genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene; and

      3. Medication prescribed by or in consultation with endocrinologist, pediatric endocrinologist, clinical geneticist, or other specialist with advanced knowledge in treating achondroplasia; and

      4. Patient has open epiphyses; and

      5. Medication dosed per FDA label based on patient's actual body weight; and

      6. Prescriber attestation that patient body weight, growth, and physical development will be monitored and assessed every three to six months; and

7. Patient has not had (within the previous 18 months) nor will they receive limb lengthening surgery.

b. Renewal Requests:

1. Patient continues to meet above criteria; and

2. Documentation of positive clinical response to therapy as demonstrated by improvement in annualized growth velocity compared to pre-treatment baseline.

c. PA Guidelines

1. PA approval will be for 12 months.

UUUU. Saphnelo® (anifrolumab-fnia)

Therapeutic Class: Systemic Lupus Erythematosus
Last reviewed by DUR Board: January 18, 2024

Saphnelo® (anifrolumab-fnia) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. Patient is ≥18 years of age; and

   b. Patient has documented diagnosis of moderate to severe SLE; and

   c. The medication is prescribed by or in consultation with a rheumatologist; and

   d. Patient does not have any of the following exclusions to therapy:

      1. Severe active CNS lupus;

      2. Severe active lupus nephritis; and

   e. Patient has failed to respond adequately to at least one standard therapy (e.g., anti-malarials, corticosteroids, or immunosuppressives) (initial request only);

   f. The medication will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); and

   g. Patient must not have a clinically significant active infection; and

   h. Patient will not receive a live or live-attenuated vaccine concurrently with treatment; and

   i. The medication will not be used in combination with other biologic therapies (including B-cell targeted therapies (e.g., belimumab [Benlysta®], voclosporin [Lupkynis™], or cyclophosphamide).

2. Renewal Requests:

   a. Patient continues to meet above criteria; and

   b. Documentation of positive clinical response to Saphnelo® therapy.

3. PA Guidelines:

   a. PA approval will be for 12 months.

VVVV. Tavneos™ (avacopan)

Therapeutic Class: Antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (GPA or MPA)
Last reviewed by DUR Board: January 18, 2024

Tavneos™ (avacopan) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. Patient is ≥18 years old; and

   b. Patient has severe active ANCA-associated vasculitis; and

      1. Patient has autoantibodies for proteinase 3 (PR3) or myeloperoxidase (MPO), as detected using indirect immunofluorescence (IIF) assay or antigen-specific ELISAs; or

      2. Disease is confirmed by tissue biopsy at the site of active disease; and

   c. Medication prescribed by or in consultation with Nephrologist, Pulmonologist, or Rheumatologist; and

   d. Prescriber has assessed baseline (pre-treatment) disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS]) (initial request only); and

   e. Tavneos™ will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab); and

   f. Patient does not have an active infection, including localized infections; and

   g. Patient does not have severe hepatic impairment (e.g., Child-Pugh C) or active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis); and

   h. Liver panel has been obtained before initiating Tavneos™ and will be repeat per package insert (every four weeks after start of therapy for first six months then as clinically indicated);

   i. Patient has been evaluated and screened for the presence of HBV prior to initiating treatment (initial criteria only).

2. Renewal Requests:

   a. Patient continues to meet above criteria; and

b. Documentation of positive clinical response to Tavneos™ therapy.

3. PA Guidelines:

a. PA approval will be for six months.

WWWW. Wainua™ (eplontersen)

Therapeutic Class: Antisense oligonucleotides
Last reviewed by DUR Board: April 18, 2024

Wainua™ (eplontersen) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

    a. The recipient is ≥18 years of age; and

    b. The recipient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy); and

    c. Medication prescribed by or in consultation with cardiologist, geneticist, neurologist, or other specialist with advanced knowledge in treating hereditary transthyretin-mediated amyloidosis; and

    d. The recipient has clinical manifestations of polyneuropathy; and

    e. Medication will not be used in combination with inotersen (Tegsedi®), tafamidis (Vyndamax®), tafamidis meglumine (Vyndaqel®), patisiran (Onpattro®), or vutrisiran (Amvuttra®); and

    f. The recipient does not have any of the following conditions:

        1. Severe renal impairment or end-stage renal disease; or

        2. Moderate or severe hepatic impairment; or

        3. Prior liver transplant; and

    g. Prescriber will supplement vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) occur.

2. Quantity limit:

    a. One pen (45 mg) monthly.

3. Recertification Requests:

    a. The recipient continues to meet the above criteria; and

    b. The recipient has demonstrated a clinical benefit based on improvement in clinical manifestations of polyneuropathy from baseline; and

c. The recipient has not experienced any treatment-restricting adverse effects (e.g., severe ocular symptoms related to vitamin A deficiency).

4. PA Guidelines:

a. Initial approval will be given for 12 months.

b. Recertification will be approved for 12 months.

XXXX. Sickle Cell

Therapeutic Class: Sickle Cell
Last reviewed by DUR Board: July 18, 2024

Sickle Cell is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Lyfgenia® (lovotibeglogene autotemcel):

   a. Initial Request:

      1. The recipient is ≥12 years of age; and

      2. The recipient has had genetic testing confirming diagnosis of severe sickle-cell disease (SCD) genotype (βS/βS or βS/βO or βS/β+); and

      3. The recipient does not have disease with >2 α-globin gene deletions; and

      4. The recipient has symptomatic disease with hydroxyurea or alternative approved agent unless contraindicated; and

      5. The recipient experienced ≥4 vaso-occlusive events/crises (VOE/VOC) in the previous 24-months;

      6. Medication prescribed by or in consultation with Hematologist; and

      7. Prescriber attestation that the recipient is candidate for autologous hematopoietic stem cell transplant (HSCT); and

      8. The recipient has not previously received an allogeneic transplant; and

      9. The recipient has not previously received any other SCD gene therapy (e.g. Casgevy®); and

      10. The recipient has been counseled and verbalized understanding the hematologic malignancy (blood cancer) has occurred in clinical studies with Lyfgenia® treatment (black box warning); and

      11. The recipient does not have any of the following conditions:

         a. Positive for presence of HIV-1 or HIV-2, HBV, HCV; or

         b. Clinically significant and active bacterial, viral, fungal, or parasitic infection; or

         c. Advanced liver disease; or

d. Inadequate bone marrow function as defined by an absolute neutrophil count of <1000/µL (<500/µL for subjects on HU treatment) or a platelet count <100,000/µL; or

e. Any history of severe cerebral vasculopathy (defined by overt or hemorrhagic stroke; abnormal transcranial Doppler [≥200 cm/sec] needing chronic transfusions, or occlusion or stenosis in the polygon of Willis; or presence of Moyamoya disease; and

12. Prescriber attestation that all necessary preparations prior to Lyfgenia® administration will be followed per package insert (including scheduled transfusions to target required Hb and HbS levels and management of other concomitant medications; and

b. Renewal Requests:

1. Coverage not renewable.

2. PA Guidelines:

a. Max one treatment course per lifetime.

2. Casgevy® (exagamglogene autotemcel)

a. Universal criteria:

1. The recipient is ≥12 years of age; and

2. Medication prescribed by or in consultation with Hematologist; and

3. Prescriber attestation that patient is candidate for autologous HSCT; and

4. The recipient has not previously received an allogeneic transplant; and

5. The recipient has not received other gene therapy for sickle-cell disease or beta-thalassemia (e.g., Lyfgenia®, Zynteglo®); and

6. The recipient does not have any of the following conditions:

a. Positive for presence of HIV-1 or HIV-2, HBV, or HCV; or

b. Clinically significant and active bacterial, viral, fungal, or parasitic infection; or

c. Advanced liver disease.

b. SCD

1. Initial Request:

a. The recipient has had genetic testing confirming diagnosis of severe SCD genotype (βS/βS or βS/βO or βS/β+); and

b. The recipient experienced ≥2 VOE/VOC per year for the previous two years; and

c. The recipient has symptomatic disease despite treatment with hydroxyurea or alternative approved agent (e.g., crizanlizumab, voxelotor), unless contraindicated; and

d. Prescriber attestation that all necessary preparations prior to Casgevy® administration will be followed per package insert (including scheduled transfusions to target required Hb and HbS levels and discontinuation of disease modifying therapies).

2. Renewal Requests:

a. Coverage not renewable.

c. Transfusion-dependent beta-thalassemia (TDT)

1. Initial Request:

a. The recipient has had genetic testing confirming diagnosis β-thalassemia; and

b. The recipient has transfusion-dependent disease defined as a history of transfusions of ≥100 mL/kg/year or ≥10 units/year of packed red blood cells (pRBCs) in the previous 2 years; and

c. The recipient does not have severely elevated iron in the heart (i.e., recipients with cardiac T2 <10 msec by MRI or LVEF of, <45% by echocardiogram); and

d. Prescriber attestation that all necessary preparations prior to Casgevy® administration will be followed per package insert (including scheduled transfusions to target required Hb levels and discontinuation of disease modifying therapies).

2. Renewal Requests:

a. Max 1 treatment course per lifetime.

YYYY. Xolremdi™ (mavorixafor)

Therapeutic Class: Xolremdi™ (mavorixafor)

Last reviewed by DUR Board: January 16, 2025

Xolremdi™ (mavorixafor) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial Request:

1. Recipient is ≥12 years of age; and

2. Recipient has a diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome with genotype-confirmed CXCR4 variant; and

3. Medication prescribed by or in consultation with geneticist, immunologist, or other specialist with advance knowledge in treating WHIM syndrome; and

4. Confirmed ANC ≤400 cells/μL (or total WBC count ≤400 cells/μL if ANC is below lower limit of detection) [initial request only]; and

5. Prescriber attestation to assess QTc at baseline and to monitor QTc periodically during treatment for patients with risk factors for QTc prolongation; and

6. Recipient is not taking any of the following:

a. Another CXCR4 antagonist (e.g., plerixafor [Mozobil®]; or

b. Any medication that is highly dependent on cytochrome P450 (CYP) 2D6 for clearance (e.g., amitriptyline, fluoxetine); or

c. A strong CYP3A4 inducer (e.g., rifampin, phenytoin); and

7. Females of reproductive potential must have a confirmed negative pregnancy test prior to initiation and must attest to use effective contraception during treatment and for three weeks after the last dose; and

8. Medication dosed per FDA label based on recipient body weight with dose reduced when used concomitantly with a strong CYP3A4 inhibitor

b. Initial Request

1. Recipient continues to meet above criteria; and

2. Positive response to therapy (e.g., improvement in ANC and/or absolute lymphocyte counts [ALC], reduction in infections); and

3. Recipient has not experienced any treatment restricting adverse effects (e.g., significant QTc prolongation)

c. PA Guidelines

1. Initial PA approval will be six months.

2. Recertification will be 12 months.

ZZZZ. Cayston® (aztreonam)

Therapeutic Class: Cayston® (aztreonam)
Last reviewed by DUR Boad: January 16, 2025

Cayston® (aztreonam) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial Request:

1. Recipient is ≥7 years old; and

2. Recipient has documented diagnosis of Cystic Fibrosis (CF) with positive sputum culture confirming pseudomonas aeruginosa of the airway; and

3. Recipient has FEV1 between 25% and 75% predicted, and prescriber attestation that the recipient is not colonized with Burkholderia cepacian; and

4. Recipient has one of the following:

a. Trial and failure, contraindication, or intolerance to inhaled tobramycin; or

b. Antibiotic susceptibility testing indicates aztreonam to be more effective than tobramycin; and

5. Medication being dosed per FDA label (75 mg every eight hours administered with 28 days on/28 days off cycle) and recipient counseled to use bronchodilator before taking a dose of Cayston®)

b. Renewal Requests:

1. Positive response to therapy as demonstrated by improvement in CF respiratory symptoms; and

2. Recipient has not experienced any treatment-restricting adverse effects (e.g., bronchospasms, allergic reactions)

c. PA Guidelines

1. Initial PA approval will be for six months.

2. Renewal PA approval will be 12 months.

AAAAA. Polyneuropathy of Hereditary Amyloidosis Agents

Therapeutic Class: Polyneuropathy of Hereditary Amyloidosis Agents
Last reviewed by DUR Board: January 16, 2025

Polyneuropathy of Hereditary Amyloidosis Agents is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Onpattro™ (patisiran)

   a. Initial Request:

      1. Recipient is ≥18 years of age; and

      2. Recipient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy); and

      3. Medication prescribed by or in consultation with cardiologist, geneticist, neurologist, or other specialist with advanced knowledge in treating hereditary transthyretin mediated amyloidosis; and

      4. The recipient has clinical manifestations of polyneuropathy; and

      5. Medication will not be used in combination with other transthyretin (TTR) reducing or stabilizing agents (e.g., eplontersen, inotersen, tafamidis, vutrisiran, etc.); and

      6. Recipient does not have any of the following conditions:

         a. Severe renal impairment or end-stage renal disease; or

         b. moderate or severe hepatic impairment; or

         c. Prior liver transplant; and

      7. Prescriber will supplement vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) occur; and

      8. Medication dosed every three weeks per FDA-label based on patient actual body weight

   b. Renewal Requests:

1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated a clinical benefit based on improvement in clinical manifestations of polyneuropathy from baseline; and

3. Recipients has not experienced any treatment restricting adverse effects (e.g., severe ocular symptoms related to vitamin A deficiency).

c. PA Guidelines:

1. Initial PA will be for 12 months.

2. Recertification requests will be for 12 months.

2. Tegsedi™ (inotersen)

a. Initial Request:

1. Recipient is ≥18 years of age; and

2. Recipient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy); and

3. Medication prescribed by or in consultation with cardiologist, geneticist, neurologist, or other specialist with advanced knowledge in treating hereditary transthyretin-mediated amyloidosis; and

4. The recipient has clinical manifestations of polyneuropathy; and

5. Medication will not be used in combination with other TTR reducing or stabilizing agents (e.g., patisiran, eplontersen, tafamidis, vutrisiran, etc.); and

6. Recipient does not have any of the following conditions:

a. Platelet count below 100 x $10^9$/L; or

b. Urinary protein to creatinine ration (UPCR) of 1000 mg/g or higher; or

c. Severe renal impairment or end-stage renal disease; or

d. Moderate or severe hepatic impairment; or

e. Prior liver transplant; and

7. Recipient will supplement vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) occur; and

8. Medication dosed per FDA-label (284 mg SC once weekly).

b. Renewal Requests:

1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated a clinical benefit based on improvement in clinical manifestations of polyneuropathy from baseline; and

3. Recipient has not experienced any treatment restricting adverse effects (e.g., platelet count $<100 \times 10^9$/L, sever ocular symptoms related to vitamin A deficiency)

c. PA Guidelines:

1. Initial PA will be for 12 months.

2. Recertification requests will be for 12 months.

BBBBB. Zynteglo® (betibeglogene autotemcel)

Therapeutic Class: Zynteglo® (betibeglogene autotemcel)
Last reviewed by DUR Board: July 18, 2024

Zynteglo® (betibeglogene autotemcel) is subject to PA and quality limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. Recipient is ≥4 years old; and

   b. Recipient has had genetic testing confirming diagnosis β-thalassemia; and

   c. Medication prescribed by or in consultation with Hematologist; and

   d. Prescriber attestation that recipient is candidate for autologous HSCT; and

   e. Recipient has not previously received an allogeneic transplant; and

   f. Recipient has not previously received other gene therapies (e.g., Casgevy®); and

   g. Recipient has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) or with ≥8 transfusions of pRBCs per year in the two years preceding therapy; and

   h. Recipient has been screened for HBV, HCV, human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2), and HIV in accordance with clinical guidelines prior to collection of cells (leukapheresis); and

   i. Recipient has not use prophylactic HIV anti-retroviral medication or hydroxyurea within 30 days prior to mobilization (or for the expected duration for elimination of those medications) and until all cycles of apheresis are completed (Note: if a patient requires anti-retrovirals for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization); and

   j. Iron chelation therapy has been discontinued for at least seven days prior to initiating myeloablative conditioning therapy and myelosuppressive iron chelators will be avoided for six months post-treatment; and

   k. Recipient does not have any of the following:

      1. Severely elevated iron in the heart (e.g., patients with cardiac T2 <10 msec by MRI; or

      2. Advanced liver disease; or

3. MRI of the liver with results demonstrating liver iron content ≥15 mg/g (unless biopsy confirms absence of advanced disease); and

l. Recipient has been counseled and verbalized understanding that hematologic malignancies may develop in individuals treated with Zynteglo® and lifelong monitoring is warranted; and

m. Prescriber attestation that all necessary preparations prior to Zynteglo® administration will be followed per package insert (including scheduled transfusions to target required Hb levels)

MAX ONE TREATMENT COURSE PER LIFETIME

2. Renewal Requests:

a. Coverage not renewable.

CCCCC. Winrevair™ (sotatercept-csrk)

Therapeutic Class: Winrevair™ (sotatercept-csrk)
Last reviewed by DUR Board: July 18, 2024

Winrevair™ (sotatercept-csrk) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. Recipient is ≥18 years of age; and

   b. Medication prescribed by or in consultation with pulmonologist or cardiologist; and

   c. Recipient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; and

   d. Diagnosis has been confirmed by submission of right heart catheterization results; and

   e. Recipient's WHO functional class is II or greater; and

   f. Recipient has been stable on background PAH therapy for ≥90 days and will continue background PAH therapy during treatment with Winrevair™, unless contraindicated (Please note: Background therapy refers to combination therapy consisting of drugs from ≥2 of the following drug classes: endothelin receptor antagonists [ERA], phosphodiesterase type 5 [PDE5] inhibitor [PDE5i], soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist); and

   g. Recipient does not have a baseline platelet count $<50 \times 10^9$/L; and

   h. Prescriber attestation that hemoglobin (Hgb) and platelet levels will be monitored per package insert (e.g., before each dose for at least the first five doses); and

   i. Females of reproductive potential have a negative pregnancy test prior to starting therapy and have been counseled on use of effective contraception during treatment; and

   j. Medication dosed per FDA label based on recipient weight.

2. Renewal Requests:

   a. Medication prescribed by or in consultation with pulmonologist or cardiologist; and

   b. Medication dosed per FDA label based on recipient weight; and

c. Documentation of positive clinical response to therapy; and

d. Recipient continues on background PAH therapy during treatment with Winrevair™, unless contraindicated (Please note: Background therapy refers to combination therapy consisting of drugs from ≥2 of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist)

3. PA Guidelines:

a. Initial PA will be for six months.

b. Recertification requests will be for 12 months.

DDDDD. Beqvez™ (fidanacogene elaparvovec-dzkt)

Therapeutic Class: Beqvez™ (fidanacogene elaparvovec-dzkt)
Last reviewed by DUR Board: July 18, 2024

Beqvez™ (fidanacogene elaparvovec-dzkt) is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. Recipient is ≥18 years of age; and

   b. Medication prescribed by or in consultation with Hematologist; and

   c. The recipient has a diagnosis of moderately severe or severe congenital factor IX deficiency (e.g., pre-treatment factor IX ≤2%); as confirmed by blood coagulation testing; and

   d. Patient has not received prior hemophilia AAV-vector-based gene therapy (e.g., Hemgenix®); and

   e. The recipient has one or more of the following:

      1. Currently uses factor IX prophylaxis therapy; or

      2. Current or historical life-threatening hemorrhage; or

      3. Repeated, serious spontaneous bleeding episodes; and

   f. The recipient has been recently tested (within two weeks prior to administration of Beqvez™) and found negative for factor IX inhibitors; and

   g. Recipient is adeno-associated virus serotype Rh74var capsid (AAVRh74var) neutralizing antibody negative as determined by an FDA-approved or CLIA-compliant test; and

   h. Recipient will have baseline liver function assessed prior to and after therapy according to the monitoring schedule outlined in the package insert with corticosteroids administered in response to elevations; and

   i. Recipients with preexisting risk factors for hepatocellular carcinoma (e.g., patients with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age will have abdominal ultrasound screenings and be

monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration; and

j. Recipient does not have current liver-related coagulopathy, hypoalbuminemia, persistent jaundice, or cirrhosis), portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis; and

k. Recipient has been tested for HIV and does not have an active infection (i.e., either CD4+ cell count <200 mm3 or viral load ≥20 copies/mL in cases of serological evidence of HIV-1 or HIV-2 infection); and

l. Prescriber attestation that factor IX (FIX) activity will be monitored post-administration periodically per package insert (e.g., once or twice weekly for four months) to confirm adequate endogenous FIX activity levels to support discontinuation of pre-infusion FIX prophylaxis therapy.

MAX ONE TREATMENT COURSE PER LIFETIME

2. Renewal Requests:

a. Coverage not renewable.

EEEEE. Primary Hyperoxaluria Agents

Therapeutic Class: Primary Hyperoxaluria Agents
Last reviewed by DUR Board: July 18, 2024

Primary Hyperoxaluria Agents is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Oxlumo™ (lumasiran)

   a. Initial Request:

      1. Recipient has a definitive diagnosis of primary hyperoxaluria type 1 (PH1) as evidenced by one of the following:

         a. Biallelic pathogenic mutation in the alanine: glyoxylate aminotransferase (AGXT) gene as identified on molecular genetic testing; or

         b. Identification of alanine: glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; and

      2. Oxlumo™ will be used to lower urinary oxalate levels; and

      3. Prescribed by or in consultation with nephrologist, urologist, or geneticist; and

      4. Recipient has not had a liver transplant; and

      5. Oxlumo™ will not be used in combination with other urinary oxalate reducing agents (e.g., Rivfloza®); and

      6. Recipient has baseline assessment for ≥1 of the following (initial request only):

         a. Urinary oxalate excretion level (corrected for BSA); or

         b. Spot urinary oxalate: creatinine ratio; or

         c. eGFR; or

         d. Plasma oxalate level

      7. Medication dosed per FDA label based on recipient weight.

b. Renewal Requests:

1. Recipient continues to meet above criteria; and

2. Recipient with disease response as evidenced by at least one of the following:

a. Decrease in urinary oxalate excretion level (corrected for BSA) from baseline; or

b. Reduction in spot urinary oxalate: creatinine ratio from baseline; or

c. Stabilization of eGFR; or

d. Decrease in plasma oxalate level from baseline.

c. PA Guidelines:

1. Initial PA will be for six months.

2. Recertification requests will be for 12 months.

2. Rivfloza™ (nedosiran)

a. Initial Request:

1. Recipient is ≥9 years of age; and

2. Recipient has a definitive diagnosis of PH1 as evidenced by one of the following:

a. Biallelic pathogenic mutation in the AGXT gene as identified on molecular genetic testing; or

b. Identification of AGT enzyme deficiency on liver biopsy; and

3. Rivfloza™ will be used to lower urinary oxalate levels; and

4. Prescribed by or in consultation with nephrologist, urologist, or geneticist; and

5. Patient does not have renal impairment defined as an eGFR <30 mL/min/1.73 m2; and

6. Recipient has not had a liver transplant; and

7. Rivfloza™ will not be used in combination with other urinary oxalate reducing agents (e.g., Oxlumo™); and

8. Recipient has baseline assessment for ≥1 of the following (initial request only):

   a. Urinary oxalate excretion level (corrected for BSA); or

   b. Spot urinary oxalate: creatinine ratio; or

   c. eGFR; or

   d. Plasma oxalate level

9. Medication dosed per FDA label based on recipient weight

b. Renewal Requests:

1. Recipient continues to meet above criteria; and

2. Recipient with disease response as evidenced by at least one of the following:

   a. Decrease in urinary oxalate excretion level (corrected for BSA) from baseline; or

   b. Reduction in spot urinary oxalate: creatinine ratio from baseline; or

   c. Stabilization of eGFR; or

   d. Decrease in plasma oxalate level from baseline

c. PA Guidelines

1. Initial PA will be for six months.

2. Recertification requests will be for 12 months.

FFFFF. Filsuvez® (birch triterpenes)

Therapeutic Class: Dystrophic and Junctional Epidermolysis Bullosa
Last Reviewed by the DUR Board: April 17, 2025

Filsuvez® is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check-Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. The recipient is ≥6 months old; and

   b. The recipient with diagnosis of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) confirmed by genetic testing; and

   c. The recipient with presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and

   d. Medication is being applied every one to four days with dressing changes; and

   e. The recipient does not have current evidence or history of squamous cell carcinoma (SCC) in the area that will undergo treatment; and

   f. The recipient does not have active infection in the area that will undergo treatment; and

   g. Medication is not being used concurrently with Vyjuvek®; and

   h. Medication is prescribed by, or in consultation with, dermatologist or geneticist.

2. Dosing Limits:

   a. One tube (23.4g) per day.

3. Renewal Requests:

   a. The recipient continues to meet the above criteria: and

   b. Documentation of positive response to therapy.

4. PA Guidelines:

   a. Initial: Three months

   b. Recertification: Six months.

GGGGG. Juxtapid™ (lomitapide)

Therapeutic Class: Antilipemic Agent, homozygous familial hypercholesterolemia (HoFH)
Last Reviewed by the DUR Board: April 17, 2025

Juxtapid™ is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check-Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. The recipient is >18 years old; and

   b. The recipient with diagnosis of homozygous familial hypercholesterolemia (HoFH), as confirmed by one of the following:

      1. Genetic testing to confirm two mutant alleles at the LDLR, APOB PCSK9, or LDLRAP1 gene locus; or

      2. An untreated LDL >500 mg/dL (or treated LDL >300 mg/dL) together with either:

         a. Cutaneous or tendon xanthoma before the age of 10 years; or

         b. Untreated elevated LDL levels consistent with heterozygous FH in both parents; and

   c. Medication is prescribed by, or in consultation with, an endocrinologist, cardiologist, or lipidologist; and

   d. The recipient is currently receiving maximum tolerated statin and one other lipid lowering therapy (e.g., ezetimibe, nicotinic acid, bile acid sequestrant, fibrate, LDL apheresis), unless contraindicated or not tolerated; and

   e. Recipient has history of intolerance, failure, or contraindication to PCSK9-inhibitor (e.g., Praluent®, Repatha®); and

   f. Medication will not be used in combination with a PCSK9-inhibitor; and

   g. The recipient has been counseled to follow a low-fat diet; and

   h. The recipient does not have moderate or severe hepatic impairment or active liver disease; and

   i. Medication will not be prescribed concomitantly with strong or moderate CYP3A4 inhibitors; and

j. Females of reproductive potential have negative pregnancy test prior to initiating and have been counseled to use effective contraception during treatment.

2. Dosing Limits:

a. One capsule daily (max dose 60 mg).

3. Renewal Requests:

a. The recipient continues to meet the above criteria; and

b. Documentation of positive response to therapy.

4. PA Guidelines:

a. Initial: Three months.

b. Recertification: Six months.

HHHHH. Tryngolza™ (olezarsen)

Therapeutic Class: Antilipemic Agent, familial chylomicronemia syndrome (FCS)
Last Reviewed by the DUR Board: April 17, 2025

Tryngolza™ is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check-Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. The recipient is >18 years old; and

   b. The recipient has a diagnosis of familial chylomicronemia syndrome (FCS), as confirmed by one of the following:

      1. Genetic confirmation of bi-allelic pathogenic variants in affected genes (e.g., LPL, ApoA5, ApoC2, LMF1, GPIHBPI, G3PDH1); or

      2. All of the following:

         a. Fasting triglyceride (TG) levels persistently >880 mg/dL while on conventional lipid lowering therapy, unless contraindicated or not tolerated (e.g., fibrates, omega-3 fatty acids, statins, niacin, ezetimibe); and

         b. Secondary causes of hypertriglyceridemia have been ruled out (e.g., alcohol use, chronic kidney disease (CKD), hypothyroidism, uncontrolled diabetes, medications [e.g., atypical antipsychotics, beta-blockers, corticosteroids, oral estrogens]); and

         c. The recipient with clinical history suggestive of FCS (e.g., pancreatitis, eruptive xanthomas, lipemia retinalis); and

      3. The recipient has been counseled to follow a low-fat diet; and

      4. Medication is prescribed by, or in consultation with, endocrinologist, cariologist, or lipidologist.

2. Dosing Limits:

   a. One injection (80 mg) monthly.

3. Renewal Requests:

   a. The recipient continues to meet the above criteria; and

b. Documentation of positive response to therapy.

4. PA Guidelines:

a. Initial and recertification are six months.

IIIII. Yorvipath® (palopegteriparatide)

Therapeutic Class: Parathyroid Hormone Analog
Last Reviewed by the DUR Board: April 17, 2025

Yorvipath® is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check-Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. The recipient is >18 years old; and

   b. The recipient has a diagnosis of hypoparathyroidism; and

   c. The recipient does not have acute post-surgical hypoparathyroidism; and

   d. Within two weeks before initiating Yorvipath®, recipient has both of the following:

      1. Serum 25(OH) vitamin D within the normal range; and

      2. Albumin-corrected serum calcium ≥7.8 mg/dL; and

2. Dosing Limits:

   a. Two pens/28 days (max dose 30 mcg daily).

3. Renewal Requests:

   a. The recipient continues to meet the above criteria; and

   b. Documentation of positive response to therapy.

4. PA Guidelines:

   a. Initial and recertification are 12 months.

JJJJJ. Ocaliva® (obeticholic acid), Iqirvo® (elafibranor), Livdelzi®(seladelpar)

Therapeutic Class: Primary Biliary Cholangitis (PBC) Agents
Last Reviewed by the DUR Board: April 17, 2025

Ocaliva® is subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check-Up Pharmacy Manual for specific quantity limits.

1. Initial Request:

   a. The recipient is >18 years old; and

   b. The recipient has diagnosis of PBC confirmed by at least two of the following:

      1. Biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation; or

      2. Presence of anti-mitochondrial antibodies (AMAs) or other PBC-specific antibodies (anti-sp100, anti gp210, Anti-Kelch-Like 12, and/or Anti-Hexokinase 1); or

      3. Histopathologic evidence of nonsuppurative cholangitis and destruction of small or medium bile ducts on liver biopsy; and

   c. The recipient meets one of the following:

      1. Requested medication is being prescribed in combination with ursodeoxycholic acid (UDCA) due to inadequate response to trial of at least 12 months with UDCA; or

      2. The recipient has a history of intolerance or contraindication to UDCA; and

   d. Medication is being prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other specialist with advanced knowledge of treating PBC; and

   e. Prescriber attestation that recipient does not have any FDA-labeled contraindications to requested medication (e.g., complete biliary obstruction, decompensated cirrhosis).

2. Dosing Limits:

   a. One capsule/tablet daily.

3. Renewal Requests:

a. The recipient continued to meet the above criteria; and

b. Documentation of positive response to therapy.

4. PA Guidelines:

a. Initial and recertification are 12 months.

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2. MEDICATIONS WITH GENDER/AGE EDITS

A. Prenatal Vitamins

1. Payable only for female recipients.

2. Exemption to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate International Classification of Diseases (ICD) code is documented on the prescription and transmitted on the claim.

B. Oral/Topical Contraceptives

1. Payable only for female recipients.

2. Exemption to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

C. Gender Edits

1. Hormones

a. Estrogen – payable only for female recipients.

b. Progestins – payable only for female recipients.

c. Estrogen and Androgen Combinations – payable only for female recipients.

d. Estrogen and Progestin Combinations – payable only for female recipients.

e. Contraceptive Hormones – payable only for female recipients.

f. Testosterone – payable only for male recipients.

g. Androgen Hormone Inhibitor – payable only for male recipients.

2. Exception to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

D. Vitamins with Fluoride

1. Payable only for recipients up to age 21 years.

3. ANTIRETROVIRALS

Antiretrovirals for the treatment of Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) are a covered benefit for Nevada Medicaid recipients. The Food and Drug Administration (FDA) approved antiretrovirals whose manufacturers participate in the federal Drug Rebate Program and are not Drug Efficacy Study and Implementation (DESI) drugs, are covered.

4. DIABETIC SUPPLY PROGRAM

Diabetic Supplies are subject to prior authorization (PA) and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act (SSA) and/or approved by the Drug Use Review (DUR) Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

PA is required for preferred and non-preferred diabetic products (including insulin delivery system and Continuous Glucose Monitor [CGM] receivers and readers).

Preferred (including sensors and transmitters) and nonpreferred (including tubing, reservoirs for pumps and transmitters and sensors for CGM's) diabetic supplies do not require a prior authorization. These items require a documented diagnosis of Diabetes Mellitus Type I (DM1), Diabetes Mellitus Type II (DM2) (if applicable), or gestational diabetes and recipients must meet all age restrictions stated on the manufacturer's label.

Pharmacy benefit allows a 100-day supply for insulin system and CGM supplies.

A. Preferred Insulin Delivery System

1. Approval will be given if the following criteria are met and documented:

a. Recipient must have a documented diagnosis of DM1 or Gestational Diabetes; and

b. The product must be prescribed by or in consultation with an endocrinologist; and

c. The recipient must meet all age restrictions stated in the manufacturer's label; and

d. The recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple day injections of insulin (requiring at least three injections per day); and

e. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 milligram (mg)/deciliter (dL), or

3. Prior use of an insulin pump with documented frequency of glucose self-testing of at least four times per day in the month immediately prior to the request.

2. PA Guidelines

a. Initial PA approval will be for one year.

3. Recertification Request

a. Recertification of PA approval will be given if the recipient has documented positive clinical response to the product (including current HbA1C).

b. Recertification PA approval will be for one year.

B. Non-Preferred Insulin Delivery System

1. Approval will be given if the following criteria are met and documented:

a. In addition to meeting the "Preferred Insulin Delivery System" criteria, the recipient must also meet the following:

1. The recipient must have been trained to use the non-preferred product; and

2. The recipient must have benefited from use of the non-preferred product; and

3. The recipient must have one of the following reasons/special circumstances:

4. Recipient has had an allergic reaction to a preferred product or related supply; or

5. Recipient has a visual impairment which requires the use of a non-preferred product; or

6. Recipient has medical necessity justification (e.g., mental or physical limitation) which requires them to stay on their current product.

C. Preferred CGMs

1. Approval will be given if the following criteria are met and documented:

a. Recipient must have a documented diagnosis of DM1, DM2, or Gestational Diabetes; and

b. Recipient must meet all age restrictions stated in the manufacturer's label; and

c. Recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple daily injections of insulin (requiring at least three injections per day); and

d. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; or

3. Recipient is currently using insulin pump therapy while continuing to need frequent dosage adjustments or experiencing recurring episodes of severe hypoglycemia (50 mg/dL).

2. PA Guidelines

a. Initial PA approval will be for one year.

D. Non-Preferred CGM

1. Approval will be given if the following criteria are met and documented:

a. In addition to meeting the Preferred CGM criteria, the recipient must also meet the following:

1. Recipient has had an allergic reaction to a preferred product or related supply; or

2. Recipient has a visual impairment which requires the use of a non-preferred product; or

3. Recipient has medical necessity justification (e.g., mental or physical limitation) which requires them to stay on their current product; or

4. The recipient must have been trained to use the non-preferred product; and

5. The recipient must have benefited from use of the non-preferred product.

E. Test Strips and Lancets

Blood Glucose monitors with special features (e.g., voice synthesizers) require a PA. For special blood glucose monitors, a diagnosis and a statement from the physician documenting the impairment is required with a PA.

5. PHYSICIAN ADMINISTERED DRUGS (PADs) REQUIRING PRIOR AUTHORIZATION (PA) AND/OR QUANTITY LIMITATIONS

A. Abraxane®; paclitaxel albumin bound

Therapeutic Class: Taxane Chemotherapy
Last Reviewed by the DUR Board: January 16, 2025

Physician Administered Drugs (PAD) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

a. Recipient is at least 18 years of age; and

b. Breast Cancer

1. Recipient failed on combination chemotherapy for metastatic disease or relapsed within six months of adjuvant therapy; and

a. Used as a single agent; and

b. Previous chemotherapy included an anthracycline unless clinically contraindicated; or

2. Recipient has recurrent unresectable (local or regional) or metastatic (Stage IV [M1]) disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

a. Disease is human epidermal growth factor (HER2)-negative hormone receptor positive disease; and

1. Used as one of the following:

a. As a single agent

b. In combination with carboplatin in recipient with high tumor burden, rapidly progressing disease, or visceral crisis; and

b. Used in one of the following treatment settings:

1. First-line therapy if no germline BRCA 1/2 mutation

2. Second-line therapy if not a candidate for fam-trastuzumab-deruxtecan-nxki

3. Third-line therapy and beyond; or

3. Recipient has triple negative breast cancer (TNBC); and

   a. Used in combination with pembrolizumab for programmed death-ligand 1 (PD-L1) positive (PD-L1 combined positive score (CPS) ≥10) disease; or

   b. Used as a single agent; and

      1. Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; or

      2. Used as subsequent therapy; or

   c. Used in combination with carboplatin in recipients with high tumor burden, rapidly progressing disease, or visceral crisis; and

      1. Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; or

      2. Used as subsequent therapy; or

4. Recipient has HER2-positive disease; and

   a. Used as fourth-line therapy and beyond in combination with trastuzumab; or

5. May be substituted for paclitaxel or docetaxel if the recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications to standard hypersensitivity premedication.

c. Non-Small Cell Lung Cancer (NSCLC)

1. Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in recipients who are not candidates for curative surgery or radiation therapy; or

2. May be substituted for paclitaxel or docetaxel if the recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications to standard hypersensitivity premedication; or

3. Used for recurrent, advanced, metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence or disseminated disease), or mediastinal lymph node recurrence with prior radiation therapy; and

   a. Used as first-line therapy; and

      1. Used in one of the following:

a. Recipients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 <1%

b. Recipients with a PS 0-2 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression positive (≥1%)

c. Recipients with a PS 0-1 who have tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); and

2. Used in combination with carboplatin and pembrolizumab for squamous cell histology or

3. Used in combination with carboplatin and atezolizumab for non-squamous histology; and

4. Used in combination with tremelimumab-actl, durvalumab, and carboplatin (excluding use in recipients with PD-L1 ≥50%); or

5. Used in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors (PS 0-2) or as a single agent (PS 2); and

a. Used in recipients with tumors that have negative actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1≥%; or

b. Used in recipients with tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1<1%; or

c. Used in recipients with tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

b. Used as subsequent therapy; and

1. Used in one of the following:

a. Recipients with a PS 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement

b. Recipients with a PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; and

c. Used in combination with carboplatin and pembrolizumab for squamous cell histology or

d. Used in combination with carboplatin and atezolizumab for non-squamous histology or

e. Used in combination with tremelimumab-actl, durvalumab, and carboplatin; or

2. Used in combination with carboplatin in patients with contraindications to PD-1 or PD-L1 inhibitors (PS 0-2); and

c. Used in recipients with tumors that are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

d. Used in recipients with tumors that are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; or

e. Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; or

4. Used as a single agent; and

a. Used for first progression after initial systemic therapy (if not previously used) in recipients with a PS 0-2; or

b. Used in recipients with a PS 2 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

c. Used in recipients with a PS 2 who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; or

d. Used in recipients with a PS 2 and PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers with prior programmed cell death protein 1 (PD-1)/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy.

d. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

1. Recipient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; and

a. Recipient has recurrent or persistent disease; and

b. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); and

c. Used a single agent; and

1. Recipient has platinum-resistant disease; and

2. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; and

d. Recipient has one of the following:

1. Platinum-resistant disease; and

a. Used for progression on primary, maintenance, or recurrence therapy; or

b. Used for stable or persistence disease if not currently on maintenance therapy; or

c. Used for complete remission and relapse <6 months after completing chemotherapy; or

2. Platinum-sensitive disease; and

a. Used for complete remission and relapse ≥6 months after completing chemotherapy; or

3. Recipient has low-grade serous carcinoma; and

a. Patient has recurrent platinum-sensitive or platinum-resistant disease; and

1. Used as a single agent; or

2. Used in combination with carboplatin in recipients with confirmed taxane hypersensitivity; or

4. May be substituted for paclitaxel if the recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications to standard hypersensitivity premedication.

e. Pancreatic Adenocarcinoma

1. Used in combination with gemcitabine; and

a. Recipient has locally advanced or metastatic disease; and

1. Used as first-line therapy; or

2. Used an induction therapy followed by chemoradiation (locally advanced disease only); or

3. Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; or

b. Recipient has local recurrent in the pancreatic operative bed or recurrent metastatic disease, post-resection; and

1. Used ≥6 months after completion of primary therapy; or

2. Used <6 months from completion of primary therapy with a fluoropyrimidine-based regimen; or

c. Used as neoadjuvant therapy; and

1. Recipient has resectable disease; or

2. Recipient has biopsy positive borderline resectable disease; or

2. Used in combination with gemcitabine and cisplatin; and

   a. Recipient has metastatic disease; and

   b. Recipient has Eastern Cooperative Oncology Group (ECOG) PS 0-1; and

   c. Used as first-line therapy.

f. Cutaneous Melanoma

   1. Patient has metastatic or unresectable disease; and

   2. Used as a subsequent therapy as a single agent or in combination with carboplatin; and

   3. Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.).

g. Uveal Melanoma

   1. Used as a single agent for metastatic or unresectable disease.

h. Endometrial Carcinoma (Uterine Neoplasms)

   1. Used as a single agent therapy; and

   2. Used as subsequent therapy for recurrent disease; and

   3. Recipient has tried paclitaxel and treatment paclitaxel was not tolerated due to a documented hypersensitivity reaction despite use of recommended premedication, or there is a documented medical contraindication to recommended premedication; and

   4. Patient has a negative skin test to paclitaxel (if available).

i. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

   1. Used in combination with gemcitabine for unresectable, resected gross residual (R2) or metastatic disease; and

      a. Used as a primary treatment; or

      b. Used as a subsequent treatment for progression on or after systemic therapy.

j. Small Bowel Adenocarcinoma

1. Recipient has advanced or metastatic disease; and

2. Used as single agent or in combination with gemcitabine; and

a. Used as initial therapy after previous FOLFOX/CAPOX in the adjuvant setting within past 12 months or contraindication; or

b. Used as subsequent therapy; or

c. Recipient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; and

k. Kaposi Sarcoma

1. Used as subsequent therapy in recipients intolerant to paclitaxel; and

2. Recipient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

3. Disease has progressed on or not responded to first-line systemic therapy; and

a. Used as a single agent for patients that do not have HIV; or

b. Used in combination with antiretroviral therapy (ART) for recipients with HIV; and

4. Disease has progressed on alternative first-line systemic therapy.

a. Used as a single agent for patients that do not have HIV; or

b. Used in combination with ART for patients with HIV

l. Ampullary Adenocarcinoma

1. Used in combination with gemcitabine; and

2. Recipient has pancreatobiliary and mixed type disease; and

a. Used as neoadjuvant therapy for localized disease in high-risk recipients (i.e., equivocal or indeterminate imaging findings, markedly elevated CA 19-9, markedly elevated carcinoembryonic antigen [CEA], large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); or

b. Used as first-line therapy for unresectable localized or metastatic disease; or

c. Used as subsequent therapy for disease progression.

m. Cervical Cancer

1. Used as a single agent as subsequent therapy; and

a. Recipient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); or

b. Recipient has recurrent or metastatic disease.

2. Dosing Limits

a. Max Units (per dose and over time) [Health Care Financing Administration (HCFA) Common Procedural Coding System (HCPCS) Unit]:

1. Kaposi Sarcoma

a. 300 billable units per 28 days

2. NSCLC

a. 900 billable units per 21 days

3. Cervical Cancer, Biliary Tract Cancers, and Ampullary Adenocarcinoma

a. 900 billable units per 28 days

4. Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer, Endometrial Carcinoma

a. 2800 billable units per 84 days

5. Cutaneous and Uveal Melanoma

a. 1200 billable units per 28 days

3. Recertification Request:

Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

c. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count {ANC} <1,500 cell/mm3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions [including anaphylactic reactions] hepatic impairment, etc.

4. PA Guidelines:

a. Coverage is provided for six months and may be renewed, unless otherwise specified.

b. Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin or in combination with pembrolizumab and carboplatin: Coverage will be provided for up to a maximum of 12 weeks of therapy (12 doses) and may not be renewed.

c. Non-Small Cell Lung Cancer (NSCLC) in combination with atezolizumab and carboplatin: Coverage will be provided for up to a maximum of 18 weeks of therapy (18 doses) and may not be renewed.

d. Neoadjuvant therapy for Ampullary Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

e. Neoadjuvant therapy for Gallbladder cancer: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

f. Neoadjuvant and induction therapy in combination with gemcitabine for Pancreatic Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

B. Anti-PD-1 Monoclonal Antibodies

Therapeutic Class: Anti-PD-1 Monoclonal Antibodies
Last Reviewed by the DUR Board: January 16, 2025

Anti-PD-1 Monoclonal Antibodies are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Bavencio® (avelumab)

   a. Coverage is provided in the following conditions:

      1. Recipient is at least 18 years of age, unless otherwise indicated; and

      2. Universal Criteria

         a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab, nivolumab/relatlimab-rmbw, retifanlimab, tislelizumab, toripalimab, etc.), unless otherwise specified; and

      3. Merkel Cell Carcinoma (MCC)

         a. Recipient is at least 12 years of age; and

         b. Used as single-agent therapy; and

            1. Recipient has primary locally advanced disease; and

               a. Both curative surgery and curative radiation therapy are not feasible; or

               b. Recipient has had disease progression on neoadjuvant nivolumab therapy; or

            2. Recipient has metastatic disease.

            3. Recipient has recurrent locally advanced or recurrent regional disease; and

               a. Both curative surgery and curative radiation therapy are not feasible.

      4. Urothelial Carcinoma (Bladder Cancer).

         a. Used as single-agent therapy; and

1. Recipient has one of the following diagnoses:

   a. Locally advanced or metastatic urothelial carcinoma

   b. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent

   c. Metastatic or local bladder cancer recurrence post cystectomy treated with curative intent

   d. Metastatic upper genitourinary (GU) tract tumors

   e. Metastatic urothelial carcinoma of the prostate

   f. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes); and

2. Used for disease that progressed during or following platinum-containing chemotherapy; or

3. Used as second-line treatment after chemotherapy other than a platinum; or

b. Used for first-line maintenance treatment; and

1. Recipient has locally advanced or metastatic urothelial carcinoma (inclusive of bladder, upper GU tract, urethra, and/or prostate cancer); and

2. Recipient has not progressed with first-line platinum-containing chemotherapy.

5. Renal Cell Carcinoma (RCC)

a. Used in combination with axitinib; and

b. Used as first-line therapy; and

c. Used for the treatment of advanced, relapsed, or stage IV disease and clear cell histology. When used as a first-line therapy for stage IV disease, disease must be M1 or unresectable T4, M0.

6. Gestational Trophoblastic Neoplasia

a. Used a single-agent therapy for multiagent chemotherapy-resistant

disease; and

1. Recipient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); and

   a. Recipient has recurrent or progressive disease; or

2. Recipient has high-risk disease (i.e., prognostic score ≥7 or International Federation of Gynecology and Obstetrics (FIGO) stage IV disease).

7. Endometrial Carcinoma (Uterine Neoplasms)

   a. Used as single-agent therapy; and

   b. Recipient has recurrent disease; and

   c. Used as subsequent therapy treatment for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

8. Extranodal NK.T-Cell Lymphomas

   a. Used as a single agent; and

   b. Used for relapsed or refractory disease following additional therapy with an alternate asparaginase-based combination chemotherapy regimen not previously used; and

   c. Participation in a clinical trial is unavailable

9. Thymic Carcinoma

   a. Used in combination with axitinib; and

      1. Recipient is unable to tolerate first-line combination regimens; and

         a. Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; or

         b. Used as postoperative systemic therapy after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; or

         c. Used as first-line therapy for recurrent, advanced, or metastatic disease; or

2. Used as second-line therapy; and

a. Recipient has unresectable or metastatic disease.

b. Dosing Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. 80 billable units (800 mg) every 14 days (all indications)

c. Recertification Request

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in section III; and

2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity/hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

d. PA Guidelines:

1. Coverage will be provided for six months and may be renewed.

2. Imfinzi® (durvalumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

b. Universal Criteria

1. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)- directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified; and

2. NSCLC

a. Recipient has unresectable stage II-III disease; and

1. Recipient has a PS of 0-1; and

2. Used as a single agent as consolidation therapy; and

3. Disease has not progressed after definitive concurrent or sequential chemoradiation; or

b. Used as neoadjuvant therapy; and

1. Recipient has resectable disease (tumors ≥4 cm or node positive); and

2. Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; and

3. Recipient has no known EGFR mutations or ALK rearrangements; or

4. Used adjuvant therapy; and

5. Used as a single agent following previous neoadjuvant durvalumab plus chemotherapy and surgery; and

6. Recipient has no known EGFR mutations of ALK rearrangements; or

c. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy; and

a. Used for one of the following:

1. Recipients with tumors that are negative for actionable molecular biomarkers and PD-L1 ≥1% to 49%

2. Recipients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 <1%

3. Recipients with PS of 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14

skipping, RET rearrangement, or ERBB2 (HER2); and

b. Used in combination with tremelimumab albumin-bound paclitaxel and carboplatin; or

c. Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

d. Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; or

2. Used as subsequent therapy; and

a. Used for one of the following:

1. Recipient with PS of 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement

2. Recipient with PS of 0-1 who are positive for one of the following molecular biomarkers and received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; and

b. Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; or

c. Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

d. Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; or

3. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy; and

a. Used as a single agent following a first-line regimen with durvalumab and tremelimumab plus chemotherapy; or

b. Used in combination with pemetrexed following a first-line regimen with durvalumab, tremelimumab, pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology.

4. Small Cell Lung Cancer (SCLC)

a. Recipient has extensive stage SCLC (ES-SCLC); and

1. Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; or

2. Used as single-agent maintenance therapy after initial therapy with etoposide and either carboplatin or cisplatin; or

b. Recipient has limited stage disease; and

1. Used as a single agent therapy; and

2. Used as adjuvant consolidation therapy; and

a. Disease has not progressed after systemic therapy with concurrent radiation therapy; and

b. Recipient has good PS and is medically inoperable or decision was made not to pursue surgical resection; or

3. Used if disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

5. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

a. Used in combination with cisplatin and gemcitabine; and

1. Used as primary treatment for unresectable, R2, locally advanced, or metastatic disease; or

2. Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant therapy; or

3. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; or

4. Used as neoadjuvant therapy for resectable locoregionally advanced disease (Note: Only applies to Gallbladder Cancer); and

a. Recipient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; or

b. Recipient has incidental finding on pathologic review (cystic duct node positive); or

c. Recipient has mass on imaging.

6. Hepatocellular Carcinoma (HCC)

a. Used a first-line therapy in combination with tremelimumab; and

1. Recipient has unresectable disease; or

2. Recipient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy;

b. Used as first-line therapy as a single agent; and

1. Recipient has liver-confined, unresectable disease and is deemed ineligible for transplant; or

2. Recipient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy.

7. Ampullary Adenocarcinoma

a. Used as first-line therapy in combination with gemcitabine and cisplatin; and

b. Recipient has good PS (e.g., ECOG 0-1, with good biliary drainage and adequate nutritional intake); and

c. Recipient has pancreatobiliary or mixed type disease; and

1. Recipient has unresectable localized disease; or

2. Recipient has stage IV resected ampullary cancer; or

3. Recipient has metastatic disease at initial presentation.

8. Cervical Cancer

a. Recipient has small cell NECC; and

1. Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; and

a. Used in combination with etoposide and either cisplatin or carboplatin; or

b. Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin.

9. Esophageal Cancer and Esophagogastric Junction Cancers

a. Used as neoadjuvant therapy in combination with tremelimumab; and

b. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or Clinical Laboratory Improvement Act (CLIA)-compliant test; and

c. Recipient has adenocarcinoma; and

d. Used as primary treatment for recipients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease.

10. Gastric Cancer

a. Used as neoadjuvant therapy in combination with tremelimumab; and

b. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

c. Recipient has adenocarcinoma; and

d. Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in recipients who are medically fit for surgery.

11. Endometrial Cancer

a. Recipient has primary advanced or recurrent disease; and

b. Recipient has dMMR disease; and

1. Used in combination with carboplatin and paclitaxel; or

2. Used as single agent maintenance therapy after initial therapy with durvalumab, carboplatin, and paclitaxel.

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. NSCLC, SCLC: 672 billable units (6,720 mg) every 84 days.

b. Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: 150 billable units (1,500 mg) every 28 days for three doses

c. Biliary Tract Cancer: 150 billable units (1,500 mg) every 21 days x eight doses, then 150 billable units (1,500 mg) every 28 days

d. HCC: 150 billable units (1,500 mg) every 28 days

e. Cervical Cancer: 150 billable units (1,500 mg) every 21 days x four doses, then 150 billable units (1,500 mg) every 28 days

f. Endometrial Cancer: 112 billable units (1,120 mg) every 21 days x six doses, then 150 billable units (1,500 mg) every 28 days

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe or life-threatening infusion-related reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, pancreatitis, etc.), complications of allogeneic HCST, etc.; and

5. Continuation Maintenance Therapy for NSCLC

a. Refer to Section III for criteria.

6. HCC

a. Cases for recipients with HCC who use treatment as part of STRIDE and experience disease progression but who are clinically stable and still deriving clinical benefit will be reviewed on a case-by-case basis.

7. Continuation Maintenance Therapy for ES-SCLC

a. Refer to Section III for criteria.

8. Continuation Maintenance Therapy for Cervical Cancer

a. Refer to Section II for Criteria

9. Continuation Maintenance Therapy for Endometrial Cancer

a. Refer to Section II for Criteria

d. PA Guidelines:

1. Coverage will be provided for six months and may be renewed (unless otherwise specified).

a. Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: Coverage will be provided for three doses

b. NSCLC (single agent use as consolidation therapy): Coverage will be provided for six months and may be renewed up to a maximum of 12 months of therapy.

c. NSCLC (resectable disease): Coverage will be provided for a maximum of 12 weeks of neoadjuvant therapy and 48 weeks of adjuvant therapy.

d. SCLC (limited stage disease): Coverage will be provided for six months and may be renewed up to a maximum of 24 months of therapy.

3. Libtayo® (cemiplimab-rwlc)

a. Coverage is provided for the following conditions:

1. Recipient is at least 18 years of age; and

2. Universal Criteria

   a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, tislelizumab, toripalimab, etc.), unless otherwise specified; and

3. Anal Carcinoma

   a. Recipient has metastatic squamous cell carcinoma (SCC); and

   b. Used as a single agent as subsequent therapy

4. Cutaneous Squamous Cell Carcinoma (cSCC)

   a. Used as a single agent; and

      1. Recipient has metastatic, locally advanced, or recurrent disease; and

         a. Recipient is not a candidate for curative surgery or curative radiation therapy; or

      2. Used as neoadjuvant therapy; and

         a. Recipient has borderline resectable disease, unresectable disease, or surgery may carry a high morbidity; or

         b. Used for one of the following:

            1. Tumor has very rapid growth

            2. In-transit metastasis

            3. Lymphovascular invasion

            4. Surgery alone may not be curative or may result in significant functional limitation; and

         c. Recipient has very high-risk disease; or

         d. Recipient has locally advanced disease.

5. Cervical Cancer

a. Used as a single agent as subsequent therapy; and

b. Recipient has recurrent or metastatic disease.

6. Basal Cell Carcinoma (BCC)

a. Used as a single agent; and

1. Recipient has locally advanced or metastatic disease; or

2. Recipient has nodal disease and surgery is not feasible.

7. NSCLC

a. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used in combination with platinum-based chemotherapy (e.g., paclitaxel and either carboplatin or cisplatin, or pemetrexed and either carboplatin or cisplatin); and

a. Used as first-line therapy for one of the following:

1. Recipients with a PS 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression <1%

2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)

3. PD-L1 expression-positive (PD-L1 ≥1%) tumors that are negative for actionable molecular biomarkers; or

b. Used as subsequent therapy for one of the following:

1. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement

2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

2. Used in combination with pemetrexed; and

a. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease after first-line therapy with cemiplimab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; or

3. Used as a single agent; and

a. Recipient has tumors that are negative for actionable molecular biomarkers and high PD-L1 expression (Tumor Proportion Score [TPS] ≥50%) as determined by an FDA-approved or CLIA compliant test; and

1. Used as first-line therapy; or

2. Used as continuation maintenance therapy in recipients who achieved a tumor response or stable disease after first-line therapy with cemiplimab as monotherapy or as part of combination therapy; or

b. Recipient has tumors with PD-L1 expression <1% or ≥1%-49%; and

1. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy with cemiplimab combination therapy.

8. Small Bowel Adenocarcinoma

a. Used as a single agent treatment; and

b. Recipient has microsatellite instability-high (MSI/H)/mismatch repair deficient (dMMR) disease or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mutations/megabase

(mut/Mb)] as determined by an FDA-approved or CLIA-compliant test; and

1. Recipient has advanced or metastatic disease; or

2. Recipient has locally unresectable or medically inoperable disease; and

a. Used as primary treatment.

9. Vaginal Cancer

a. Used as a single agent as subsequent therapy; and

b. Recipient has recurrent or metastatic therapy; and

10. Vulvar Cancer

a. Used as a single agent as subsequent therapy; and

b. Recipient has advanced or recurrent/metastatic disease

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. 350 billable units (350 mg) every 21 days.

c. Recertification Request

Coverage may be renewed based on the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, etc.), complications of allogeneic HSCT, etc.; and

4. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

a. NSCLC (continuation maintenance therapy):

1. Refer to Section III for criteria

d. PA Guidelines

Coverage will be provided for six months and may be renewed, unless otherwise specified.

1. Neoadjuvant therapy in cSCC can be authorized up to a maximum of four doses and cannot be renewed.

2. Treatment for metastatic, locally advanced, or recurrent cSCC, and BCC can be renewed up to a maximum of 24 months of therapy (35 doses).

3. Treatment for recurrent or metastatic Cervical Cancer, recurrent or metastatic Vaginal Cancer and advanced, recurrent, or metastatic Vulvar Cancer can be authorized up to a maximum of 96 weeks of therapy (32 doses)

4. Ocrevus® (ocrelizumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

2. Recipient has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and does not have active disease (i.e., positive hepatitis B surface antigen (HBsAg) and anti-HBV tests); and

3. Recipient has had baseline serum immunoglobulins assessed; and

4. Recipient does not have a history of life-threatening administration reactions to ocrelizumab.

5. Universal Criteria

a. Recipient will not receive live or live-attenuated vaccines while on therapy or within four weeks prior to the initiation of treatment; and

b. Recipient does not have an active infection; and

c. Must be used as single agent therapy; and

d. Recipient has not received a dose of ocrelizumab or ublituximab within the past five months; and

6. Multiple Sclerosis (MS)

a. Recipient must have a confirmed diagnosis of MS as documented by laboratory report (i.e., magnetic resonance imaging (MRI)); and

1. Recipient has diagnosis of relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS); or

2. Recipient has a diagnosis of primary progressive MS (PPMS); and

a. Recipient is <65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of ≤6.5.

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. Initial Dose

1. 300 billable units (300 mg) on day one and day 15.

b. Subsequent Doses

1. 600 billable units (600 mg) every six months.

c. Recertification Request

Coverage can be renewed based on the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy malignancy, hypogammaglobulinemia, immune-mediated colitis, etc.; and

3. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, timed 25-foot walk (T25-FW), nine-hole peg test (9-HPT].

a. Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥1 relapse, ≥2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

4. PPMS

a. Recipient continues to be ambulatory, defined as an EDSS score of <7.5.

d. PA Guidelines

1. Coverage will be provided for 12 months and may be renewed annually thereafter.

5. Opdivo® (nivolumab)

a. Coverage is provided for the following conditions:

1. Recipient is at least 18 years of age (unless otherwise specified); and

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, tislelizumab, toripalimab, etc.), unless otherwise specified; and

3. Ampullary Adenocarcinoma

a. Recipient's disease is MSI-H or dMMR disease as determined by an FDA approved or CLIA-compliant test; and

b. Used in combination with ipilimumab; and

1. Used as first-line therapy for unresectable or metastatic intestinal type disease; or

2. Used as subsequent therapy for disease progression.

4. Anal Carcinoma

a. Recipient has metastatic squamous cell disease; and

b. Used as a single agent for subsequent therapy.

5. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

   a. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

   b. Used in combination with ipilimumab; and

      1. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

         a. Disease is refractory to standard therapies or there are no standard treatment options available.

      2. Used as neoadjuvant therapy for resectable locoregionally advanced disease (Note: Only applies to Gallbladder Cancer); and

         a. Recipient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; or

         b. Recipient has incidental finding on pathologic review (cystic duct nod positive); or

         c. Recipient has mass on imaging.

6. Urothelial Carcinoma (Bladder Cancer)

   a. Used as a single agent; and

      1. Used for disease that progressed during or following platinum-containing chemotherapy or as a second-line treatment after chemotherapy other than a platinum; and

         a. Recipient has one of the following diagnoses:

            1. Locally advanced or metastatic urothelial carcinoma

            2. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder

            3. Metastatic or local bladder cancer recurrence post-cystectomy

4. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)

5. Metastatic upper GU tract tumors

6. Metastatic urothelial carcinoma of the prostate; or

2. Used as adjuvant therapy; and

a. Recipient has urothelial carcinoma of the bladder, bulbar urethra, prostate with stromal invasion, ureter, or renal pelvis; and

b. Recipient underwent radical surgical resection; and

c. Recipient is at high risk for disease recurrence; or

b. Used in combination with cisplatin and gemcitabine followed by nivolumab maintenance therapy; and

1. Used as first-line systemic therapy in cisplatin eligible recipient; and

a. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma

2. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder

3. Metastatic or local bladder cancer recurrence post-cystectomy

4. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)

5. Metastatic upper GU tract tumors

6. Metastatic urothelial carcinoma of the prostate.

7. Bone Cancers

   a. Recipient has one of the following: Ewing sarcoma, chondrosarcoma (excluding mesenchymal chondrosarcoma), osteosarcoma, or chordoma; and

   b. Recipient has TMB-H tumors [≥10 mut/Mb] as determined by an FDA-approved or CLIA-compliant test; and

   c. Used in combination with ipilimumab; and

   d. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

   e. Recipient has no satisfactory alternative treatment options.

8. Adult Central Nervous System (CNS) Cancers

   a. Used in one of the following treatment settings:

      1. Used as initial treatment in recipients with small asymptomatic brain metastases

      2. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options

      3. Used for recurrent limited brain metastases

      4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; and

   b. Used as a single-agent or in combination with ipilimumab for the treatment of brain metastases in recipients with BRAF non-specific melanoma; or

   c. Used as a single-agent for the treatment of brain metastases in recipients with PD-L1 (TPS ≥1%) positive NSCLC.

9. Pediatric CNS Cancers

   a. Recipient is ≤18 years of age; and

   b. Recipient has hypermutated diffuse high-grade glioma; and

      1. Used for recurrent or progressive disease as a single agent (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); or

2. Used as adjuvant therapy (excluding diffuse midline glioma, H3 K27-altered or pontine location); and

a. Recipient is <3 years of age and used as a single agent; or

b. Recipient is ≥3 years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide.

10. Cervical Cancer

a. Used as subsequent therapy as a single agent; and

b. Recipient has recurrent, or metastatic disease; and

c. Tumor expressed PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test.

11. Colorectal Cancer (CRC)

a. Recipient is at least 12 years of age; and

b. Recipient's disease is MSI-H/dMMR disease or POLE/POLD1 mutation as determined by an FDA-approved or CLIA-compliant test; and

c. Used in combination with ipilimumab (if candidate for intensive therapy) or as a single agent; and

1. Used as subsequent therapy and

a. Recipient has metastatic, unresectable, or medically inoperable disease; or

2. Used as primary or initial treatment; and

a. Used for isolated pelvic/anastomotic recurrence of rectal cancer; or

b. Recipient has metastatic, unresectable, or medically inoperable disease; or

3. Used as neoadjuvant therapy; and

a. Recipient has clinical T4b colon cancer (for dMMR/MSI-H disease only); or

b. Recipient has resectable liver and/or lung metastases; or

c. Recipient has T3, N Any; T1-2. N1-2; T4, N Any locally unresectable, or medically inoperable rectal cancer (single agent therapy for dMMR/MSI-H disease only).

12. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation as determined by an FDA-approved or CLIA-compliant test; and

b. Used in combination with ipilimumab (if candidate for intensive therapy) or as a single agent or; and

c. Recipient has advanced or metastatic disease.

13. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

a. Used as first-line therapy; and

1. Recipient has squamous cell carcinoma (SCC); and

a. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; and

1. Used in combination with ipilimumab; or

2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Recipient has adenocarcinoma; and

1. Recipient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; and

a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Used in combination with ipilimumab; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy; and

1. Recipient has SCC; and

a. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; and

1. Used as a single agent; or

2. Used in combination with ipilimumab; and

3. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

2. Recipient has adenocarcinoma; and

a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

b. Used in combination with ipilimumab; and

c. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

c. Used as adjuvant treatment of completely resected disease; and

1. Used as a single agent in recipient with residual disease following neoadjuvant chemoradiotherapy (CRT).

d. Used as neoadjuvant or perioperative therapy; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

2. Recipient has adenocarcinoma; and

a. Used in combination with ipilimumab; and

1. Used as primary treatment for recipients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; or

b. Used as a single agent; and

1. Used as postoperative management following R0 resection in recipients who have received preoperative therapy with nivolumab and ipilimumab; or

e. Used as induction systemic therapy for relieving dysphagia; and

1. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; and

a. Used in combination with ipilimumab; and

1. Recipient has SCC; or

2. Recipient has adenocarcinoma

a. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and

1. Recipient has SCC; or

2. Recipient has adenocarcinoma; and

a. Tumor expresses PD-L1 (e.g., CPS ≥5) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test.

14. Gastric Cancer

a. Used as first-line therapy; and

1. Recipient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; and

a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Used in combination with ipilimumab; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy; and

1. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

2. Used in combination with ipilimumab; and

3. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

c. Used as neoadjuvant or perioperative therapy; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

a. Used in combination with ipilimumab; and

1. Used as primary treatment prior to surgery for potentially resectable locoregional disease (cT2 or higher, any N) in recipient who are medically fit for surgery; or

b. Used as a single agent; and

1. Used as postoperative management following R0 resection in recipients who have received preoperative therapy with nivolumab and ipilimumab; or

d. Used as systemic therapy for early-stage disease; and

1. Recipient has endoscopic features suggestive of deep submucosal invasion including converging folds, irregular

surface pattern, and ulceration in a large gastric mass with favorable histology; and

2. Recipient has completed an endoscopic resection; and

a. Used in combination with ipilimumab; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used in combination with oxaliplatin and fluorouracil or capecitabine; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

2. Tumor expresses PD-L1 (e.g., CPS ≥5) as determined by an FDA-approved or CLIA-compliant test.

15. Gestational Trophoblastic Neoplasia

a. Used as single-agent or in combination with ipilimumab; and

b. Recipient has multiagent chemotherapy-resistant disease; and

1. Recipient has intermediate PSTT or ETT; and

a. Recipient has recurrent or progressive disease; and

2. Recipient has high risk disease (i.e., ≥7 Prognostic score or stage IV disease).

16. Squamous Cell Carcinoma of the Head and Neck (SCCHN)

a. Recipient has Cancer of the Nasopharynx; and

1. Used in combination with cisplatin and gemcitabine for oligometastatic or metastatic disease; or

b. Recipient has very advanced Head and Neck Cancer; and

1. Recipient has nasopharyngeal cancer; and

a. Used in combination with cisplatin and gemcitabine for recipients with PS 0-1; and

b. Used for one of the following:

1. Unresectable locoregional recurrence with prior RT

2. Unresectable second primary with prior RT

3. Unresectable persistent disease with prior RT

4. Recurrent/persistent disease with distant metastases; or

2. Recipient has non-nasopharyngeal cancer; and

a. Used as a single agent; and

1. Recipient has unresectable, recurrent, persistent, or metastatic disease; and

2. Disease has progressed on or after platinum-containing chemotherapy.

b. Used in combination with cetuximab for recipients with PS 0-1; and

1. Used for one of the following:

a. Metastatic disease at initial presentation

b. Recurrent/persistent disease with distant metastases

c. Unresectable locoregional recurrence with prior RT

d. Unresectable second primary with prior RT

e. Unresectable persistent disease with prior RT.

17. HCC

a. Used as subsequent therapy; and

b. Used as a single agent or in combination with ipilimumab; and

c. Used for one of the following:

1. Recipient was previously treated with sorafenib (for use in combination with ipilimumab only)

2. Recipient has liver confined, unresectable disease and deemed ineligible for transplant

3. Recipient has extrahepatic/metastatic disease and deemed ineligible for resection, transplant, or locoregional therapy.

18. Adult Classical Hodgkin Lymphoma (cHL)

a. Used as a single agent; and

1. Recipient has relapsed or progressive disease after autologous HSCT and brentuximab vedotin; or

2. Used for disease that is refractory to at least three prior lines of therapy; or

3. Used as palliative therapy in recipient >60 years of age or with poor PS or with substantial comorbidities; and

a. Recipient has relapsed or refractory disease; or

b. Used in combination with brentuximab vedotin or ifosfamide, carboplatin, etoposide (ICE) in recipients 18 to 60 years of age; and

1. Used as second-line therapy for relapsed or refractory disease; or

2. Used as subsequent therapy (if not previously used) for relapse or refractory disease; and

a. Recipient has a Deauville scale score of 4 or 5 following restaging with fluorodeoxyglucose (FDG)-positron emission tomography (PET)/ computed tomography (CT); or

c. Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD); and

1. Used as primary treatment for stage III-IV disease.

19. Pediatric cHL

a. Recipient is ≤18 years of age; and

1. Used as primary treatment for intermediate or high-risk stage III-IV disease; and

a. Used in combination with AVD (applies to recipients ≥12 years of age only); or

b. Recipient has relapsed or refractory disease; and

c. Used in recipients heavily pretreated with platinum or anthracycline-based chemotherapy or if a decrease in cardiac function was observed; and

1. Used as subsequent therapy (if not previously used); and

a. Used as a single agent or in combination with brentuximab vedotin; or

2. Used as re-induction therapy; and

a. Used in combination with brentuximab vedotin; or

b. Used in combination with brentuximab vedotin and radiation therapy (ISRT) in highly favorable recipients who may avoid autologous stem cell rescue (ASCR) (i.e., initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 >1 year, absence of extranodal disease or B symptoms at relapse).

20. Kaposi Sarcoma

a. Used as a single agent or in combination with ipilimumab; and

b. Used as subsequent therapy; and

c. Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

d. Disease has progressed on or not responded to first-line therapy; and

e. Disease has progressed on alternate first-line therapy

21. RCC

a. Used in combination with ipilimumab; and

1. Recipient has clear cell histology; and

a. Used as first-line therapy in recipients with poor or intermediate risk advanced, relapsed, or stage IV disease; or

b. Used as first-line therapy in recipients with favorable risk relapsed or stage IV disease; or

c. Used as subsequent therapy in recipients with relapsed or stage IV disease; or

b. Used as a single agent; and

1. Used as subsequent therapy in recipients with advanced, relapsed, or stage IV disease and clear cell histology; or

2. Recipient has relapsed or stage IV disease and non-clear cell histology; or

c. Used in combination with cabozantinib (Cabometyx® only); and

1. Recipient has clear cell histology; and

a. Used as first-line therapy for advanced, relapsed, or stage IV disease; or

b. Used as subsequent therapy in recipients with relapsed or stage IV disease; or

2. Recipient has non-clear cell histology; and

a. Recipient has relapsed or stage IV disease; or

b. Recipient has hereditary leiomyomatosis and renal cell carcinoma (HLRCC)

22. Cutaneous Melanoma

a. Used as first-line therapy for unresectable or metastatic disease; and

1. Recipient is at least 12 years of age; and

2. Used as a single agent or in combination with ipilimumab; or

b. Used as subsequent therapy for unresectable or metastatic disease; and

1. Recipient is at least 12 years of age; and

a. Used a re-induction therapy in recipients who experienced disease control (i.e., complete or partial response or stable disease) and no residual toxicity from prior anti-PD-1 immunotherapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; and

1. Used as a single agent or in combination with ipilimumab; or

b. Used after disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/ trametinib, vemurafenib/ cobimetinib, encorafenib/ binimetinib, etc.); and

1. Used as a single agent or in combination with ipilimumab if anti-PD-1 was not previously used; or

2. Used in combination with ipilimumab for disease progression on single agent anti-PD-1 therapy; or

c. Used as adjuvant treatment; and

1. Used as a single agent; and

a. Recipient is at least 12 years of age; and

b. Recipient has stage IIB, stage IIC, or metastatic disease and has undergone complete resection; or

c. Recipient has stage III disease; and

1. Recipient has undergone complete resection; or

2. Recipient has resected sentinel node positive disease during radiographic surveillance or after complete lymph node dissection (CLND); or

3. Recipient has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND); or

4. Recipient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision to clear margins; or

5. Used following wide excision alone or wide excision with negative sentinel lymph node biopsy (stage IIIB/C/D disease only); or

6. Used following wide excision with negative sentinel lymph node biopsy; or

7. Used for disease that is sentinel lymph node negative or sentinel lymph node biopsy not performed (stage IIIB/C/D disease only); or

d. Recipient has local satellite/in-transit recurrence and has NED after complete excision; or

e. Recipient has resectable disease limited to nodal recurrence following excision and complete TLND or following neoadjuvant therapy; or

f. Recipient has oligometastatic disease and NED following metastasis-directed therapy (i.e., talimogene laherparepvec (T-VEC)/intralesional therapy, stereotactic ablative therapy or complete resection) or systemic therapy followed by resection; or

g. Used in combination with ipilimumab; and

1. Recipient has oligometastatic disease and no evidence of disease following metastasis- directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or systemic therapy followed by resection; or

h. Used as neoadjuvant therapy; and

i. Used as a single agent or in combination with ipilimumab; and

1. Recipient has stage III disease; and

a. Used as a primary treatment for clinically positive, resectable nodal disease; or

b. Used for limited resectable disease with clinical satellite/in-transit metastases; or

j. Recipient has limited resectable local satellite/in-transit recurrence; or

k. Recipient has resectable disease limited to nodal recurrence.

23. Uveal Melanoma

a. Recipient has distant metastatic or resectable disease; and

b. Used as a single agent or in combination with ipilimumab.

24. Merkel Cell Carcinoma

a. Used as neoadjuvant treatment; and

1. Used as a single agent; and

a. Recipient is a surgical candidate with primary clinical N0 locally advanced disease where curative surgery and curative radiation therapy were originally deemed not feasible; or

b. Recipient has primary clinical N+, M0 regional disease with biopsy positive draining nodal basin; or

b. Used for M1 disseminated disease; and

1. Used as a single agent; or

2. Used in combination with ipilimumab; and

a. Recipient progressed on anti-PD-L1 or anti-PD-1 therapy or anti-PD-L1 or anti-PD-1 therapy is contraindicated.

25. Peritoneal Mesothelioma (PeM)

a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); or

b. Used in combination with ipilimumab as first-line therapy; and

1. Used as adjuvant treatment for medically operable disease following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); and

    a. Recipient has surgical or pathologic high-risk features; or

2. Recipient has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features; or

3. Recipient has disease progression following CRS and HIPEC if no prior adjuvant systemic therapy was given.

26. Pleural Mesothelioma (PM)

    a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); or

    b. Used in combination with ipilimumab; and

        1. Used as first-line therapy; or

        2. Used as induction therapy prior to surgical exploration; and

            a. Recipient has clinical stage I disease and epithelioid histology

27. NSCLC

    a. Recipient has resectable (tumors ≥4 cm or node positive) disease; and

        1. Recipient has no known EGFR mutations or ALK rearrangements; and

        2. Used as neoadjuvant therapy in combination with platinum-doublet chemotherapy (e.g., cisplatin/carboplatin in combination with paclitaxel, pemetrexed, or gemcitabine) with the option of continuing single agent nivolumab as adjuvant treatment after surgery; or

    b. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy; and

   a. Used for one of the following:

      1. Recipients with a PS 0-1 who have tumors that are negative for actionable molecular biomarkers; and PD-L1 expression <1%

      2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)

      3. PD-L1 expression-positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

   b. Used in combination with one of the following:

      1. Used in combination with ipilimumab; or

      2. Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); or

c. Used as subsequent therapy; and

   1. Used as a single agent; or

   2. Used for one of the following:

      a. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement

      b. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; and

d. Used in combination with ipilimumab; or

e. Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

f. Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; or

g. Used as continuation maintenance therapy in combination with ipilimumab; and

1. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.

28. Pediatric Aggressive Mature B-Cell Lymphomas – Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

a. Recipient is ≤18 years of age; and

1. Used in combination with brentuximab vedotin; and

a. Used as consolidation/additional therapy if a partial response was achieved after therapy for relapsed or refractory disease; or

2. Used as a single agent for relapsed or refractory disease

29. Small Bowel Adenocarcinoma

a. Used as a single agent or in combination with ipilimumab; and

b. Recipient has MSI-H or dMMR or POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., TMB >50 mut/Mb] as determined by an FDA- approved or CLIA-compliant test; and

c. Recipient has advanced or metastatic disease; or

d. Recipient has locally unresectable or medically inoperable disease; and

1. Used as primary treatment.

30. SCLC

a. Used as subsequent systemic therapy as a single agent; and

b. There has been a chemotherapy-free interval of ≤6 months; and

1. Recipient has relapsed disease following a complete or partial response or stable disease after primary treatment; or

2. Recipient has primary progressive disease.

31. Soft Tissue Sarcoma (STS)

a. Extremity/Body Wall or Head/Neck

1. Used as a single agent or in combination with ipilimumab; and

2. Used as subsequent therapy for advanced/metastatic disease with disseminated metastases; and

a. Recipient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; or

b. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

1. Recipient has no satisfactory alternative treatment options

b. Retroperitoneal/Intra-Abdominal

1. Used in a single agent or in combination with ipilimumab; and

2. Used as one of the following:

a. Alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease; or

b. Palliative subsequent therapy for stage IV disease with disseminated metastases; and

3. Used for one of the following:

a. Recipient has myxofibrosarcoma, UPS, dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; or

b. Recipient has TMB-H [ >10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

1. Recipient has no satisfactory alternative treatment options.

c. Pleomorphic Rhabdomyosarcoma

1. Used as a single agent or in combination with ipilimumab; and

2. Used as subsequent therapy; and

d. Angiosarcoma

1. Used in combination with ipilimumab.

32. Extranodal NK/T-Cell Lymphomas

a. Used as a single agent for relapsed or refractory disease; and

b. Used following additional therapy with an alternative asparaginase-based chemotherapy regimen not previously used; and

c. Participation in a clinical trial is unavailable.

33. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as a single agent; and

b. Used as second-line therapy for recurrent disease; and

c. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test.

34. Vulvar Cancer

a. Used as single agent; and

b. Recipient has adenocarcinoma or SCC; and

c. Used as subsequent therapy for HPV-related advanced, recurrent, or metastatic disease.

35. Thyroid Carcinoma

a. Used as a single agent; and

b. Used for stage IVC (metastatic) anaplastic carcinoma.

36. Vaginal Cancer

a. Used as subsequent therapy as single agent; and

b. Recipient has recurrent or metastatic disease; and

c. Tumor expresses PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test. Tumor expresses PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test

37. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

a. Recipient has histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL); and

b. Used as a single agent or in combination with ibrutinib; and

1. Recipient is positive for del(17p)/TP53 mutation; or

2. Recipient is chemotherapy refractory or unable to receive chemoimmunotherapy

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

Extranodal NK/T-Cell Lymphoma80 BU: 28 days

Biliary, Bone, cHL, Cutaneous Melanoma, Gastric, Gestational Trophoblastic Neoplasia (GTN), Head and Neck, HCC, Kaposi Sarcoma, RCC, STS, Thyroid Carcinoma, Vulvar Cancer, Vaginal Cancer, and Cervical Cancer1440 BU: 84 days

Uveal Melanoma 6960 BU: 84 days

Endometrial Carcinoma Initial 340 BU: 14 days x eight doses Maintenance 480 BU: 28 days

Ampullary Adenocarcinoma Initial 340 BU: 21 days Maintenance 680 BU: 28 days

Urothelial Carcinoma (Bladder Cancer) Initial 60 BU: 28 days

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisites therapy), performance status, etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, complications of allogeneic HSCT, severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis/hepatotoxicity, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), etc.; and

4. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

5. Cutaneous Melanoma (re-induction therapy)

   a. Refer to Section III for criteria (see Cutaneous Melanoma – Used for retreatment of disease as re-induction)

6. NSCLC (maintenance therapy)

   a. Refer to Section III for criteria.

d. PA Guidelines

Coverage will be provided for six months and may be renewed (unless otherwise specified)

1. Use in the treatment of cHL:

   a. Adult cHL in combination with brentuximab vedotin can be authorized up to a maximum of 24 weeks of therapy (84 doses) and may not be renewed; and

   b. Adult cHL in combination with ICE can be authorized up to a maximum of 12 weeks of therapy (six doses) and may not be renewed.

   c. Pediatric cHL in combination with brentuximab vedotin can be authorized up to a maximum of 24 weeks of therapy (84 doses) and may not be renewed.

d. Adult and Pediatric cHL in combination with doxorubicin, vinblastine, dacarbazine (AVD) can be authorized up to a maximum of 24 weeks of therapy (12 doses) and may not be renewed.

2. Neoadjuvant or Perioperative Therapy of MSI-H/dMMR, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancer can be authorized for a maximum of 12 weeks of pre-operative therapy (six doses), followed by a maximum of 36 weeks (nine doses) of postoperative therapy after surgery

3. Neoadjuvant or Perioperative Therapy of Gastric Cancer can be authorized for a maximum of 12 weeks of pre-operative therapy (six doses), followed by a maximum of 36 weeks (nine doses) of post-operative therapy after surgery.

4. Neoadjuvant treatment of MCC can be authorized up to a maximum of two doses and may not be renewed

5. Neoadjuvant treatment followed by optional adjuvant treatment of NSCLC may be authorized for a maximum of four neoadjuvant doses and 13 adjuvant doses.

6. Neoadjuvant treatment of Cutaneous Melanoma in combination with ipilimumab may be authorized for a maximum of two doses and may not be renewed.

7. Neoadjuvant treatment of Cutaneous Melanoma as a single agent may be authorized for a maximum of four doses and may not be renewed.

8. Adjuvant treatment of Cutaneous Melanoma in combination with ipilimumab may be authorized for a maximum of four doses and may not be renewed.

9. Neoadjuvant treatment of Gallbladder Cancer may be authorized up to a maximum of six months (1224 doses) and may not be renewed.

10. Adjuvant treatment of the following indications may be renewed up to a maximum of one year of therapy:

    a. Cutaneous Melanoma (single agent)

    b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

    c. Urothelial Carcinoma.

11. The following indications may be renewed up to a maximum of two years of therapy:

a. Biliary Tract Cancer

b. Bone Cancer

c. Cervical Cancer

d. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line therapy or induction therapy for relieving dysphagia)

e. MSI-H/dMMR, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer (first-line or subsequent therapy)

f. Gastric Cancer (first-line therapy, subsequent therapy, or early-stage disease following endoscopic resection)

g. Kaposi Sarcoma (in combination with ipilimumab)

h. RCC (in combination with cabozantinib)

i. PM (initial therapy in combination with ipilimumab)

j. PeM (initial therapy in combination with ipilimumab)

k. NSCLC (in combination with ipilimumab with or without platinum-doublet chemotherapy)

l. Vaginal Cancer

m. Vulvar Cancer

n. Urothelial Carcinoma (first-line systemic therapy in combination with gemcitabine and cisplatin, followed by nivolumab maintenance therapy).

6. Tecentriq® (atezolizumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age (unless otherwise specified); and

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1) = - directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified; and

b. Therapy will not be used concomitantly with subcutaneous atezolizumab; and

3. Non-Small Cell Lung Cancer (NSCLC)

a. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy; and

a. Used as a single agent; and

1. Recipients with PS 0-2 who have tumors that are negative for actionable molecular markers (may be KRAS G12C mutation positive) and PD-L1 ≥50% (PD-L1 stained ≥50% of tumor cells [TC ≥50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥10% of the tumor area [IC ≥10%]), as determined by an FDA-approved test or CLIA-compliant test; or

2. Recipients with PS 3 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) regardless of PD-L1 status; or

3. Recipients with PS 3 who have tumors positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, ERBB2 (HER2); or

b. Used in combination with one of the following:

1. Carboplatin, paclitaxel, and bevacizumab

2. Carboplatin and albumin-bound paclitaxel; and

c. Used for non-squamous disease; and

1. Recipients with PS 0-1 who have tumors that are negative for actionable molecular

markers (may be KRAS G12C mutation positive) and PD-L1 <1%; or

2. Recipients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression positive tumors (PD-L1 ≥1%); or

3. Recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); or

2. Used as subsequent therapy; and

a. Used as a single agent; and

1. Recipients with PS 0-2; or

2. Recipients with PS 3 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement; or

3. Recipients with PS 3 who are positive for one of the following molecular biomarkers and received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R, EGFR S768I, L861Q and/or G719X, ALK rearrangement, or ROS1 rearrangement; or

b. Used in combination with one of the following:

1. Carboplatin, paclitaxel, and bevacizumab;

2. Carboplatin and albumin-bound paclitaxel; and

c. Used for non-squamous disease; and

1. Recipients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

2. Recipients with PS 0-1 who are positive for one of the following molecular biomarkers and received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; or

3. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy; and

a. Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; or

b. Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; or

c. Used as a single agent following a first-line regimen with single agent atezolizumab; or

4. Used as adjuvant therapy as a single agent; and

a. Tumor expresses PD-L1 ≥1% as determined by an FDA-approved test or CLIA-compliant test; and

b. Used following resection and previous adjuvant chemotherapy; and

1. Recipient has stage II to IIIA disease; or

2. Recipient has stage IIIB (T3, N2) disease; and

a. Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements.

4. Small Cell Lung Cancer (SCLC)

a. Recipient has ES-SCLC; and

1. Used as first-line therapy in combination with etoposide and carboplatin; or

2. Used as single-agent maintenance therapy after initial therapy with atezolizumab, etoposide, and carboplatin.

5. Hepatocellular Carcinoma (HCC)

a. Used in combination with bevacizumab; and

1. Used as first-line therapy for unresectable or metastatic disease; or

2. Used as adjuvant therapy following resection or ablation; and

a. Recipient is at high risk of recurrence (defined as size >5 cm, >3 tumors, macrovascular invasion or micro vessel invasion on histology or grade 3/4 histology).

6. Peritoneal Mesothelioma (PeM)

a. Used as subsequent therapy in combination with bevacizumab.

7. Cutaneous Melanoma

a. Recipient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; and

b. Used in combination with cobimetinib and vemurafenib; and

c. Recipient has unresectable or metastatic disease; and

1. Used as first-line therapy; or

2. Used as subsequent therapy for disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; or

3. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy but subsequently have disease progression/relapse >3 months after treatment discontinuation.

8. Alveolar Soft Part Sarcoma (ASPS)

a. Recipient is at least two years of age; and

b. Used as a single agent; and

9. Cervical Cancer

a. Recipient has small cell neuroendocrine carcinoma of the cervix (NECC); and

1. Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; and

a. Used in combination with etoposide and either cisplatin or carboplatin.

2. Used as a single agent maintenance therapy after initial therapy with atezolizumab, etoposide, and either carboplatin or cisplatin.

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. PeM (including pericardial and tunica vaginalis testis mesothelioma): 120 billable units every 21 days.

b. All other indications:

1. 504 billable units every 84 days.

c. Recertification Request

Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis, including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)] myocarditis, pericarditis, vasculitis, solid organ transplant rejection etc.), severe infusion-related reactions, complications of allogeneic HSCT, etc.

5. Cutaneous Melanoma (re-induction therapy)

   a. Refer to Section III for criteria

6. Continuation Maintenance Therapy for NSCLC or SCLC

   a. Refer to Section III for criteria

7. Continuation Maintenance Therapy for Cervical Cancer

   a. Refer to Section III for criteria

d. PA Guidelines

1. Coverage will be provided for six months and may be renewed (unless otherwise specified).

2. Adjuvant therapy in NSCLC can be renewed up to a maximum of 12 months of therapy.

3. Adjuvant therapy in HCC can be renewed up to a maximum of 12 months of therapy.

C. Beovu® (brolucizumab-dbll)

Therapeutic Class: Ophthalmic-Macular Degeneration
Last Reviewed by the DUR Board: January 16, 2025

Beovu® (brolucizumab-dbll) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age; and

   b. Universal Criteria

      1. Recipient is free of ocular and/or peri-ocular infections; and

      2. Recipient does not have active intraocular inflammation; and

      3. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, ranibizumab, bevacizumab, faricimab, etc.); and

      4. Recipients best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; and

      5. Recipient has a definitive diagnosis of the following:

         a. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

         b. Diabetic Macular Edema (DME)

2. Dosing Limits

   a. Quantity Limit (max daily dose) [NDC Unit]

      1. Neovascular AMD:

         a. 6 mg single-dose vial or pre-filled syringe for injection: one vial/syringe per eye every 25 days for three doses initially, then one vial/syringe every eight weeks.

      2. DME

         a. 6 mg single-dose vial or pre-filled syringe for injection: one vial/syringe per eye every six weeks for five doses initially, then one vial/syringe every eight weeks.

      3. Neovascular AMD

a. MU for Initial Dosing

1. 12 billable units every 25 days x three doses.

b. MU for Maintenance Dosing

1. 12 billable units every 56-84 days.

4. DME

a. MU for Initial Dosing

1. 12 billable units every six weeks x five doses.

b. MU for Maintenance Dosing

1. 12 billable units every 56-84 days.

3. Recertification Request

Coverage can be renewed based upon the following criteria:

a. Recipient continues to meet the universal and indication-specific relevant criteria as identified in Section III; and

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity: endophthalmitis and retinal detachment, increase in intraocular pressure, arterial thromboembolic events, retinal vasculitis, and/or retinal vascular occlusion etc.; and

c. Continued administration is necessary for the maintenance treatment of the condition; and

d. Neovascular (Wet) AMD

1. Recipient has had a beneficial response to therapy (e.g., improvement in the BCVA, etc.); and

2. Decreasing the interval of maintenance doses from 12 weeks to eight weeks will be allowed if the recipient has received all three-loading doses and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 16:

a. Decrease in BCVA of ≥5 letters compared to baseline; or

b. Decrease in BCVA of ≥3 letters and central subfield thickness (CST) increase ≥75 microns compared with week 12; or

c. Decrease in BCVA of ≥5 letters due to neovascular AMD disease activity compared with week 12; or

d. New or worsening intra-retinal cysts or fluid compared with week 12.

e. DME

1. Recipient has had a beneficial response to therapy (e.g., improvement in BCVA from baseline, etc.); and

2. Decreasing the interval or maintenance doses from 12-weeks to eight-weeks will be allowed if the recipient has received all five loading doses and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 28:

a. Decrease in BCVA of ≥5 letters compared to baseline; and

b. Increase in central subfield thickness compared to baseline.

4. PA Guidelines:

a. Coverage will be provided annually and may be renewed.

D. Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™; Avzivi® (bevacizumab)

Therapeutic Class: ANP -Human Vascular Endothelial Growth Factor Inhib Rec-MC Antibody
Last Reviewed by the DUR Board: January 16, 2025

Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™; Avzivi®(bevacizumab) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age, unless otherwise specified; and

   b. Universal Criteria

      1. Recipient has no recent history of hemoptysis (i.e., the presence of ≥2.5mL of blood in sputum); and

      2. Recipient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; and

   c. Ampullary Adenocarcinoma

      1. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/ 5-FU or capecitabine) based regimen for intestinal type disease; and

         a. Used as first-line therapy for unresectable localized or metastatic disease or

         b. Used for disease progression.

   d. Adult CNS Cancers

      1. Used as single-agent symptomatic mass effect to radiation necrosis, brain edema; and

         a. Recipient has a diagnosis of one of the following CNS cancers

            1. Circumscribe Glioma

            2. Primary CNS Lymphoma

            3. Meningiomas

            4. Brain or Spine metastases

            5. Primary Spinal Cord Tumor

6. Medulloblastoma

7. Glioblastoma/Gliosarcoma

8. H3-mutated high-grade glioma/High-grade astrocytoma with piloid features (HGPA/ Pleomorphic xanthoastrocytoma (PXA) World Health Organization (WHO) Grade 3

9. IDH-mutant Astrocytoma (WHO Grade 2-4)

10. IDH-mutant, 1p19q co-deleted Oligodendroglioma (WHO Grade 2 or 3)

11. Intracranial or Spinal Ependymoma (excluding subependymoma); or

2. Used for recurrent disease or progressive disease; and

a. Recipient has a diagnosis of one of the following CNS cancers:

1. IDH-mutant, 1p19q co-deleted Oligodendroglioma (WHO Grade 3)

2. Glioblastoma/Gliosarcoma/H3-mutated high-grade glioma

3. IDH-mutant Astrocytoma (WHO Grade 3 or 4); and

b. Used as a single agent; or

c. Used in combination with carmustine, lomustine, or temozolomide; and

1. Recipient has failed bevacizumab monotherapy; or

d. Used as a single agent for Intracranial or Spinal Ependymoma (excluding subependymoma) after prior radiation therapy; or

e. Used in combination with temozolomide and irinotecan for Medulloblastoma (recurrent disease only); or

f. Used as a single agent for surgically inaccessible Meningioma when radiation is not possible; or

3. Used as single agent for Neurofibromatosis type 2 vestibular schwannomas with hearing loss.

e. Cervical Cancer

1. Disease has adenocarcinoma, adenosquamous, or SCC histology; and

    a. Recipient has recurrent, or metastatic disease; and

        1. Used in combination with paclitaxel and either cisplatin, carboplatin, or topotecan; or

        2. Used in combination with pembrolizumab, paclitaxel, and cisplatin or carboplatin; and

            a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test; or

        3. Used as a single agent as subsequent therapy; or

    b. Recipient has small cell NECC; and

        1. Recipient has persistent, recurrent, or metastatic disease; or

            a. Used in combination with paclitaxel and topotecan; or

            b. Used as a single agent as subsequent therapy.

f. Colorectal Cancer (CRC)

    1. Will not be used as part of adjuvant treatment; and

        a. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/ 5-FU or capecitabine) based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; and

            1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

            2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation and

                a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

        b. Used in combination with irinotecan based therapy as initial treatment for unresectable metastatic disease; and

            1. Recipient has pMMR/MSS disease; and

2. Recipient received previous FOLFOX or CAPOX within the past 12 months; or

c. Used in combination irinotecan as subsequent therapy for advanced metastatic disease; and

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

d. Used in combination with a fluoropyrimidine-irinotecan-or fluoropyrimidine-oxaliplatin-based regimen (not used first-line) as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab-containing regimen; or

e. Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease; and

1. Recipient progressed through all available regimens (e.g., oxaliplatin-based therapy, irinotecan-based therapy, fluoropyrimidine-based therapy, etc.); and

2. Recipient has pMMR/MSS disease; or

3. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

4. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

f. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; and

1. Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) based regimen; and

a. Used if resection is contraindicated following total neoadjuvant therapy; and

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

2. Used if resection is contraindicated following neoadjuvant/ definitive immunotherapy; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

g. Appendiceal Adenocarcinoma – Colon Cancer

1. Used as initial therapy for advanced or metastatic disease; and

a. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/ 5-FU or capecitabine) based regimen; or

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

2. Used as subsequent therapy for progression of advanced or metastatic disease; and

a. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/ 5-FU or capecitabine) or irinotecan-based regimen following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy; and

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

b. Used in combination with trifluridine and tipiracil and

1. Recipient progressed through all available regimens (e.g., oxaliplatin-based therapy, irinotecan-based therapy, therapy without irinotecan or oxaliplatin, etc.); and

a. Recipient has pMMR/MSS disease; or

b. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

1. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Recipient has recurrent disease; and

a. Used as a single agent; and

1. Used as subsequent therapy for disease that has progressed on prior cytotoxic chemotherapy; or

2. Used as continuation maintenance therapy following use in combination with carboplatin and paclitaxel; or

b. Used in combination with carboplatin and paclitaxel.

i. HCC

1. Used as first-line therapy in combination with atezolizumab; and

a. Recipient has unresectable or metastatic disease; or

b. Recipient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; and

1. Recipient has Child-Pugh Class A or B hepatic impairment; or

c. Recipient has extensive liver tumor burden; and

1. Recipient has Child-Pugh Class A or B hepatic impairment.

j. PeM

1. Used as adjuvant therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin; and

b. Recipient has unicavitary disease with epithelioid histology; and

2. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible); and

1. Recipient has biphasic/sarcomatoid histology or bicavitary disease; or

2. Recipient has unicavitary disease with epithelioid histology; and

a. Recipient is medically inoperable and/or complete cytoreduction is not achievable (including high-risk features); or

b. Recipient has recurrent disease after prior CRS plus HIPEC and no previous adjuvant systemic therapy was given; or

3. Used as subsequent therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible); and

1. Immunotherapy was administered as first-line treatment; or

2. Used as a rechallenge if pemetrexed-based treatment was administered first-line with good response; or

4. Used in combination with atezolizumab; and

a. Recipient has not received previous therapy with immune checkpoint inhibitors (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/ relatlimab, retifanlimab, toripalimab, etc.)

k. PM

1. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin; and

1. Recipient has clinical stage I-IIIA disease and epithelioid histology; or

2. Recipient has clinical stage IIIB or IV disease, sarcomatoid or biphasic histology, or medically inoperable tumors; or

2. Used as subsequent therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin; and

1. Immunotherapy was administered as first-line treatment; or

2. Used as a rechallenge if pemetrexed-based treatment with administered first-line with good response.

l. Non-Squamous NSCLC

1. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

a. Used as first-line therapy; and

1. Used in combination with erlotinib for EGFR exon 19 deletion or exon 21 L858R mutations; or

2. Used for one of the following:

a. Recipients with a PS ≤1who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression <1%; or

b. PD-L1 expression positive (PD-L1 ≥1%) that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive); or

c. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

3. Used in combination with one of the following:

a. Carboplatin and paclitaxel; or

b. Pemetrexed and either carboplatin or cisplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors

c. Atezolizumab, carboplatin, and paclitaxel; or

b. Used for subsequent therapy in recipients with a PS ≤1; and

1. Used for one of the following:

   a. EGFR exon 19 deletion or exon 21 L858R mutation, EGFR S7681, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement positive tumors and recipient received prior targeted therapy for those aberration

   b. BRAF V600E mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation or RET rearrangement positive tumors

   c. PD-L1 expression-positive (PD-L1 ≥1%) tumors that are negative for actionable molecular biomarkers after prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; and

2. Used in combination with one of the following:

   a. Carboplatin and paclitaxel in recipient with contraindications to PD-1 or PD-L1 inhibitors

   b. Pemetrexed and either carboplatin or cisplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors

   c. Atezolizumab, carboplatin, and paclitaxel (excluding use in recipients who have received prior PD-1/PD-L1 inhibitor therapy); or

c. Used as continuation maintenance therapy in recipients who achieved a tumor response or stable disease after first-line systemic therapy; and

   1. Used as a single agent (bevacizumab must have been included in the first-line regimen); or

   2. Used in combination with pemetrexed following a first-line bevacizumab/ pemetrexed/ platinum chemotherapy regiment; or

   3. Used in combination with atezolizumab following a first-line atezolizumab/ carboplatin/ paclitaxel/ bevacizumab regimen; or

d. Used as continuation of therapy following disease progression on erlotinib with bevacizumab; and

1. Recipient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; and

2. Recipient has T790M negative disease.

m. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

1. Recipient has malignant stage II-IV sex cord-stromal tumors

a. Used a single agent therapy for clinically relapsed disease; or

2. Recipient has epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

a. Recipient has persistent or recurrent disease; and

1. Bevacizumab has not been used previously; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); and

a. Recipient has platinum sensitive disease; and

1. Used as a single agent; or

2. Used in combination with carboplatin and either gemcitabine, paclitaxel, or liposomal doxorubicin; or

b. Recipient has platinum resistant disease; and

1. Used as a single agent; or

2. Used in combination with one of the following: oral cyclophosphamide, gemcitabine, liposomal doxorubicin, paclitaxel, or topotecan; or

3. Used in combination with oral cyclophosphamide and pembrolizumab; or

4. Used in combination with mirvetuximab soravtansine-gynx (in folate receptor-alpha expressing tumors); or

5. Used in combination with carboplatin and either gemcitabine, paclitaxel, or liposomal doxorubicin; or

3. Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in recipients who have received no prior chemotherapy (mucinous, clear cell, carcinosarcoma, endometrioid, and high-grade serous histology only); or

4. Used in combination with paclitaxel and carboplatin for recurrence in recipients who have received no prior chemotherapy (low-grade serous histology only); or

5. Used as maintenance therapy; and

a. Used for stage II-IV disease following primary therapy including bevacizumab; and

1. Used as a single agent in recipients that are BRCA1/2 wild-type or unknown and homologous recombination (HR) proficient, HR deficient, or status unknown (grade 2/3 endometrioid and high-grade serous histology only); or

2. Used in combination with olaparib or niraparib (if unable to tolerate olaparib); and

a. Recipient is BRCA1/2 wild-type or unknown and HR deficient (grade 2/3 endometrioid and high-grade serous histology only), or

b. Recipient has a germline or somatic BRCA1/2 mutation (grade 2/3 endometrioid, high grade serous, clear cell, carcinosarcoma histology only), or

3. Used a single agent following recurrence therapy with chemotherapy plus bevacizumab for platinum-sensitive disease; or

4. Used as continued treatment for stable disease following neoadjuvant therapy (endometrioid and serous histology only); and

a. Used in combination with carboplatin and paclitaxel or docetaxel;

b. Used in combination with oxaliplatin and docetaxel; or

b. Used as neoadjuvant therapy (endometrioid and serous histology only); and

1. Used in combination with one of the following:

a. Carboplatin and paclitaxel or docetaxel

b. Oxaliplatin and docetaxel; and

2. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; or

c. Used as adjuvant therapy; and

1. Used in combination with oxaliplatin and docetaxel; and

a. Recipient has pathologic stage II-IV disease (mucinous, clear cell carcinosarcoma, grade 2/3 endometrioid, and high-grade serous histology only); or

b. Used following interval debulking surgery (IDS) in patients with a response or stable disease to neoadjuvant therapy (endometrioid and serous histology only); and

1. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; or

2. Used in combination with carboplatin and paclitaxel or docetaxel; and

a. Recipient has pathologic stage II-IV disease; or

b. Used following IDS in patients with a response or stable disease to neoadjuvant therapy (endometrioid and serous histology only); and

1. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction.

n. Pediatric CNS Cancers

1. Recipient is ≤18 years of age; and

2. Recipient has diffuse high-grade glioma (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); and

   a. Used as a single agent for palliation; or

3. Recipient has medulloblastoma; and

   a. Used in part of the temozolomide, irinotecan, bevacizumab (TEMR) regimen; or

   b. Used as part of thalidomide, celecoxib, fenofibrate, etoposide, cyclophosphamide, bevacizumab (MEMMAT) regimen.

o. RCC

1. Used in combination with interferon alfa for metastatic disease; or

2. Recipient has relapsed or stage IV disease with non-clear cell histology; and

   a. Used in combination with everolimus; or

   b. Used in combination with erlotinib for advanced papillary disease including hereditary leiomyomatosis and RCC (HLRCC)-associated RCC.

p. Small Bowel Adenocarcinoma

1. Recipient has advanced or metastatic disease; and

2. Used in combination with fluoropyrimidine-(e.g., 5-fluorouracil/5-FU or capecitabine) based regimen.

q. Soft Tissue Sarcoma (STS)

1. Used as a single agent for angiosarcoma; or

2. Used in combination with temozolomide for solitary fibrous tumor.

r. Vulvar Cancer

1. Used in combination with paclitaxel and cisplatin; and

2. Recipient has SCC or adenocarcinoma; and

3. Recipient has advanced, recurrent, or metastatic disease.

2. Dosage Limits

a. Max Units (per dose and over time) [HCPCS Unit]:

1. Oncology Indications :

a. Small Bowel Adenocarcinoma/Ampullary Adenocarcinoma:

1. 180 billable units per 42 days.

b. NSCLC, Cervical Cancer, HCC, Vulvar Cancer, PM, and PeM:

1. 170 billable units per 21 days.

c. CRC and Appendiceal Adenocarcinoma, CNS Cancer, RCC, and all other indications:

1. 360 billable units per 42 days

3. Recertification Request:

Coverage may be renewed based upon the following criteria

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

c. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: gastrointestinal perforations and fistulae, surgical/wound healing complications, necrotizing fasciitis, hemorrhage, arterial and venous thromboembolic events (ATE and VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, proteinuria, severe infusion-related reactions, ovarian failure, congestive heart failure (CHF), etc.; and

e. Adult CNS Cancers (in combination with carmustine, lomustine, or temozolomide or temozolomide and irinotecan):

1. Refer to Section III for criteria.

f. CRC (after first-line bevacizumab-containing regimen):

1. Refer to Section III for criteria

g. Endometrial Carcinoma (Uterine Neoplasms) (maintenance therapy)

1. Refer to Section III for criteria.

h. PeM (combination therapy with atezolizumab):

1. Refer to Section III for criteria.

i. Non-Squamous NSCLC (maintenance therapy or continuation therapy in combination with erlotinib):

1. Refer to Section III for criteria.

j. Ovarian Fallopian Tube and Primary Peritoneal Cancer (maintenance therapy):

1. Refer to Section III for criteria.

4. PA Guidelines:

a. Coverage will be provided for six months and may be renewed (unless otherwise specified).

b. Adult CNS Cancers (symptom management), coverage will be provided for 12 weeks and may not be renewed.

E. Darzalex® (daratumumab)

Therapeutic Class: Antineoplastic
Last Reviewed by the DUR Board: January 16, 2025

Darzalex® (daratumumab) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age (unless otherwise specified); and

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies; and

   c. Multiple Myeloma (MM)

      1. Used in the treatment of newly diagnosed disease in recipients who are eligible for autologous stem cell transplant (ASCT) in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone; or

         b. Bortezomib, melphalan, and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipient who are eligible for ASCT in combination with one of the following regimens:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. Bortezomib, thalidomide, and dexamethasone (VTD); or

         c. Carfilzomib, lenalidomide, and dexamethasone (ixazomib may be substituted for carfilzomib; or

         d. Cyclophosphamide, bortezomib, and dexamethasone; or

      3. Used for disease relapse after six months following primary induction therapy with the same regimen in combination with one of the following regiments:

         a. Lenalidomide and dexamethasone for non-transplant candidates; or

b. Cyclophosphamide, bortezomib, and dexamethasone; or

4. Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and one of the following:

a. Lenalidomide; or

b. Bortezomib; or

c. Carfilzomib; or

d. Carfilzomib and pomalidomide

e. Cyclophosphamide and bortezomib; or

f. Selinexor; or

g. Venetoclax (for recipients with t(11;14) only); or

5. Used in combination with pomalidomide and dexamethasone after therapy including lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.); or

6. Used as single agent therapy; and

a. Recipient received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); or

b. Recipient is double refractory to a proteasome inhibitor and immunomodulatory agent; or

7. Used as maintenance therapy for symptomatic disease in transplant candidates; and

a. Used in combination with lenalidomide; and

1. Used after response to primary myeloma therapy; or

2. Used for response or stable disease following an autologous hematopoietic cell transplant (HCT); or

3. Used for response or stable disease following a tandem autologous or allogeneic HCT for high-risk recipients; or

a. Used for the management of polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS) syndrome; and

b. Used as induction therapy for transplant eligible recipients; and

c. Used in combination with lenalidomide and dexamethasone.

d. Systemic Light Chain Amyloidosis

1. Used for newly diagnosed disease or as a repeat of initial therapy if relapse free for several years; and

a. Used in combination with bortezomib, cyclophosphamide, and dexamethasone (D-VCd); or

b. Used as a single agent; and

1. Recipient has stage IIIb disease with no significant neuropathy; or

2. Used for relapsed or refractory disease; and

a. Used in combination with lenalidomide and dexamethasone; or

b. Used as a single agent.

e. Pediatric Acute Lymphoblastic Leukemia (ALL)

1. Recipient age ≥1 and ≤30 years; and

2. Recipient has relapsed/refractory T-cell all; and

3. Used in combination with vincristine, pegaspargase/calaspargase, doxorubicin, and prednisone/dexamethasone.

2. Dosage Limits

a. Max Units (per dose and over time) [HCPCS Unit]:

1. Multiple Myeloma (MM):

a. 180 billable units every seven days for 12 doses, every 14 days for eight doses, every 21 days for 16 doses, then every 28 days.

2. Systemic Light Chain Amyloidosis:

a. 180 billable units every seven days for eight doses, every 14 days for eight doses, then every 28 days.

3. Pediatric ALL:

a. 180 billable units every seven days for eight doses.

3. Recertification Request

Coverage can be renewed based upon the following criteria:

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III: and

b. Duration of authorization has not been exceeded; and

c. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia, etc.

4. PA Guidelines:

Coverage will be provided for six months and may be renewed (unless otherwise specified).

a. Use for newly diagnosed MM in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

b. Use for newly diagnosed MM in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

c. Use for newly diagnosed or relapsed MM in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

d. Use for newly diagnosed MM in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

e. Use as maintenance therapy for MM in combination with lenalidomide may be renewed for up to a maximum of two years.

f. Use for newly diagnosed or repeat of initial therapy is relapse-free for several years systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone may be renewed for up to a maximum of two years.

g. Use for pediatric ALL may not be renewed.

h. Initial approval will be given for six months.

i. Recertification will be given for six months.

F. Darzalex Faspro® (daratumumab and hyaluronidase-fihj)

Therapeutic Class: Antineoplastic – CD38 Specific Recombinant Monoclonal Antibody Agent
Last Reviewed by the DUR Board: January 16, 2025

Darzalex Faspro® (daratumumab and hyaluronidase-fihj) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Recipient is at least 18 years of age; and

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies (i.e., daratumumab, isatuximab, etc.); and

   c. Multiple Myeloma (MM)

      1. Used in the treatment of newly diagnosed disease in recipients who are ineligible for ASCT in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone; or

         b. Bortezomib, melphalan and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipients who are eligible for ASCT in combination with one of the following regiments:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. VTD; or

         c. Carfilzomib, lenalidomide, and dexamethasone; or

         d. Cyclophosphamide, bortezomib, and dexamethasone; or

      3. Used for disease relapse after six months following primary induction therapy with the same regimen in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone for non-transplant candidates; or

         b. Cyclophosphamide, bortezomib, and dexamethasone; or

4. Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and one of the following:

a. Lenalidomide; or

b. Bortezomib; or

c. Carfilzomib; or

d. Cyclophosphamide and bortezomib; or

e. Selinexor; or

5. Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib); or

6. Used as singe agent therapy; and

a. Recipient received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); or

b. Recipient is double refractory to a proteasome inhibitor and an immunomodulatory agent.

d. Systemic Light Chain Amyloidosis

a. Recipient must not have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease; and

1. Used in combination with bortezomib, cyclophosphamide, and dexamethasone (D-VCD); and

a. Used for newly diagnosed disease; or

b. Used as a repeat of initial therapy for relapsed/refractory disease if the recipient has been relapse-free for several years; or

2. Used as single agent therapy for the treatment of relapsed/refractory disease.

2. Dosage Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Darzalex Faspro® 1,800 mg/30,000-unit single dose vial for injection: 1 vial per dose

    a. Weekly Weeks one to eight, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards.

b. Max Units (per dose and over time) [HCPCS Unit]:

    1. Up to 180 billable units per dose

        a. Weekly Weeks one to eight, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards.

3. Recertification Request

Coverage can be renewed based upon the following criteria:

a. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirement (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Disease response with treatment as defined by stabilization of disease and decrease in size of tumor of tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity and other administration reactions (e.g., systemic administration-related reactions, local injection-site reactions, etc.), neutropenia, thrombocytopenia, cardiac toxicity, etc.; and

d. MM

    1. Used for newly diagnosed MM in combination with bortezomib, thalidomide and dexamethasone may not be renewed.

        a. Used for newly diagnosed MM when used as part of the Induction and Consolidation Therapy Regimen in combination with bortezomib, lenalidomide, and dexamethasone may not be renewed.

        b. Used for newly diagnosed MM when used as part of the Induction, Consolidation, and Maintenance Therapy Regimen in combination with bortezomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

    2. Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib, and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

3. Use for newly diagnosed disease in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for a maximum of 32 weeks.

e. Systemic Light Chain Amyloidosis (newly diagnosed disease)

1. Use for newly diagnosed disease or repeat of initial therapy for relapsed/refractory disease (after being relapse-free for several years) in combination with D-VCD may be renewed for a maximum of two years of therapy.

4. PA Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be given for six months.

c. Use for newly diagnosed MM in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

d. Used for newly diagnosed MM in combination with bortezomib, lenalidomide, and dexamethasone may be renewed for a maximum of 32 weeks.

e. Use for newly diagnosed or repeat of initial therapy for relapsed/refractory (after being relapse-free for several years) systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone may be renewed for up to a maximum of two years.

G. Elaprase® (idursulfase)

Therapeutic Class: Lysosomal Enzymes
Last Reviewed by the DUR Board: April 18, 2024

Elaprase® (idursulfase) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 16 months of age; and

   b. Documented baseline age-appropriate values for one or more of the following have been obtained:

      1. Recipients five years of age or greater: six-minute walk test (6-MWT), percent predicted forced vital capacity (FVC), joint range of motion, left ventricular hypertrophy, growth, quality of life (Childhood Health Assessment Questionnaire [CHAQ]/Health Assessment Questionnaire [HAQ]/Mucopolysaccharidoses Health Assessment Questionnaire [MPS HAQ]), and/or urinary glycosaminoglycan (uGAG); or

      2. Recipients 16 months to <5 years of age: spleen volume, liver volume, FVC, 6-MWT, and/or uGAG; and

   c. Universal Criteria

      1. Therapy is being used to treat non-central nervous system manifestations of the disease and recipient does not have severe, irreversible cognitive impairment; and

   d. Hunter syndrome (Mucopolysaccharidosis II (MPS II))

      1. Recipient has a definitive diagnosis of MPS II as confirmed by one of the following:

         a. Deficient or absent iduronate 2-sulfate (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; or

         b. Detection of pathogenic mutations in the IDS gene by molecular genetic testing.

2. Dose Limits

   a. Quantity Limit (max daily dose) [NDC Unit]:

1. Elaprase® 6 mg/3 mL vial: 10 vials per seven days.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. 60 billable units every seven days.

3. Recertification Request

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions including anaphylaxis, antibody development and serious adverse reactions in Hunter Syndrome recipients with severe genetic mutations, acute respiratory complications, acute cardiorespiratory failure, etc.; and

c. Recipient has demonstrated a beneficial response to therapy compared to pretreatment age-appropriate baseline values in one or more of the following:

1. Recipients five years of age or greater: stabilization or improvement in percent predicted FVC and/or 6-MWT, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index), and/or reduction in uGAG levels; or

2. Recipients 16 months to <5 years of age: reductions in spleen volume and/or liver volume stabilization/improvement in FVC and/or 6-MWT, and/or reduction in uGAG levels.

4. PA Guidelines:

a. Coverage will be provided for 12 months and may be renewed.

H. Anti-Angiogenic Ophthalmic Agents: Eylea®; Eylea® HD (intravitreal)

Therapeutic Class: Anti-angiogenic ophthalmic agents
Last Reviewed by the DUR Board: January 16, 2025

Anti-angiogenic Ophthalmic Agents are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Eylea®

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

2. Universal Criteria

a. Recipient is free of ocular and/or peri-ocular infections; and

b. Recipient does not have active intraocular inflammation; and

c. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., brolucizumab-dbll, ranibizumab, bevacizumab, faricimab-svoa, etc.); and

d. Recipient's BCVA is measured at baseline and periodically during treatment; and

e. Recipient has a definitive diagnosis of one of the following:

1. Neovascular (Wet) AMD

2. Macular Edema following Retinal Vein Occlusion (RVO)

3. DME

4. Diabetic Retinopathy (DR)

5. Retinopathy of Prematurity (ROP)

f. Recipient is a premature infant with a maximum gestational age at birth of 32 weeks or a birth weight of >800 to 1500g.

b. Dosage Limit

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Eylea® 2 mg/0.05 mL injection: one single dose vial kit or single dose pre-filled syringe per eye every 28 days.

b. Eylea HD® 8 mg/0.07 mL injection: one single dose vial per eye every 25 days

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Diagnosis

1. Neovascular AMD

a. MU for Initial Dosing

1. Four units (4 mg) every 28 days x three doses.

a. MU for Maintenance Dosing

1. Four units (4 mg) every 28 days.

2. Macular edema following RVO

a. MU for Initial Dosing

1. Four units (4 mg) every 28 days.

a. MU for Maintenance Dosing

1. Four units (4 mg) every 28 days.

3. DME/DR

a. MU for Initial Dosing

1. Four units (4 mg) every 28 days x five doses.

a. MU for Renewal Dosing

1. Four units (4 mg) every 28 days.

4. ROP

a. MU for Initial Dosing

1. Four units (4 mg) x one dose.

a. MU for Initial Dosing

1. Four units (4 mg) every 28 days.

c. Recertification Request:

Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet the universal and indication-specific requirements relevant criteria as identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, retinal detachments with or without occlusion, increase in intraocular pressure, arterial thromboembolic events; and

a. ROP (Eylea® Only)

1. Recipient still has the presence of active ROP requiring treatment; and

2. At least 10 days have elapsed since receiving initial treatment; and

3. Recipient has not exceeded a maximum of three total doses per each affected eye.

b. All Other Indications

1. Recipient has had a beneficial response to therapy (e.g., improvement in best corrected visual acuity (BCVA) from baseline, etc.) and continued administration is necessary for the maintenance treatment of the condition.

d. PA Guidelines:

1. Coverage will be provided annually and may be renewed, unless otherwise specified.

2. Coverage for ROP will be provided initially for a total of two doses (one dose per eye) and may be renewed as re-treatment for up to an additional four doses (two doses per eye).

2. Lucentis®; Byooviz™; Cimerli™ (ranibizumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

2. Universal Criteria

a. Recipient is free of ocular and/or peri-ocular infections; and

b. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab via ocular implant, etc.); and

c. Recipient's BCVA is measured at baseline and periodically during treatment; and

d. Recipient has a definitive diagnosis of one of the following:

1. Neovascular (Wet) AMD

2. DME (Lucentis® and Cimerli™ Only)

3. DR (Lucentis® and Cimerli™ Only)

4. Macular Edema following RVO

5. Myopic Choroidal Neovascularization (mCNV).

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. 0.3 mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days.

b. 0.5 mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Neovascular AMD/Macular Edema following RVO/mCNV

1. Ten billable units every 28 days.

b. DME/DR – (Lucentis® and Cimerli™ only)

1. Six billable units every 28 days.

c. Recertification Request

Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet the universal and indication-specific relevant criteria as identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events, etc.; and

   a. Recipient has had a beneficial response to therapy (e.g., improvement in BCVA from baseline, etc.) and continued administration is necessary for the maintenance treatment of the condition; or

   b. Myopic choroidal neovascularization only: continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub/retinal fluid or active leakage).

d. PA Guidelines

   1. Coverage for mCNV will be provided for three months and may be renewed.

   2. Coverage for all other indications will be provided annually and may be renewed.

3. Susvimo® (ranibizumab)

   a. Approval will be given if the following criteria are met and documented

      1. Recipient is at least 18 years of age; and

      2. Universal Criteria

         a. Recipient is free of ocular and/or peri-ocular infections; and

         b. Recipient does not have ocular inflammation; and

         c. Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab, faricimab, etc.) unless supplemental treatment is necessary (refer to sections IV and V); and

         d. Recipient has not required removal of a Susvimo implant in the past; and

e. Recipient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis®, Byooviz™, Cimerli™, etc.); and

f. Recipient's BCVA is measured at baseline and periodically during treatment; and

3. Neovascular (Wet) AMD

a. Recipient has previously responded to at least two intravitreal injections of a VEGF inhibitor medication (e.g., aflibercept, brolucizumab, bevacizumab, ranibizumab, faricimab).

b. Dosage and Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Susvimo™ 100 mg/mL solution for injection SDV: one vial per eye every 24 weeks.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Neovascular AMD

1. 200 billable units every 24 weeks.

c. Recertification Request

1. Recipient continues to meet the universal and indication-specific relevant criteria as identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, septum dislodgement, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs, etc.; and

a. Recipient has had a beneficial response to therapy (e.g., improvement in BCVA from baseline, etc.) and continued administration is necessary for the maintenance treatment of the condition; or

b. Supplemental treatment only: Recipient has had an insufficient response during initial or maintenance therapy with Susvimo™ administered every 24 weeks and requires supplemental treatment with intravitreal ranibizumab.

d. PA Guidelines

1. Initial coverage will be given for six months and may be renewed annually thereafter.

2. Recertification will be given for six months.

I. Immune Globulins (immunoglobin):
Asceniv™; Alyglo™; Bivigam®; Flebogamma®; Gamunex-C®; Gammagard® Liquid; Gammagard® S/D; Gammaked™; Gammaplex®; Octagam®; Privigen®; Panzyga®; Yimmugo®

Therapeutic Class: Immune Globulin
Last Reviewed by DUR Board: April 18, 2024, and July 18, 2024

Immune Globulins (immunoglobulin) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Immune Globulins

a. Coverage is provided for the following conditions:

1. Baseline values for BUN and serum creatinine within 30 days of request; and

2. Primary immunodeficiency (PID)

a. Such as: Wiskott-Aldrich syndrome, x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, antibody deficiency with near normal immunoglobulin levels, and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [list not all inclusive].

1. Recipient has an IgG level <200 mg/dL or:

2. Recipient meets both of the following:

a. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

1. Four or more ear infections within one year; or

2. Two or more serious sinus infections within one year; or

3. Two or more months of antibiotics with little effect; or

4. Two or more pneumonias within one year; or

5. Recurrent or deep skin abscesses; or

6. Persistent thrush in the mouth of fungal infections on the skin

7. Need for intravenous (IV) antibiotics to clear infections; or

8. Two or more deep-seated infections including septicemia; or

9. Family history of PID; and

b. The recipient has a deficiency in producing antibodies in response to vaccination; and

1. Titers were drawn before challenging with vaccination; and

2. Titers were drawn between four and eight weeks of vaccination.

3. IgG Subclass Deficiency

a. Recipient's IgG level is <400 mg/dL; and

b. Recipient has a history of recurrent infections; and

c. Recipient is receiving prophylactic antibiotic therapy.

4. Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP)

a. For acute ITP:

1. Used to manage acute bleeding due to severe thrombocytopenia (platelet count <30 x $10^9$/L); or

2. Used to increase platelet counts prior to invasive surgical procedures such as splenectomy (platelet count <100 x $10^9$/L).

3. Recipient has severe thrombocytopenia (platelet count <20 x $10^9$/L.

4. Authorization will be given for one month only and cannot be renewed.

b. For chronic ITP:

1. Recipient is at increased risk for bleeding as indicated by a platelet count <30 x $10^9$/L; and

2. Recipient has a history of failure, contraindication, or intolerance to corticosteroids; and

3. Duration of illness >6 months

5. Chronic Inflammatory Demyelination Polyneuropathy (CIDP)

a. Recipient's disease course is progressive or relapsing and remitting for >2 months; and

b. Recipient has abnormal or absent deep tendon reflexes in upper or lower limbs; and

c. Electrodiagnostic testing indicating demyelination:

1. Partial motor conduction block in at least two motor nerves or in one nerve plus one other demyelination criterion listed here in at least one other nerve; or

2. Distal Compound Muscle Action Potential (CMAP) duration increase in at least one nerve plus one other demyelination criterion listed here in at least one other nerve; or

3. Abnormal temporal dispersion conduction must be present in at least two motor nerves; or

4. Reduced motor conduction velocity in at least two motor nerves; or

5. Prolonged distal motor latency in at least two motor nerves; or

6. Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least one other nerve; or

7. Prolonged F wave latency in at least two motor nerves; and

d. Recipient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; and

e. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., inflammatory neuropathy cause and treatment (INCAT), Medical Research Council (MRC), muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

f. Initial authorization will be given for three months.

6. Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

a. Recipient has severe disease (i.e., recipient requires assistance to ambulate); and

b. Onset of symptoms are recent (i.e., <1 month); and

c. Recipient has abnormal or absent deep tendon reflexes in upper or lower limbs; and

d. Recipient's diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; and

e. Approval will be granted for a maximum of two courses of therapy within six weeks of onset.

f. Authorization is valid for two months only and cannot be renewed.

7. Multifocal Motor Neuropathy (for Gammagard® Liquid)

a. Recipient has progressive, focal, asymmetric limb weakness (without sensory symptoms) for >1 month; and

b. Recipient has complete or partial conduction block or abnormal temporal dispersion conduction in at least two motor nerves; and

c. Recipient has normal sensory nerve conduction on all nerves tested: and

d. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, MRC, muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

e. Initial authorization is valid for three months.

8. HIV Infected Children: Bacterial Control or Prevention

a. Recipient ≤13 years of age; and

b. Recipients IgG level <400 mg/dL.

9. Myasthenia Gravis

   a. Recipient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and

   b. Recipient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); and

   c. Recipient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); and

   d. Recipient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.).

   e. Authorization is valid for one course (one month) only and cannot be renewed.

10. Dermatomyositis (for Octagam® 10%)/Polymyositis

   a. Recipient has severe active disease; and

   b. Recipient has proximal weakness in all upper and/or lower limbs; and

   c. Diagnosis has been confirmed by muscle biopsy; and

   d. Recipient has failed a trial of corticosteroids (i.e., prednisone); and

   e. Recipient has failed a trial of an immunosuppressant (e.g., methotrexate, azathioprine, etc.); and

   f. Recipient will be on combination therapy with corticosteroids or other immunosuppressants; and

   g. Recipient has a documented baseline physical exam and muscular strength/function.

   h. Initial authorization is valid for three months.

11. Complications of Transplanted Solid Organ (kidney, liver, lung, heart, pancreas), and Bone Marrow Transplant (BMT)

   a. Coverage is provided for one or more of the following (list not all inclusive):

1. Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation.

2. Treatment of antibody-mediated rejection of solid organ transplantation.

3. Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus, etc.).

12. Stiff-Person Syndrome

a. Recipient has anti-glutamic acid decarboxylase (GAD) antibodies; and

b. Recipient has failed ≥2 of the following treatments: benzodiazepines (e.g., diazepam, clonazepam, alprazolam, lorazepam, oxazepam, temazepam, etc.), anti-spasticity agents (e.g., baclofen, tizanidine, etc.), or anti-epileptics (e.g., gabapentin, valproate, tiagabine, or levetiracetam, etc.); and

c. Recipient has a documented baseline on physical exam.

13. Allogeneic Bone Marrow or Stem Cell Transplant

a. Used for prevention of Acute Graft-Versus-Host-Disease (aGvHD) or infection; and

b. Recipient's BMT or HSCT was allogeneic; and

c. Recipient has an IgG level <400 mg/dL.

d. Initial authorization is valid for three months.

14. Kawasaki's Disease

a. Authorization is valid for one course (one month) only and cannot be renewed.

15. Fetal Alloimmune Thrombocytopenia (FAIT)

a. Recipient has a history of one or more of the following:

1. Previous FAIT pregnancy; or

2. Family history of the disease.

3. Screening reveals platelet alloantibodies.

b. Authorization is valid through the delivery date only and cannot be renewed.

16. Neonatal Alloimmune Thrombocytopenia (NAIT)

a. Authorization is valid for one course (one month) only and cannot be renewed.

17. Auto-immune Mucocutaneous Blistering Diseases

a. Recipient has been diagnosed with one of the following:

1. Pemphigus Vulgaris

2. Pemphigus Foliaceus

3. Bullous Pemphigoid

4. Mucous Membrane Pemphigoid (a.k.a. Cicatricial Pemphigoid)

5. Epidermolysis bullosa acquisita

6. Pemphigus gestationis (Herpes gestationis)

7. Linear IgA dermatosis; and

b. Recipient has severe disease that is extensive and debilitating; and

c. Diagnosis has been confirmed by biopsy; and

d. Recipient has progressive disease; and

e. Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); and

f. Recipient has a documented baseline on physical exam.

18. Acquired Immune Deficiency Secondary to ALL or MM

a. Used for prevention of infection; and

b. Recipient has an IgG level <400 mg/dL.

19. Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

a. Recipient has an IgG level <200 mg/dL; or

b. Recipient has an IgG level >500 mg/dL; and

1. Recipient has recurrent sinopulmonary infections requiring IV antibiotics or hospitalization; or

2. Recipient meets both of the following:

a. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

1. Four or more ear infections within one year; or

2. Two or more serious sinus infections within one year; or

3. Two or more months of antibiotics with little effect; or

4. Two or more pneumonias within one year; or

5. Recurrent or deep skin or organ abscesses; or

6. Persistent thrush in the mouth or fungal infections on the skin; or

7. Need for IV antibiotics to clear infections; or

8. Two or more deep-seated infections including septicemia; and

3. The recipient has a deficiency in producing antibodies in response to vaccination: and

a. Titers were drawn before challenging with vaccination; and

b. Titers were drawn between four and eight weeks of vaccination.

c. Other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis.

20. Toxic Shock Syndrome (TSS)

a. Authorization is valid for one course (one month) only and cannot be renewed.

21. Management of Immune-Checkpoint-Inhibitor Related Toxicity

a. Recipient has been receiving therapy with immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, retifanlimab, etc.); and

b. Recipient has one of the following toxicities related to their immunotherapy:

1. Severe (G3) or life-threatening (G4) bullous dermatitis as an as an adjunct to rituximab

2. SJS

3. TEN

4. Severe (G3-4) myasthenia gravis

5. Demyelinating disease (optic neuritis, transverse myelitis, acute demyelinating encephalomyelitis)

6. Myocarditis as further intervention if no improvement within 24-48 hours of starting pulse-dose methylprednisolone

7. Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-dose methylprednisolone

8. Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids

9. Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone

10. Encephalitis used in combination with high-dose methylprednisolone for severe or progressing symptoms

11. Moderate, severe, or life-threatening steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids.

22. Management of CAR T-Cell-Related Toxicity

a. Recipient has been receiving treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

1. Used for the management of G4 cytokine release syndrome that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); or

2. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels <600 mg/dL and serious, persistent, or recurrent infections; or

b. Recipient has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); and

1. Used for the management of G4 CRS that is refractory to high dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); or

2. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels ≤400 mg/dL; or

c. Used as prophylactic therapy prior to receiving treatment with anti-CD19 or BCMA-targeted CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, ciltacabtagene autoleucel, etc.); and

1. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels ≤400 mg/dL and serious, persistent, or recurrent bacterial infections.

23. Supportive Care after Rethymic® transplant

a. Used as immunoglobulin replacement therapy in pediatric recipients with congenital athymia after surgical implantation of Rethymic®; or

b. Used as re-initiation of treatment two months after stopping immunoglobulin replacement therapy in pediatric recipients who have an IgG trough level lower than normal range for age.

24. Recertification Request (Unless otherwise specified, renewal authorizations are provided for one year):

a. Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet indication-specific relevant criteria identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include renal dysfunction and acute renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions/ transfusion-related acute lung injury (TRALI), hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, volume overload, etc.; and

3. BUN and serum creatinine have been obtained within the last six months and the concentration and rate of infusion have been adjusted accordingly; and

4. PID

a. Disease response as evidence by one or more of the following:

1. Decrease in the frequency of infection.

2. Decrease in the severity of infection.

5. IgG Subclass Deficiency

a. Disease response as evidenced by one or more of the following:

1. Decrease in the frequency of infection

2. Decrease in the severity of infection; and

b. Continued treatment is necessary to decrease the risk of infection.

6. Immune Thrombocytopenia/ITP

a. Acute ITP

1. May not be renewed.

b. Chronic ITP

1. Disease response as indicated by the achievement and maintenance of a platelet count of ≥30 X $10^9$/L and at least doubling the baseline platelet count

7. Chronic Inflammatory Demyelinating Polyneuropathy

a. Renewals will be authorized for recipients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, MRC, muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

8. Guillain-Barre Syndrome (Acute Inflammatory polyneuropathy)

a. May not be renewed.

9. Multifocal Motor Neuropathy

a. Renewals will be authorized for recipients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, MRC muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

10. HIV infected children: Bacterial Control or Prevention

a. Disease response as evidenced by one or more of the following:

1. Decrease in the frequency of infection.

2. Decrease in the severity of infection; and

b. Recipient continues to be at an increased risk of infection necessitating continued therapy as evidenced by an IgG level <400 mg/dL.

11. Myasthenia Gravis

a. May not be renewed.

12. Dermatomyositis/Polymyositis

a. Recipient had an improvement from baseline on physical exam and/or muscular strength and function.

b. Renewal authorizations are provided for six months.

13. Complications of Transplanted Solid Organ (kidney, liver, lung, heart, pancreas), and BMT

a. Disease response as evidenced by one or more of the following:

1. Decrease in the frequency of infection.

2. Decrease in the severity of infection; and

b. Continued treatment is necessary to decrease the risk of infection.

14. Stiff Person Syndrome

a. Documented improvement from baseline on physical exam.

15. Allogeneic Bone Marrow or Stem Cell Transplant

a. Recipient continues to be at an increased risk of infection necessitating continued therapy as evidenced by an IgG level <400 mg/dL.

b. Renewal authorizations are provided for three months.

16. Kawasaki's Disease

a. May not be renewed.

17. FAIT

a. Authorization is valid through the delivery date only and cannot be renewed.

18. Neonatal Alloimmune Thrombocytopenia

    a. May not be renewed.

19. Auto-Immune Mucocutaneous Blistering Diseases

    a. Documented improvement from baseline on physical exam.

    b. Renewal authorizations are provided for six months.

20. Acquired Immune Deficiency Secondary to ALL, CLL, SLL, or MM

    a. Disease response as evidenced by one or more of the following:

        1. Decrease in the frequency of infection.

        2. Decrease in the severity of infection; and

    b. Continued treatment is necessary to decrease the risk of infection.

21. TSS

    a. May not be renewed.

22. Management of Immune Checkpoint Inhibitor Related Toxicity

    a. May not be renewed.

23. Management of CAR T-Cell-Related Toxicity

    a. Recipient has received treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

        1. Recipient has serum IgG levels <600 mg/dL; or

    b. Recipient has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); and

1. Recipient has serum IgG levels <400 mg/dL

24. Supportive Care after Rethymic® transplant

a. Renewals for use as initial immunoglobulin replacement therapy will be authorized until all of the following criteria are met:

1. Recipient is no longer on immunosuppression (at least 10% of CD3+ T cells are naïve in phenotype); and

2. Recipient is at least nine months post-treatment; and

3. Recipient's phytohemagglutinin (PHA) response within normal limits; or

b. Renewals for use as re-initiation of treatment after stopping immunoglobulin replacement therapy for recipients with an IgG trough level lower than normal range will be continued for one year before being retested using the above guidelines.

b. PA Guidelines:

1. Initial and renewal authorization periods vary by specific covered indication.

2. Unless otherwise specified, the initial authorization will be provided for six months and may be renewed annually.

2. SCIG (immunoglobulin SQ): Hizentra®, Gammagard® Liquid, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify®

a. Coverage is provided in the following conditions:

1. Baseline values for BUN and serum creatinine obtained within 30 days of request; and

2. PID

a. Such as: Wiskott-Aldrich Syndrome, x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined

deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome)

1. Recipient is at least two years of age; and

   a. Recipient has an IgG level <200 mg/dL or

   b. Recipient meets both of the following:

      1. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

         a. Four or more ear infections within one year

         b. Two or more serious sinus infections within one year

         c. Two or more serious months of antibiotics within little effect

         d. Two or more pneumonias within one year

         e. Recurrent or deep skin abscesses

         f. Persistent thrush in the mouth or fungal infection on the skin

         g. Need for IV antibiotics to clear infections

         h. Two or more deep-seated infections including septicemia

         i. Family history of PID; and

   c. The recipient has a deficiency in producing antibodies in response to vaccination; and

      1. Titers were drawn before challenging with vaccination; and

      2. Titers were drawn between four and eight weeks of vaccination.

3. CIDP [Hizentra® and HyQvia® Only]

a. Recipient is at least 18 years of age; and

b. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, MRC muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); and

1. Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); or

2. Used for re-initiation of maintenance therapy after experiencing a relapse and requiring pre-induction therapy with IVIG (see Section IV for criteria).

4. Acquired Immune Deficiency secondary to CLL/SLL

a. Recipient has an IgG level <200 mg/dL or

b. Recipient has an IgG level <500 mg/dL; and

1. Recipient has recurrent sinopulmonary infections requiring IV antibiotics or hospitalization; or

c. Recipient meets both of the following:

1. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

a. Four or more ear infections within one year

b. Two or more serious sinus infections within one year

c. Two or more months of antibiotics with little effect

d. Two or more pneumonias within one year

e. Recurrent or deep skin or organ abscesses

f. Persistent thrush in the mouth or fungal infection on the skin

g. Need for IV antibiotics to clear infections

h. Two or more deep-seated infections including septicemia; and

2. The recipient has a deficiency in producing antibodies in response to vaccination; and

a. Titers were drawn before challenging with vaccination; and

b. Titers were drawn between four and eight weeks of vaccination.

b. Dosage/Administration

1. Dosing should be calculated using adjusted body weight if one or more of the following criteria are met:

a. Recipient's body mass index (BMI) is 30 kg/m2 or more; or

b. Recipient's actual body weight is 20% higher than his or her ideal body weight (IBW)

c. Recertification Request

1. Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet the indication-specific relevant criteria identified in Section III; and

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity/anaphylaxis, thrombosis, aseptic meningitis syndrome, hemolytic anemia, hyperproteinemia, acute lung injury, etc.; and

c. BUN and serum creatinine obtained within the last six months and the concentration and rate of infusion have been adjusted accordingly; and

d. PID

1. Disease response as evidenced by one or more of the following:

a. Decrease in the frequency of infection.

b. Decrease in the severity of infection.

2. CIDP [Hizentra® and HyQvia® Only]

a. Renewals will be authorized for recipients that have demonstrated a beneficial clinical response to maintenance therapy, without relapse, based on an objective clinical measuring tool (e.g., INCAT, MRC muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); or

b. Recipient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra® or HyQvia®; and

1. Recipient improved and stabilized on IVIG treatment; and

2. Recipient was not receiving maximum dosing or Hizentra® or HyQvia® prior to relapse.

3. Acquired Immune Deficiency secondary to CLL/SLL

a. Disease response as evidenced by one or more of the following:

1. Decrease in the frequency of infection

2. Decrease in the severity of infection; and

b. Continued treatment is necessary to decrease the risk of infection.

d. PA Guidelines

1. Initial coverage will be provided for six months and may be renewed annually thereafter.

J. Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)

Therapeutic Class: Antineoplastic-Anti-PD-1
Last Reviewed by DUR Board: January 16, 2025

Antineoplastic-Anti-PD-1 are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Jemperli® (dostarlimab-gxly)

   a. Coverage is provided in the following conditions:

      1. Recipient is at least 18 years of age; and

      2. Universal Criteria

         a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, nivolumab/relatlimab-rmbw, tislelizumab, toripalimab, etc.), unless otherwise specified; and

      3. Endometrial Carcinoma (Uterine Neoplasms)

         a. Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; and

            1. Recipient has primary advanced or recurrent disease; or

            2. Used as primary treatment for recipients with stage III-IV tumors; or

            3. Used as adjuvant therapy for recipients with stage III-IV tumors; or

            4. Used as first-line therapy for recurrent disease; and

               a. Recipient does not have isolated metastases; or

            5. Used as subsequent therapy for recurrent disease

      4. Mismatch Repair Deficient (dMMR)/Microsatellite Instability High (MSI-H) Cancer

         a. Recipient has dMMR or MSI-H cancer as determined by an FDA-approved or CLIA-compliant test; and

1. Used as a single agent; and

   a. Used as subsequent therapy for unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic disease; and

      1. Recipient has endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen in any setting; or

      2. Recipient has solid tumors that have progressed on or following prior treatment; or

   b. Used as induction systemic therapy for relieving dysphagia (applies to Esophageal and Esophagogastric Junction Cancers only); and

      1. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions; lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; or

   c. Used in initial therapy; and

      1. Recipient has one of the following cancers:

         a. Advanced or metastatic Appendiceal Adenocarcinoma

         b. Advanced or metastatic Colon Cancer

         c. Esophageal and Esophagogastric Junction Cancers

         d. Gastric Cancer

         e. Advanced or metastatic Rectal Cancer

         f. Unresectable or medical inoperable advanced or metastatic Small Bowel Adenocarcinoma; and

g. Endometrial Carcinoma (Uterine Neoplasms) (excluding recipients with isolated metastases); or

d. Used as neoadjuvant therapy; and

1. Recipient has advanced or metastatic Appendiceal Adenocarcinoma, Colon Cancer, or Rectal Cancer

5. Polymerase Epsilon/Delta (POLE/POLD1) Mutation Cancer

a. Used as a single agent; and

1. Recipient has advanced or metastatic Appendiceal Adenocarcinoma, Colon Cancer, or Rectal Cancer; or

2. Recipient has unresectable or medically inoperable, advanced or metastatic Small Bowel Adenocarcinoma; and

a. Recipient has disease with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) >50 mut/Mb).

6. Anal Carcinoma

a. Recipient has metastatic SCC; and

b. Used as subsequent therapy as a single agent.

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. Endometrial Cancer

1. Initial: 50 BU - 21 days x six doses

2. Subsequent: 100 BU – 42 days

b. All other indications

1. Initial: 50 BU – 21 days x four doses

2. Subsequent: 100 BU – 42 days

c. Recertification Request:

1. Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Duration of authorization has not been exceeded (refer to Section I); and

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash), complications of allogeneic HSCT, etc.

d. PA Guidelines:

1. Coverage will be provided for six months and may be renewed, unless otherwise specified.

2. Endometrial Carcinoma (Uterine Neoplasms): Use in combination with carboplatin and paclitaxel followed by single agent maintenance therapy thereafter may be renewed for up to a maximum of three years (30 doses).

2. Keytruda® (pembrolizumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age (unless otherwise specified); and

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.), unless otherwise specified; and

3. Anal Carcinoma

a. Recipient has metastatic SCC; and

b. Used as a single agent for subsequent therapy.

4. Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

a. Used as single agent; and

1. Recipient is at least six months of age; and

2. Recipient has relapsed or refractory disease; and

3. Recipient does not require urgent cytoreductive therapy; or

b. Used in combination with brentuximab vedotin; and

1. Recipient is at least six months to 39 years of age; and

2. Used as consolidation/additional therapy in recipients who achieve a partial response after therapy for relapsed or refractory disease.

5. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

a. Used in combination with gemcitabine and cisplatin

1. Recipient has unresectable, R2, or metastatic disease; or

2. Recipient has resectable locoregionally advanced disease (Note: Only applies to Gallbladder Cancer) and

a. Used as neoadjuvant therapy; and

1. Recipient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; or

2. Recipient has incidental finding of pathologic review (cystic duct node positive); or

3. Recipient has mass on imaging.

6. Urothelial Carcinoma (Bladder Cancer)

a. Used in combination with enfortumab-vedotin; and

1. Used as first-line therapy; and

2. Recipient has one of the following diagnoses:

a. Locally advanced or metastatic urothelial carcinoma;

b. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent

c. Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent

d. Metastatic primary carcinoma of the urethra

e. Metastatic upper GU tract tumors

f. Metastatic urothelial carcinoma of the prostate; and

b. Used as a single agent; and

1. Recipient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMBIC) and:

a. Recipient has CIS; and

b. Recipient is ineligible for or has elected not to undergo cystectomy; or

2. Recipient has one of the following diagnoses:

a. Locally advanced or metastatic urothelial carcinoma; or

b. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent; or

c. Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent; or

d. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes);

e. Primary carcinoma of the urethra that is stage T3-4 cN1-2 or cN1-2 with palpable inguinal lymph nodes (first-line therapy only)

f. Metastatic upper GU tract tumors

g. Metastatic urothelial carcinoma of the prostate; and

3. Used for disease that progressed during or following platinum-containing chemotherapy; or

4. Used as second-line treatment after chemotherapy other than a platinum; or

5. Used as first-line therapy in cisplatin-ineligible recipients; and

a. Recipient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible).

7. Triple-Negative Breast Cancer (TNBC)

a. Recipient has recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used in combination with chemotherapy; and

2. Tumor expresses PD-L1 (CPS ≥10) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has high-risk early-stage disease (i.e., stage II-III); and

1. Used as neoadjuvant therapy in combination with chemotherapy; or

2. Used as adjuvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy.

8. Adult CNS Cancer

a. Used as a single agent; and

b. Primary tumor is due to BRAF non-specific melanoma or PD-L1 positive (TPS ≥1%) NSCLC; and

1. Used as initial treatment in recipients with small asymptomatic brain metastases; or

2. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

3. Used for recurrent limited brain metastases; or

4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

9. Pediatric CNS Cancers

a. Recipient is ≤18 years of age; and

b. Recipient has hypermutated diffuse high-grade glioma; and

1. Used for recurrent or progressive disease as a single agent (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); or

2. Used as adjuvant therapy (excluding diffuse midline glioma, H3 K27-altered or pontine location); and

a. Recipient is <3 years of age and used as a single agent; or

b. Recipient is ≥3 years of age and used following standard brain RT with or without concurrent temozolomide.

10. Cervical Cancer

a. Recipient has FIGO 2014 Stage III-IVA disease; and

1. Used in combination with CRT; or

b. Tumor expressed PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; and

1. Used as a single agent; and

a. Used as subsequent therapy for recurrent or metastatic disease; or

2. Used in combination with chemotherapy, with or without bevacizumab; and

a. Recipient has persistent, recurrent, or metastatic disease.

c. Pembrolizumab may be continued as maintenance therapy.

11. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancer:

a. Recipient is medically fit and planned for esophagectomy; and

1. Used as induction systemic therapy for relieving dysphagia; and

2. Recipient has cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3 cm, poorly differentiated), Ct1b-cT2, N+ or cT3-cT4, Any N disease; and

a. Tumor expresses PD-L1 (CPS ≥10) as determined by an FDA approved or CLIA compliant test; and

1. Used in combination with platinum and fluoropyrimidine-based chemotherapy; or

b. Recipient has HER2-positive adenocarcinoma; and

1. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

2. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test; or

b. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

1. Used as first-line therapy and

a. Recipient has HER2-positive adenocarcinoma; and

1. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

b. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA approved or CLIA compliant test; or

c. Recipient has HER2-negative adenocarcinoma; and

1. Used in combination with platinum- and fluoropyrimidine-based chemotherapy; or

d. Recipient has SCC; and

1. Used in combination with platinum- and fluoropyrimidine-based chemotherapy; and

2. Tumor expresses PD-L1 (CPS ≥10) as determined by an FDA-approved or CLIA Compliant test; or

2. Used as subsequent therapy; and

a. Used as a single agent; and

b. Recipient has SCC; and

c. Tumor expresses PD-L1 (CPS ≥10) as determined by an FDA-approved or CLIA-compliant test.

12. Gastric Cancer

a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

b. Used as first-line therapy; and

1. Recipient has HER2-positive adenocarcinoma; and

a. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

b. Tumor expresses PD-L1 (CPA ≥1) as determined by an FDA approved or CLIA compliant test; or

2. Recipient has HER2-negative carcinoma; and

a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

13. Gestational Trophoblastic Neoplasia

a. Used as a single agent for multiagent chemotherapy-resistant disease; and

1. Recipient has intermediate PSTT or ETT; and

a. Used for recurrent or progressive disease; or

2. Recipient has high risk disease (i.e., ≥7 prognostic score or stage IV disease).

14. SCCHN

a. Recipient has Cancer of the Nasopharynx; and

1. Used in combination with cisplatin and gemcitabine; and

2. Used for oligometastatic or metastatic disease; or

b. Recipient has salivary gland tumors; and

1. Used as a single agent; and

2. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; and

c. Recipient has recurrent disease with one of the following:

1. Distant metastases; or

2. Unresectable locoregional recurrence with prior RT; or

3. Unresectable second primary with prior RT; or

d. Recipient has very advanced Head and Neck Cancer; and

1. Recipient has nasopharyngeal cancer; and

a. Recipient has a PS 0-1; and

b. Used in combination with cisplatin and gemcitabine; and

c. Used for one of the following:

1. Unresectable locoregional recurrence with prior RT

2. Unresectable second primary with prior RT

3. Unresectable persistent disease with prior RT

4. Recurrent/persistent disease with distant metastases; or

2. Recipient has non-nasopharyngeal cancer; and

a. Recipient is unfit for surgery or has T4b, N0-3, M0 disease; and

1. Used as a single agent as first-line therapy in recipients with a PS 3; and

2. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has unresectable, recurrent, persistent, or metastatic disease; and

1. Used as a single agent; and

a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; or

2. Used in combination with cetuximab; and

a. Recipient has a PS 0-1; or

3. Used in combination with carboplatin or cisplatin and either fluorouracil, docetaxel, or paclitaxel; and

a. Recipient has a PS 0-1

15. HCC

a. Used as a single agent; and

1. Disease is secondary to hepatitis B; and

    a. Recipient has received prior systemic therapy other than a PD-1/PD-L1-containing regimen; or

2. Used as subsequent therapy for progressive disease; and

    a. Recipient has liver-confined unresectable disease and deemed ineligible for transplant; or

    b. Recipient has extrahepatic/metastatic disease and deemed ineligible for resection, transplant, or locoregional therapy.

16. CLL/SLL

    a. Used for histologic (Richter) transformation to DLBCL (clonally related or unknown clonal status); and

    b. Used as a single agent or in combination with ibrutinib and

        1. Recipient is positive for del(17p)/TP53 mutation; or

        2. Recipient is chemotherapy refractory or is unable to receive chemoimmunotherapy.

17. Adult cHL

    a. Recipient has relapsed or refractory disease; and

        1. Used as a single agent; or

        2. Used in combination with gemcitabine, vinorelbine, liposomal doxorubicin (GVD) or ICE; and

            a. Recipient ≥60 years of age

18. Pediatric cHL

    a. Recipient is at least six months of age; and

    b. Used as a single agent; and

        1. Recipient has refractory disease; or

        2. Recipient has relapsed disease; and

a. Used after two or more prior lines of therapy; or

b. Used as subsequent therapy in recipients heavily pretreated with platinum or anthracycline-based chemotherapy; or

c. Used as subsequent therapy in recipients with an observed decrease in cardiac function.

19. Kaposi Sarcoma

a. Used as a single agent as subsequent therapy; and

b. Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

c. Disease has progressed on or has not responded to first-line systemic therapy; and

d. Disease has progressed on alternate first-line systemic therapy; and

e. Recipient does not have multicentric Castleman disease (MCD) or KSHV-associated inflammatory cytokine syndrome (KICS).

20. RCC

a. Recipient has clear cell histology; and

1. Used in combination with axitinib or lenvatinib; and

a. Used as first-line therapy for advanced, relapsed, or stage IV disease; or

b. Used as subsequent therapy for relapsed or stage IV disease; or

2. Used as a single agent; and

a. Used as adjuvant therapy; and

1. Recipient has undergone a nephrectomy prior to receiving treatment; and

a. Recipient has stage II disease with grade four tumors (with or without sarcomatoid features); or

b. Recipient has stage III disease; or

c. Recipient has resectable stage IV (T4, M0) disease; or

2. Recipient has undergone a metastasectomy with complete resection of disease within one year of having undergone a nephrectomy for relapsed or stage IV disease; or

b. Recipient has non-clear cell histology; and

1. Recipient has relapsed or stage IV disease; and

a. Used as a single agent; or

b. Used in combination with lenvatinib

21. Peritoneal Mesothelioma (PeM)

a. Used in combination with pemetrexed and platinum chemotherapy as first-line therapy; and

b. Used as adjuvant treatment for medically operable disease following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); and

1. Recipient has surgical or pathologic high-risk features; or

a. Recipient has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features; or

b. Recipient has disease progression following CRS plus HIPEC if no prior adjuvant systemic therapy was given.

22. Pleural Mesothelioma (PM)

a. Used in combination with pemetrexed and platinum chemotherapy; and

1. Used as first-line therapy; or

2. Used as induction therapy prior to surgical exploration; and

a. Recipient has clinical stage I disease and epithelioid histology

23. Cutaneous Melanoma

a. Used as first-line therapy as a single agent for unresectable or metastatic disease; or

b. Used as subsequent therapy; and

1. Used for metastatic or unresectable disease with progression following treatment with anti PD-1/PD-L1-based therapy. Including in combination with anti-CTLA04 (e.g., ipilimumab) for ≥2 doses; and

a. Used in combination with lenvatinib; or

2. Used for metastatic or unresectable disease with disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; and

a. Recipient has BRAF V600 activating mutation positive disease; and

b. Used in combination with trametinib and dabrafenib; or

3. Used for disease progression or relapse following treatment with BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy; and

a. Recipient has BRAF V600 activating mutation positive disease; and

b. Used in combination with trametinib and dabrafenib; and

c. Used as re-induction therapy in who experienced disease control (i.e., complete response, partial response, or stable disease) and no residual toxicity from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; or

4. Used for metastatic or unresectable disease with progression or relapse following treatment with anti-PD-1 therapy; and

   a. Used as a single agent; and

   b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease) and no residual toxicity from prior anti-PD-1 therapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; or

5. Used for metastatic or unresectable disease with progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/ trametinib, vemurafenib/ cobimetinib, encorafenib/ binimetinib, etc.); and

6. Used as a single agent; and

   a. Anti-PD-1 therapy was not previously used; or

   b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease) and no residual toxicity from prior anti-PD-1 therapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; or

7. Used in combination with ipilimumab; and

   a. Used after progression on single-agent anti-PD-1 therapy and combination ipilimumab/anti-PD-1 therapy was not previously used; or

   b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease) and no residual toxicity from prior combination ipilimumab/anti-PD-1 therapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; or

c. Used as a single agent for neoadjuvant treatment; and

   1. Recipient has stage III disease; and

a. Used as primary treatment for clinically positive, resectable nodal disease; or

b. Used for limited resectable disease with clinical satellite/in-transit metastases; or

2. Recipient has limited resectable local satellite/in-transit occurrence; or

3. Recipient has resectable disease limited to nodal recurrence; or

d. Used as a single agent for adjuvant treatment; and

1. Recipient has stage IIB or IIC melanoma following complete resection; and

a. Recipient is at least 12 years of age; or

2. Recipient has stage III disease; and

a. Used following complete resection; and

1. Recipient is at least 12 years of age; or

b. Recipient has resected sentinel node positive disease either during radiographic surveillance or after CLND; or

c. Recipient has clinically positive node(s) following wide excision of the primary tumor and TLND; or

d. Recipient has clinical satellite/in-transit metastases and has NED after complete excision; or

3. Recipient has local satellite/in-transit recurrence and has NED after complete excision to clear margins; or

4. Recipient has resectable disease limited to nodal recurrence following excision and complete TLND; or

5. Recipient has oligometastatic disease and NED after receiving metastasis-directed therapy (e.g., complete resection, stereotactic ablative therapy, T-VEC/ intralesional therapy) or systemic therapy followed by resection.

24. Uveal Melanoma

a. Used as a single agent; and

b. Recipient has metastatic or unresectable disease.

25. MCC

a. Recipient is at least six months of age; and

b. Used as a single agent; and

1. Recipient has primary locally advanced disease; and

a. Both curative surgery and curative radiation therapy are not feasible; or

b. Recipient has had disease progression on neoadjuvant nivolumab therapy; or

2. Recipient has recurrent locally advanced or metastatic disease.

26. Adrenal Gland Tumors

a. Recipient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); and

b. Used with or without mitotane.

27. NSCLC

a. Used for stage III disease; and

1. Used as a first-line therapy as a single-agent in recipients who are not candidates for surgical resection or definitive chemoradiation; and

2. Used in recipients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test and with no EGFR or ALK genomic tumor aberrations; or

b. Used as neoadjuvant therapy; and

1. Recipient has resectable disease (tumors ≥4 cm or node positive); and

2. Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; or

c. Used as adjuvant therapy; and

1. Used as a single agent; and

a. Used following resection and previous adjuvant chemotherapy; and

1. Recipient has stage IB (T2A ≥4 cm), II, or IIIA disease; or

2. Recipient has stage IIIB (T3, N2) disease; and

a. Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements; or

b. Used following previous neoadjuvant pembrolizumab plus chemotherapy and resection; or

d. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy; and

a. Used for one of the following:

1. PD-L1 expression-positive (TPS ≥1%) tumors, as detected by an FDA-approved or CLIA compliant test, that are negative for actionable molecular biomarkers

2. Recipients with PS 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression <1%

3. Recipients with PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3

gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

b. Used in combination with pemetrexed and either carboplatin or cisplatin for non-squamous cell histology; or

c. Used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology; or

d. Used as single agent therapy (for PD-L1 expression-positive tumors only); or

2. Used as subsequent therapy; and

a. Used in recipients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test; and

1. Used as single agent therapy; or

b. Used for one of the following:

1. Recipients with PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719x-, ALK rearrangement, or ROS1 rearrangement

2. Recipients with PS 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; and

c. Used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology; or

d. Used in combination with pemetrexed and either carboplatin or cisplatin for non-squamous cell histology; or

3. Used as continuation maintenance therapy in recipients who have achieved tumor response or table disease following initial systemic therapy; and

a. Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for non-squamous cell histology; or

b. Used as a single agent following a first-line pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology; or

c. Used as a single agent following a first-line pembrolizumab monotherapy regimen.

28. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

a. Recipient has epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

b. Used in combination with oral cyclophosphamide and bevacizumab; and

c. Recipient has platinum-resistant disease; and

1. Recipient has persistent or recurrent disease; and

a. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); or

2. Recipient has recurrent disease (low-grade serous carcinoma only).

29. Penile Cancer

a. Used in combination with fluorouracil and either cisplatin or carboplatin, followed by single agent maintenance therapy; and

1. Used as first-line chemotherapy; and

2. Recipient has penile SCC; and

a. Recipient has metastatic disease; or

b. Recipient has local recurrence in the inguinal region and received prior inguinal lymphadenectomy or radiotherapy.

30. Primary Cutaneous Lymphomas

a. Used as a single agent systemic therapy; and

1. Recipient has Mycosis Fungoides/Sezary Syndrome; and

a. Used as primary therapy or as subsequent therapy for relapsed or persistent disease; and

1. Recipient has stage IIB Mycosis Fungoides with generalized tumor lesions (for primary therapy only); or

2. Recipient has stage III Mycosis Fungoides; or

3. Recipient has stage IV Sezary Syndrome; or

4. Recipient has generalized cutaneous or extracutaneous lesions with large cell transformation (LCT); or

b. Used as subsequent therapy for disease refractory to multiple previous therapies (excluding use in recipients with stage IA Mycosis Fungoides); or

2. Recipient has primary cutaneous CD30+ T-Cell lymphoproliferative disorders; and

a. Used for relapsed or refractory disease; and

b. Used for primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional node (N1) (excludes systemic ALCL).

31. SCLC

a. Used as subsequent therapy as a single agent; and

b. Recipient has had a chemotherapy-free interval of ≥6 months; and

1. Recipient has relapsed disease following a complete or partial response or stable disease with primary treatment; or

2. Recipient has primary progressive disease.

32. STS

a. Used in combination with axitinib; and

1. Recipient has ASPS; or

b. Used as a single agent; and

1. Recipient has ASPS; or

2. Recipient has cutaneous angiosarcoma; or

3. Recipient has myxofibrosarcoma, UPS, dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; and

a. Used as subsequent therapy for advanced/ metastatic disease with disseminated metastases (Note: only applies to Extremity/Body Wall. Head/Neck); or

b. Used as alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease (Note: only applies to Retroperitoneal/Intra-Abdominal); or

c. Used as subsequent therapy for stage IV disease with disseminated metastases (Note: only applies to Retroperitoneal/Intra-Abdominal); or

4. Recipient has pleomorphic rhabdomyosarcoma; and

33. Cutaneous Squamous Cell Carcinoma (cSCC)

a. Used as a single agent; and

1. Recipient has locally advanced, recurrent, or metastatic disease that is not curable by surgery or radiation.

34. Extranodal NK/T-Cell Lymphomas

a. Used as a single agent;

b. Used for relapsed or refractory disease following additional therapy with an alternate asparaginase-based combination chemotherapy regimen not previously used; and

c. Participation in a clinical trial is unavailable.

35. Thymic Carcinoma

a. Used as a single agent: and

1. Recipient is unable to tolerate first-line combination regimens; and

a. Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; or

b. Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; or

c. Used as first-line therapy for recurrent, advanced, or metastatic disease; or

2. Used as second-line therapy; and

a. Recipient has unresectable or metastatic disease.

36. Thyroid Carcinoma (Anaplastic Carcinoma)

a. Used as a single agent or in combination with lenvatinib; and

b. Recipient has stage IVC disease; and

1. Used as aggressive first-line therapy; or

2. Used as second-line therapy

37. Endometrial Carcinoma (Uterine Neoplasms)

a. Used in combination with lenvatinib; and

1. Disease is pMMR as determined by an FDA-approved or CLIA-compliant test or not MSI-H; and

a. Used as first-line therapy for recurrent disease after prior platinum-based therapy (excluding use in recipients with isolated metastases); or

b. Used as subsequent therapy for advanced, recurrent, or metastatic disease; or

b. Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; and

1. Used as primary or adjuvant treatment (excluding use in recipients with carcinosarcoma); and

a. Recipient has Stage III or IV disease; or

2. Used for recurrent disease (excluding use in recipients with carcinosarcoma; or

c. Used as a single agent as maintenance therapy following treatment with pembrolizumab in combination with carboplatin and paclitaxel.

38. Vaginal Cancer

a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; and

b. Recipient has recurrent or metastatic disease; and

1. Used as a single agent as subsequent therapy; or

2. Used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab; and

a. Used as first-line therapy; or

b. Used as subsequent therapy (if not previously used as first-line).

39. Vulvar Cancer

a. Used as a single agent; and

b. Recipient has adenocarcinoma or SCC; and

c. Recipient has advanced, recurrent, or metastatic disease; and

d. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; and

e. Used as second-line therapy for disease progression on or after chemotherapy.

40. MSI-H or dMMR Cancer

a. Recipient is at least six months of age; and

b. Recipient has MSI-H or dMMR solid tumors, as determined by an FDA approved or CLIA compliant test; and

c. Recipient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; and

1. Used as a single agent; and

a. Used for disease progression following prior treatment; or

b. Used as initial therapy; and

1. Recipient has one of the following cancers:

a. Ampullary Adenocarcinoma

b. Biliary Tract Cancers (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)

c. Appendiceal Adenocarcinoma – Colon Cancer

d. Colorectal Cancer

e. Esophageal Cancer or Esophagogastric/Gastroesophageal Junction Cancer

f. Gastric Cancer

g. Salivary Gland Tumors

h. Very advanced SCC of the Head and Neck (non-nasopharyngeal-type)

i. Occult Primary/Cancer of Unknown Primary (CUP)

j. Pancreatic Adenocarcinoma

k. Small Bowel Adenocarcinoma

l. Endometrial Carcinoma (Uterine Neoplasms) (excluding recipients with isolated metastases); or

c. Used as induction systemic therapy to relieve dysphagia; and

d. Recipient has Esophageal Cancer or Esophagogastric/Gastroesophageal Junction Cancer; and

e. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; or

1. Used as neoadjuvant therapy; and

a. Recipient has one of the following cancers:

1. Colorectal Cancer

2. Esophageal or Esophagogastric/ Gastroesophageal Junction Adenocarcinoma

3. Gastric Cancer; or

4. Biliary Tract Cancers (Gallbladder Cancer only) (excluding recipients with disease presenting as jaundice); or

2. Used as postoperative management; and

a. Used following R0 resection in recipients who have received preoperative therapy with pembrolizumab; and

b. Recipient has one of the following cancers:

1. Esophageal or Esophagogastric/ Gastroesophageal Junction Adenocarcinoma

2. Gastric Cancer; or

f. Used in combination with oxaliplatin and either fluorouracil or capecitabine; and

1. Recipient has esophageal or Esophagogastric/Gastroesophageal Junction Cancer; and

a. Used as first-line therapy; or

b. Used as induction systemic therapy to relieve dysphagia; and

1. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesion; lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; or

2. Recipient has Gastric Cancer; and

a. Used as first-line therapy.

41. POLE/POLD1 Mutation Cancer

a. Used as a single agent; and

1. Recipient has advanced or metastatic Appendiceal Adenocarcinoma, Colon Cancer, or Rectal Cancer; or

2. Recipient has advanced or metastatic Small Bowel Adenocarcinoma with ultra-hypermutated phenotype [e.g., TMB >50 mut/Mb].

42. TMB-H Cancer

a. Recipient is at least six months of age; and

b. Recipient has TMB-H0 (≥10 mut/Mb) solid tumors as determined by an FDA-approved or CLIA-compliant test; and

c. Used as a single agent; and

d. Pediatric recipients must not have a diagnosis of TMB-H central nervous system cancer; and

e. Recipient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; and

1. Used for disease progression following prior treatment; or

2. Used as initial therapy; and

a. Recipient has one of the following cancers:

b. Ampullary Adenocarcinoma

c. Salivary Gland Tumors

d. Very advanced SCC of the Head and Neck (non-nasopharyngeal type)

e. Occult Primary/CUP

f. Pancreatic Adenocarcinoma

g. Medullary Thyroid Carcinoma

h. Follicular, Oncocytic, or Papillary Thyroid Carcinoma (only applicable to recipients not amenable to radioactive iodine therapy)

i. Endometrial Carcinoma (Uterine Neoplasms) (excluding recipients with isolated metastases).

b. Dosage Limits

1. Keytruda® 100 mg/4 mL single use vial: 12 vials per 14-day supply.

c. Recertification Requests:

Coverage will be provided for six months and may be renewed (unless otherwise specified).

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section 2(a); and

2. Duration of authorization has not been exceeded (refer to Section I; and)

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), hepatotoxicity when used in combination with axitinib, complications of allogeneic HSCT, etc.; and

5. NSCLC (continuous maintenance treatment)

   a. Refer to Section III for criteria

6. Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy or BRAF/MEK + anti-PD-1 immunotherapy)

   a. Refer to Section III for criteria

7. Endometrial Carcinoma (continuous maintenance treatment)

   a. Refer to Section III for criteria

8. Cervical Cancer (continuous maintenance treatment)

   a. Refer to Section III for criteria

9. Penile Cancer (continuous maintenance treatment)

   a. Refer to Section III for criteria.

d. PA Guidelines:

1. Coverage will be provided for six months and may be renewed (unless otherwise specified).

a. Adrenal Gland Tumors, Anal Carcinoma, Biliary Tract Cancer (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma), Bladder Cancer/Urothelial Carcinoma, Cervical Cancer, cHL, CNS Cancer, Cutaneous Melanoma (in combination with ipilimumab, lenvatinib, or trametinib and dabrafenib), cSCC, Endometrial Carcinoma (Uterine Neoplasms), Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line or subsequent therapy), Gastric Cancer (first-line therapy), Gestational Trophoblastic Neoplasia, HCC, CLL/SLL, MCC, MSI-H/dMMR Cancer, NSCLC (first-line or subsequent therapy), PMBCL, POLE/POLD1 Mutation Cancer, Primary Cutaneous Lymphomas, RCC (first-line or subsequent therapy), SCCHN, SCLC, Thymic Carcinoma, Thyroid Carcinoma (Anaplastic), TMB-H Cancer, TNBC (recurrent unresectable or metastatic disease), Uveal Melanoma, Vaginal Cancer, and Vulvar Cancer, PM and PeM can be authorized up to a maximum of 24 months of therapy.

b. Neoadjuvant therapy for Biliary Tract Cancer with or without MSI-H/dMMR may not be renewed.

c. Kaposi Sarcoma may not be renewed.

d. Therapy for MSI-H/dMMR Esophageal, Esophagogastric/ Gastroesophageal Junction, and Gastric Cancer can be authorized for a maximum of 48 weeks (16 doses) of postoperative therapy after surgery.

e. Adjuvant therapy in NSCLC and RCC can be authorized up to a maximum of 12 months of therapy.

f. Therapy for resectable NSCLC can be authorized for up to a maximum of 12 weeks of neoadjuvant therapy and 39 weeks of adjuvant therapy.

g. Therapy for Cutaneous Melanoma can be authorized for up to a maximum of eight weeks of neoadjuvant therapy (three doses), followed by a maximum of 44 weeks (15 doses) of adjuvant therapy.

h. Adjuvant therapy in Cutaneous Melanoma (if no previous neoadjuvant pembrolizumab was used) can be authorized up to a maximum of 12 months of therapy.

i. Neoadjuvant therapy in TNBC can be authorized up to a maximum of 24 weeks of therapy.

j. Adjuvant therapy in TNBC can be authorized up to a maximum of 27 weeks of therapy.

k. Therapy for Penile Cancer can be authorized for up to a maximum of six cycles (18 weeks) of combination therapy with fluorouracil and cisplatin or carboplatin and up to 34 cycles (102 weeks) of single agent maintenance therapy.

K. Kadcyla® (ado-trastuzumab emtansine)

Therapeutic Class: Antineoplastic-Antibody Drug Conjugates (ADCs)
Last Reviewed by DUR Board: April 18, 2024

Kadcyla® (ado-trastuzumab emtansine) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age; and

   b. Universal Criteria

      1. Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

      2. Used as a single agent; and

      3. Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/ trastuzumab and hyaluronidase-zzxf, etc.); and

   c. Breast Cancer

      1. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

         a. Used as adjuvant therapy; and

            1. Recipient has locally advanced or node positive disease; and

               a. Used for residual disease following completion of planned chemotherapy and mastectomy or breast-conserving surgery (BCS); or

               b. Used in recipients not considering pre-operative systemic therapy; or

            2. Recipient has inflammatory breast cancer; and

               a. Used in recipients who had a response to preoperative systemic therapy, followed by surgery, and needs to complete planned chemotherapy; or

b. Recipient has residual disease following preoperative therapy; or

3. Recipient has early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based therapy; or

b. Recipient has metastatic or recurrent unresectable disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used as second-line therapy and beyond; or

c. Recipient has metastatic disease that recurred during or within six months of completing adjuvant therapy; and

1. Recipient previously received trastuzumab and a taxane, separately or in combination.

d. CNS Cancer

1. Recipient has HER2-positive disease as determined by an FDA approved or CLIA-compliant test; and

2. Used for the treatment of brain metastases in recipients with breast cancer; and

a. Used as initial treatment in recipients with small asymptomatic brain metastases; or

b. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

c. Recipient has recurrent limited brain metastases; or

d. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

e. NSCLC

1. Recipient has ERBB2 (HER2) mutation positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Used as subsequent therapy; and

3. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of

disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy.

f. Head and Neck Cancer

1. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Recipient has salivary gland tumors; and

3. Used for one of the following:

a. Recurrent disease with distant metastases

b. Unresectable locoregional recurrence with prior RT

c. Unresectable second primary with prior RT.

2. Dosing Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Kadcyla® 100 mg single-dose vial: one vial every 21 days.

2. Kadcyla® 160 mg single-dose vial: three vials every 21 days.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. 480 billable units every 21 days.

3. Renewal Criteria:

Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: left ventricular dysfunction, hepatotoxicity, pulmonary toxicity (i.e., interstitial lung disease, pneumonitis), thrombocytopenia, neurotoxicity, infusion-related and hypersensitivity reactions, hemorrhage, extravasation at infusion site, etc.; and

d. LVEF obtained within the previous three months as follows:

1. Metastatic or Recurrent Breast Cancer: LVEF is >45% or LVEF is 40% to ≤45% and absolute decrease is <10% from baseline; or

2. All other indications: LVEF is ≥50% or LVEF is 45% to <50% and absolute decrease is <10% from baseline; and

e. Breast Cancer (adjuvant treatment)

1. Recipient has not exceeded a maximum of 14 cycles of therapy (42 weeks total). (May be given up for up to 17 cycles in recipients who did not receive preoperative therapy).

4. PA

a. Coverage will be provided for six months and may be renewed, unless otherwise specified.

b. Adjuvant treatment in breast cancer is limited to 14 cycles (42 weeks total). (May be given for up to 17 cycles in recipients who did not receive preoperative therapy).

L. Aranesp® (darbepoetin alfa)

Therapeutic Class: Recombinant Human Erythropoietins
Last Reviewed by DUR Board: January 16, 2025

Aranesp® (darbepoetin alfa) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age (unless otherwise specified); and

   b. Initiation of therapy Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%; and

   c. Universal Criteria

      1. Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); and

      2. Recipient has adequate iron stores as demonstrated by serum ferritin ≥100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥20% (measured within the previous three months for renewal); and

      3. Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; and

      4. Recipient does not have uncontrolled hypertension; and

   d. Anemia Due to Myelodysplastic Syndrome (MDS)

      1. Recipient has symptomatic anemia; and

      2. Recipient has a serum erythropoietin level ≤500 mU/mL (unless otherwise specified); and

      3. Recipient has lower risk disease (i.e., defined by IPSS-R [Very Low, Low, Intermediate]); and

         a. Recipient does not have del(5q) mutation; and

            1. Recipient has ring side oblasts <15% (or <5% with an SF3B1 mutation); and

               a. Used as a single agent; or

b. Used in combination with either lenalidomide or a granulocyte-colony stimulating factor (G-CSF); and

1. Recipient had no response (despite adequate iron stores) to or relapse after an erythropoiesis-stimulating agent (ESA) alone; or

2. Recipient had no response to or relapse after luspatercept; or

2. Recipient has ring side oblasts ≥15% (or ring side oblasts ≥5% with an SF3B1 mutation); and

a. Used as a single agent; or

1. Recipient had no response to or relapse after luspatercept; or

2. Recipient has a serum erythropoietin level <200 mU/mL; or

b. Used in combination with a G-CSF

1. Recipient had no response to or relapse after luspatercept.

e. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

1. Recipient has myelofibrosis-associated anemia with serum erythropoietin level of <500 mU/mL; and

a. Recipient has symptomatic splenomegaly and/or constitutional symptoms currently controlled on a JAK inhibitor; and

1. Used in combination with ruxolitinib; or

b. Recipient has no symptomatic splenomegaly and/or constitutional symptoms; and

1. Used as a single agent.

f. Anemia Due to Chemotherapy Treatment

1. Recipient has anemia due to concomitant myelosuppressive chemotherapy for non-myeloid malignancy; and

2. Recipient is receiving chemotherapy that is not intended to cure their disease (i.e., palliative treatment); and

3. There are a minimum of two additional months of planned chemotherapy.

g. Anemia Due to Chronic Kidney Disease (CKD) (Non-Dialysis Recipients)

1. Recipient at least one month of age.

2. Dosage Limits

a. Max Units (per dose and over time) [HCPCS Unit]:

1. MDS (J0881 only): 500 billable units every 14 days

2. MPN: 300 billable units every seven days

3. CKD (Non-Dialysis Recipients): 600 billable units every 28 days

4. Chemotherapy-induced: 600 billable units every 21 days

3. Recertification Requests:

a. Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

2. Previous dose was administered within the past 60 days; and

3. Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in recipients with cancer, severe cutaneous reactions (erythema multiforme, SJS/TEN, etc.), etc.; and

5. Anemia Due to Myelodysplastic Syndrome (MDS):

a. Hemoglobin (Hb) <12 g/dL and/or Hematocrit (Hct) <36%

6. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis:

a. Hb <10 g/dL and/or Hct <30%

7. Anemia Due to Chemotherapy Treatment:

   a. Refer to Section III for criteria

8. Anemia Due to Chronic Kidney Disease (CKD) (Non-Dialysis Recipients):

   a. Pediatric recipients: Hb <12 g/dL and/or Hct <36%

   b. Adult recipients: Hb <11 g/dL and/or Hct <33%.

4. PA Guidelines:

   a. Initial approval will be given for 45 days and may be renewed.

M. Long-Acting Granulocyte Colony Stimulating Factors (LA-gCSF):
Neulasta®; Fulphila®; Udenyca®; Ziextenzo®; Nyvepria™; Fylnetra®; Stimufend®

Therapeutic Drug Class: Colony Stimulating Factors
Last Reviewed by DUR Board: July 19, 2024

Colony Stimulating Factors are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Pegfilgrastim

a. Coverage is provided in the following conditions:

1. Prophylactic use in recipients with solid tumors or non-myeloid malignancy

a. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of >20%; or

b. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20% and one or more recipient related risk factors.

2. Recipient who experience a neutropenic complication from a prior cycle of the same chemotherapy

3. Recipients acutely exposed to myelosuppressive doses from radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

4. BMT failure or engraftment delay (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend® only)

5. Peripheral blood progenitor cell (PBPC) mobilization and transplant (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend® only)

6. Wilms Tumor (nephroblastoma) (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend® only)

a. Recipient has favorable histology disease; and

b. Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Neulasta® 6 mg single-dose prefilled syringe: one syringe per 14 days

b. Neulasta® 6 mg single-dose prefilled syringe Onpro kit: one kit per 14 days

c. Fulphila® 6 mg single-dose prefilled syringe: one syringe per 14 days

d. Udenyca® 6 mg single-dose prefilled syringe: one syringe per 14 days

e. Udenyca® 6 mg single-dose prefilled autoinjector: one autoinjector per 14 days

f. Udenyca® 6 mg single-dose prefilled syringe ONBODY kit: one kit per 14 days

g. Ziextenzo® 6 mg single-dose prefilled syringe: one syringe per 14 days

h Nyvepria™ 6 mg single-dose prefilled syringe: one syringe per 14 days

i. Fylnetra® 6 mg single-dose prefilled syringe: one syringe per 14 days

j. Stimufend® 6 mg single-dose prefilled syringe: one syringe per 14 days

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Acute Radiation Exposure

1. 12 billable units weekly x two doses

2. 12 billable units x two doses

b. BMT failure or engraftment delay/PBPC mobilization and transplant

1. 12 billable units x two doses

c. All other indications:

1. 12 billable units per 14 days

c. Recertification Requests:

1. Coverage for all other indications can be renewed based upon the following criteria:

   a. Recipient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

   b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia in recipients with breast and lung cancer, etc.; and

   c. BMT failure or engraftment delay (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend® only)

      1. Coverage may not be renewed.

   d. PBPC mobilization and transplant (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend® only)

      1. Coverage may not be renewed.

   e. Acute exposure to myelosuppressive doses of radiation (H-ARS)

      1. Coverage may not be renewed.

d. PA Guidelines:

   1. BMT failure or engraftment delay: Coverage will be provided for one dose only and may not be renewed.

   2. PBPC mobilization and transplant: Coverage will be provided for one dose only and may not be renewed.

   3. Acute exposure to myelosuppressive doses of radiation (H-ARS): Coverage will be provided for two doses and may not be renewed.

   4. All other indications: Coverage will be provided for four months and may be renewed unless otherwise specified.

N. Pemetrexed
Alimta®; Pemfexy™; Pemetrexed

Therapeutic Drug Class: Antimetabolites
Last Reviewed by DUR Board: January 16, 2025

Antimetabolites are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 18 years of age; and

   b. CNS Cancers

      1. Used as single agent: and

         a. Recipient has Primary CNS Lymphoma; and

            1. Used as induction therapy in recipients unsuitable for or intolerant to high-dose methotrexate (MTX); or

            2. Used for relapsed or refractory disease.

         b. Recipient has leptomeningeal metastases from EGFR mutation-positive NSCLC; and

            1. Used as primary treatment in recipient with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed); or

            2. Used as maintenance treatment in recipients with negative CSF cytology or in clinically stable recipients with persistently positive CSF cytology

   c. Cervical Cancer

      1. Used as subsequent therapy for recurrent or metastatic disease; and

      2. Recipient has SCC, adenocarcinoma, or adenosquamous carcinoma; and

      3. Used as a single agent.

   d. Peritoneal Mesothelioma (PeM)

1. Used as adjuvant therapy; and

   a. Recipient has unicavitary disease with epithelioid histology; and

   b. Recipient has surgical/pathologic high-risk features, and no neoadjuvant therapy was given; and

   c. Used as a single agent or in combination with one of the following regimens:

      1. Cisplatin or carboplatin; or

      2. Bevacizumab and either cisplatin or carboplatin; or

      3. Pembrolizumab and either cisplatin or carboplatin; or

2. Used as first-line therapy; and

   a. Recipient has biphasic/sarcomatoid histology or bicavitary disease; or

   b. Recipient has unicavitary disease with epithelioid histology; and

      1. Recipient is medically inoperable and/or complete cytoreduction is not achievable (including high-risk features); or

      2. Recipient has recurrent disease after prior cytoreductive surgery (CRS) plus hyperthermic intraperitoneal (IP) chemotherapy (HIPEC) and no previous adjuvant systemic therapy was given; and

   c. Used as a single agent or in combination with one of the following regimens:

      1. Cisplatin or carboplatin; or

      2. Bevacizumab and either cisplatin or carboplatin; or

      3. Pembrolizumab and either cisplatin or carboplatin; or

3. Used as subsequent therapy; and

   a. Used as a single agent or in combination with cisplatin or carboplatin, with or without bevacizumab,

1. Immunotherapy (i.e., nivolumab/ipilimumab) was administered as first-line treatment; or

2. Used as rechallenge if pemetrexed was administered first-line with good response.

e. Pleural Mesothelioma (PM)

1. Used as induction therapy; and

a. Used in combination with cisplatin or carboplatin in recipients with clinical stage I-IIIA disease and epithelioid histology; or

2. Used as first-line therapy; and

a. Cisplatin or carboplatin; or

b. Bevacizumab and either cisplatin or carboplatin; or

c. Pembrolizumab and either cisplatin or carboplatin; or

3. Used as subsequent therapy; and

a. Used as a single agent or in combination with cisplatin or carboplatin, with or without bevacizumab; and

1. Immunotherapy (i.e., nivolumab/ipilimumab) was administered as first-line treatment; or

2. Used as rechallenge if pemetrexed was administered first-line with a good response.

f. Non-Squamous Non-Small Cell Lung Cancer (NS-NSCLC)

1. Used in combination with carboplatin or cisplatin-containing regimen; or

2. Used in combination with bevacizumab, pembrolizumab, cemiplimab, or durvalumab for continuation maintenance therapy if previously used first-line and recipient achieved a tumor response or stable disease following initial therapy; or

3. Used as a single agent; and

a. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy for tumors that are negative for actionable molecular biomarkers; or

2. Used as first-line therapy for EGFR exon 20 mutation, BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon-14 skipping mutation, EGFR exon 20 mutation, KRAS G12C mutation, or RET rearrangement, or ERBB2 (HER2) mutation positive tumors; or

3. Used as subsequent therapy; or

4. Used continuation or switch maintenance therapy in recipients who have achieved tumor response or stable disease following initial therapy.

g. Thymomas/Thymic Carcinoma

1. Used as a single agent; and

a. Recipient is unable to tolerate first-line combination regimens; and

1. Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; or

2. Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection

3. Used as first-line therapy for recurrent, advanced, or metastatic disease; or

b. Used as second-line therapy; and

1. Recipient has unresectable or metastatic disease.

h. Ovarian Fallopian Tube, and Primary Peritoneal Cancer

1. Used as single agent; and

a. Recipient has recurrent or persistent Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, or Clear Cell Carcinoma of the Ovary; and

1. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); or

b. Recipient has recurrent Low-Grade Serous Carcinoma.

i. Vaginal Cancer

1. Used as a single agent; and

2. Used as subsequent therapy for recurrent or metastatic disease.

2. Dosage Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Alimta® 100 mg powder for injection in a single-use vial: four vials every 21 days

2. Alimta® 500 mg powder for injection in a single-use vial: four vials every 21 days

3. Pemfexy™ 500 mg solution for injection in a multi dose vial: four vials every 21 days

4. Pemetrexed 750 mg powder for injection: two vials every 21 days

5. Pemetrexed 1000 mg powder for injection: two vials every 21 days

6. Pemetrexed 100 mg/4 mL solution for injection: four vials every 21 days

7. Pemetrexed 500 mg/20 mL solution for injection: four vials every 21 days

8. Pemetrexed 850 mg/34 mL solution for injection: two vials every 21 days

9. Pemetrexed 1000 mg/40 mL solution for injection: two vials every 21 days

10. Pemrydi RTU® 100 mg/10 mL solution for injection: four vials every 21 days

11. Pemrydi RTU® 500 mg/50 mL solution for injection: four vials every 21 days

12. Pemrydi RTU® 1000 mg/100 mL solution for injection: two vials every 21 days.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. Pemfexy™ (500 mg MDV):

a. Primary CNS Lymphoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube and Primary Peritoneal Cancer: 225 billable units every 21 days

b. Leptomeningeal Metastases from NSCLC: five billable units on days one and five of a seven day cycle, then five billable units every 21 days

c. Thymomas/Thymic Carcinoma, Non-Squamous NSCLC, and Mesotheliomas: 125 billable units every 21 days for six cycles.

2. Pemetrexed (BluePoint) (100 mg, 500 mg, 750 mg, and 1000 mg SDV):

a. Primary CNS Lymphoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer: 225 billable units every 21 days

b. Leptomeningeal Metastases from NSCLC: 10 billable units on days one and five of a seven-day cycle, then 10 billable units every 21 days

c. Thymomas/Thymic Carcinoma, Non-Squamous NSCLC, and Mesotheliomas: 130 billable units every 21 days.

3. Recertification Request

Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Duration of authorization has not been exceeded; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal toxicity (CrCL <45 mL/min), bullous and exfoliative skin toxicity (e.g., SJS/TEN), interstitial pneumonitis, radiation recall, etc.; and

d. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. PA Guidelines

a. Coverage will be provided for six months and may be renewed, unless otherwise specified.

1. Thymomas/Thymic Carcinoma: Coverage will be provided for six cycles and may not be renewed

2. Mesothelioma (including PeM, PM, pericardial mesothelioma and tunica vaginalis testis mesothelioma):

a. In combination with bevacizumab and either cisplatin or carboplatin: Coverage will be provided for six cycles and may not be renewed.

b. In combination with pembrolizumab and either cisplatin or carboplatin: Coverage will be provided for six doses and may not be renewed.

O. HER2 Inhibitors

Therapeutic Drug Class: HER2 Inhibitors
Last Reviewed by DUR Board: January 16, 2025

HER2 Inhibitors are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Perjeta® (pertuzumab)

    a. Coverage is provided in the following conditions:

        1. Recipient is at least 18 years of age; and

        2. Universal Criteria

            a. LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

            b. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

            c. Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo®); and

        3. Breast Cancer

            a. Used as neoadjuvant or preoperative therapy; and

                1. Recipient has locally advanced, node positive, or inflammatory disease; and

                2. Used in combination with trastuzumab and chemotherapy; or

            b. Used as adjuvant therapy; and

                1. Recipient has locally advanced, node positive, or inflammatory disease; and

                    a. Used in combination with trastuzumab and chemotherapy; or

                    b. Used in combination with trastuzumab; or

c. Used for recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used as first-line therapy in combination with trastuzumab and either paclitaxel or docetaxel; or

2. Used as subsequent therapy in combination with trastuzumab with or without cytotoxic therapy; and

a. Recipient was previously treated with trastuzumab and chemotherapy; and

b. Recipient has not previously received pertuzumab.

4. CNS Cancer

a. Used for the treatment of brain metastases in recipients with breast cancer; and

b. Used in combination with trastuzumab; and

1. Used as initial treatment in recipients with small asymptomatic brain metastases; or

2. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

3. Recipient has recurrent limited brain metastases; or

4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

5. CRC

a. Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; and

1. Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CAPOX within the past 12 months; and

a. Recipient has pMMR/MSS disease; or

2. Used as primary treatment for unresectable (or medically inoperable) or metastatic disease if intensive therapy is not recommended; and

a. Recipient has not previously received HER2-targeted therapy; and

b. Used in one of the following:

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

3. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or unresectable (or medically inoperable) rectal cancer if intensive therapy is not recommended; and

a. Used if resection is contraindicated following total neoadjuvant therapy; and

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

b. Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; and

1. Recipient has dMMR/MSI-H disease; or

4. Used as subsequent therapy for progression of advanced or metastatic disease; and

a. Recipient has not previously received HER2-targeted therapy; and

b. Used in one of the following:

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

6. Appendiceal Adenocarcinoma – Colon Cancer

a. Used for RAS and BRAF WT disease in combination with trastuzumab; and

b. Recipient has not previously received HER2-targeted therapy; and

c. Used for one of the following

1. Used as initial therapy for advanced or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease; and

d. Used in one of the following:

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

7. Head and Neck Cancer

a. Recipient has salivary gland tumors; and

b. Used in combination with trastuzumab; and

c. Used for one of the following:

1. Recurrent disease with distant metastases

2. Unresectable locoregional recurrence with prior RT

3. Unresectable second primary with prior RT.

8. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma

a. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

b. Used in combination with trastuzumab.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

   a. Perjeta® 420 mg/14 mL solution for injection:

      1. Loading Dose: two vials

      2. Maintenance Dose: one vial every 21 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

   a. Loading Dose: 840 billable units x one dose

   b. Maintenance Dose: 420 billable units every 21 days.

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: left ventricular dysfunction, severe infusion-related reactions, hypersensitivity reactions/anaphylaxis, etc.; and

4. LVEF obtained within the previous three months as follows:

   a. Neoadjuvant and adjuvant treatment of breast cancer: LVEF is ≥50% or LVEF has had an absolute decrease of <10% from baseline

   b. All other indications: LVEF is >45% or LVEF is 40% to 45% and absolute decrease is <10% from baseline.

5. Breast Cancer (neoadjuvant or adjuvant therapy)

   a. Recipient has not exceeded a maximum of one year or treatment (total of 18 cycles).

d. PA Guidelines

1. Coverage is provided for six months and may be renewed (unless otherwise specified).

2. Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of one year of treatment [18 cycles].

2. Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (trastuzumab)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

2. Universal Criteria

a. Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

b. Recipient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

c. Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for seven months after the last dose; and

d. Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla®) or fam-trastuzumab deruxtecan-nxki (Enhertu®); and

e. Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin®, Hylecta®) or pertuzumab/ trastuzumab and hyaluronidase-zzxf (Phesgo®); and

3. Breast Cancer

a. Used as adjuvant therapy; and

1. Recipient has ≥T1 disease, node positive, or inflammatory disease; and

a. Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; or

b. Used in combination with pertuzumab; or

c. Used as a single agent; or

2. Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; and

a. Recipient has ≥ypT0N0 or pathological complete response (pCR) disease by axillary staging; and

b. Used as a single agent or in combination with pertuzumab; or

b. Used as neoadjuvant or preoperative therapy; and

1. Recipient has ≥T1c disease, node positive, or inflammatory disease; and

2. Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; or

c. Used for recurrent unresectable (local or regional) or metastatic disease or inflammatory breast cancer; and

1. Used as a single agent in recipients who have received one or more prior chemotherapy regimens for metastatic disease; or

2. Used in combination with one of the following:

a. Paclitaxel as first-line therapy for metastatic disease; or

b. Endocrine therapy (e.g., tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib) in recipients with hormone-receptor positive disease; and

1. Recipient is post-menopausal; or

2. Recipient is pre-menopausal and is treated with ovarian ablation/suppression; or

3. Recipient is pre-menopausal and will not receive ovarian ablation/suppression (with tamoxifen only); or

4. Recipient is a male (sex assigned at birth).

c. Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy

d. Capecitabine and tucatinib as second-line therapy and beyond

e. Cytotoxic chemotherapy as fourth-line therapy and beyond

f. Lapatinib (without cytotoxic therapy) as fourth-line therapy and beyond

g. Pertuzumab with or without cytotoxic therapy as subsequent therapy in recipients previously treated with chemotherapy and trastuzumab (without pertuzumab).

4. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from breast cancer; and

1. Trastuzumab will be administered intrathecally or intraventricularly; and

a. Used as primary treatment in recipients with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, or reasonable systemic treatment options if needed); or

b. Used as maintenance therapy in recipient with negative CSF cytology or in clinically stable recipient with persistently positive CSF cytology; or

b. Recipient has brain metastases from breast cancer; and

1. Used in combination with one of the following:

a. Pertuzumab

b. Capecitabine and tucatinib in recipients previously treated with at least one HER2-directed regimen; and

2. Used in one of the following treatment settings:

a. Used as initial treatment in recipients with small asymptomatic brain metastases; or

b. Recipient has recurrent limited brain metastases; or

c. Recipient has recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; or

d. Recipient has relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options.

5. Gastric, Esophageal, and Esophagogastric Junction Cancers

a. Recipient has adenocarcinoma; and

1. Used as induction systemic therapy for relieving dysphagia (applies to Esophageal and Esophagogastric Junction Cancers only); and

a. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions, lymphovascular invasion, ≥3 cm, poorly differentiated), cT1B-cT2, N+ or cT3-cT4a, Any N disease; and

1. Used in combination with chemotherapy; or

2. Used in combination with pembrolizumab, fluoropyrimidine- and platinum-containing chemotherapy; and

a. Tumor expressed PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-complaint test

2. Recipient has early-stage disease with favorable histology (applies to Gastric Cancer only); and

a. Recipient has completed an endoscopic resection; and

1. Used in combination with chemotherapy; or

2. Used in combination with pembrolizumab, fluoropyrimidine- and platinum-containing chemotherapy; and

a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-complaint test; or

3. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic adenocarcinoma; and

a. Used as first-line therapy; and

1. Used in combination with chemotherapy; or

2. Used in combination with pembrolizumab, fluoropyrimidine-and platinum-containing chemotherapy; and

a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test.

6. Endometrial Carcinoma – Uterine Neoplasms

a. Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; and

b. Recipient has uterine serous carcinoma or carcinosarcoma; and

1. Recipient has stage III/IV disease; or

2. Recipient has recurrent disease and has not received prior trastuzumab therapy; and

a. Used as first-line therapy; and

1. Recipient does not have isolated metastases; or

b. Used in subsequent therapy.

7. Colorectal Cancer (CRC)

a. Recipient has RAS and BRAF wild-type (WT) disease; and

b. Used in combination with pertuzumab, lapatinib, or tucatinib; and

1. Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CAPOX within the past 12 months; and

a. Recipient has mismatch repair proficient/ microsatellite-stable (pMMR/MSS) disease; or

2. Used as primary treatment for unresectable (or medically inoperable) or metastatic disease if intensive therapy is not recommended; and

   a. Recipient has not previously received HER2-directed therapy; and

      1. Recipient has pMMR/MSS disease; or

      2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

         a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

3. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or unresectable (or medically inoperable) rectal cancer if intensive therapy is not recommended; and

   a. Used if resection is contraindicated following total neoadjuvant therapy; and

      1. Recipient has pMMR/MSS disease; or

      2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

         a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

   b. Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; and

      1. Recipient has dMMR/MSI-H disease; or

4. Used as subsequent therapy for progression of advanced or metastatic disease; and

   a. Recipient has not previously received HER2-directed therapy; and

      1. Recipient has pMMR/MSS disease; or

      2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

b. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.

8. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient has RAS and BRAF WT disease; and

b. Used in combination with pertuzumab, lapatinib or tucatinib; and

c. Recipient has not previously received HER2-targeted therapy; and

d. Used for one of the following:

1. Used as initially therapy for advanced or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease; and

e. Used in one of the following:

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.

9. Head and Neck Cancers

a. Recipient has salivary gland tumors; and

b. Used as a single agent or in combination with either docetaxel or pertuzumab; and

c. Recipient has recurrent disease with one of the following:

1. Distant metastases

2. Unresectable locoregional recurrence with prior RT

3. Unresectable second primary with prior RT.

10. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

a. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

b. Used in combination with pertuzumab.

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. Herceptin (150 mg SDV):

1. Gastric, Esophageal, and Esophagogastric Junction Cancer:

a. Load: 90 billable units x one dose

b. Maintenance: 75 billable units every 14 days

2. CNS Cancer: 300 billable units every 28 days

3. Breast Cancer, CRC, and Appendiceal Adenocarcinoma, All other indications: 90 billable units every 21 days

b. Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant (420 mg MDV):

1. Gastric, Esophageal, and Esophagogastric Junction Cancer:

a. Load: 92 billable units x one dose

b. Maintenance: 69 billable units every 14 days

2. CNS Cancer: 276 billable units every 28 days

3. Breast Cancer, CRC, and Appendiceal Adenocarcinoma, All other indications: 92 billable units every 21 days

c. Recertification Request

1. Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisites therapy), performance status, etc. identified in Section III; and

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiomyopathy (e.g., left ventricular cardiac dysfunction, arrhythmias, cardiac failure, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, etc.), severe or febrile neutropenia, severe infusion-related reactions, etc.; and

d. LVEF obtained within the previous three months as follows:

1. LVEF is within the institutional normal limits, and has not had an absolute of ≥16% from pre-treatment baseline; or

2. LVEF is below the institutional lower limits of normal and has not had an absolute decrease of ≥10% from pre-treatment baseline; and

d. PA Guidelines

1. Coverage is provided for six months and may be renewed (unless otherwise specified).

a. Neoadjuvant/preoperative and adjuvant treatment in Breast Cancer may be authorized up to a maximum of 52 weeks of treatment.

P. CD20 Monoclonal Antibodies

Therapeutic Class: Antirheumatic, CD20 Monoclonal Antibodies
Last Reviewed by the DUR Board: January 16, 2025

CD20 Monoclonal Antibodies are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Rituxan®, Truxima®, Ruxience™, Riabni™ (rituximab)

   a. Coverage is provided in the following conditions:

      1. Recipient is at least 18 years of age (unless otherwise specified); and

      2. Universal Criteria

         a. Recipient does not have a severe, active infection; and

         b. Recipient has been screened for the presence of HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and recipients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; and

         c. Recipient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; and

      3. Oncology Indications

         a. Recipient CD20 antigen expression is positive (excluding use for cGvHD, Hematopoietic Cell Transplantation, and Management of Immunotherapy-Related Toxicity); and

      4. Pediatric Mature B-Cell Acute Leukemia (B-AL)

         a. Recipient is at least six months of age; and

         b. Used in combination with chemotherapy for previously untreated disease

      5. Adult Acute Lymphoblastic Leukemia (ALL)

         a. Recipient has Philadelphia chromosome-positive (Ph+) disease; and

            1. Used in combination with a tyrosine kinase inhibitor (TKI)-based regimen; and

a. Recipient is <65 years of age without significant comorbidities; or

2. Used in combination with methotrexate, vincristine, pegaspargase, dexamethasone (MOpAD) for TKI-refractory disease; or

b. Recipient has Philadelphia chromosome-negative (Ph-) disease; and

1. Used as a component of a multiagent chemotherapy.

6. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from lymphomas; and

b. Recipient has primary CNS lymphoma; and

1. Used for induction therapy; and

a. Used as a single agent or in combination with a methotrexate-containing regimen, temozolomide, or lenalidomide; or

b. Recipient has CSF positive or spinal MRI positive disease; or

2. Used for consolidation (monthly maintenance) therapy; and

a. Used as continuation of induction regimen in recipients with complete response or complete response unconfirmed (CRu) to induction therapy; and

1. Used as a single agent; or

2. Used in combination with dose methotrexate; or

3. Used for relapsed or refractory disease; and

a. Used as a single agent, or in combination with systemic therapy in recipients with prior whole brain radiation therapy; and

1. Recipient has CSF positive or spinal MRI positive disease; or

b. Used as a single agent or in combination with either temozolomide, lenalidomide, or high-dose methotrexate/high-dose methotrexate-containing regimen.

7. Adult Hodgkin Lymphoma

a. Recipient has nodular lymphocyte-predominant disease.

8. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

a. Used in combination with fludarabine and cyclophosphamide (FC); or

b. Recipient has disease without del (17p)/TP53 mutation; and

1. Used as first-line therapy in combination with bendamustine (excluding use in frail recipients); or

2. Used as subsequent therapy in combination with one of the following:

a. Bendamustine (recipients <65 years of age without significant comorbidities; excluding use in frail recipients)

b. Idelalisib

c. Lenalidomide

d. Venetoclax; or

c. Recipient has disease with del(17p)/TP53 mutation; and

1. Used as first-line therapy in combination with high-dose methylprednisolone; or

2. Used as subsequent therapy in combination with one of the following:

a. Alemtuzumab

b. High-dose methylprednisolone

c. Idelalisib

d. Lenalidomide

e. Venetoclax; or

3. Used as first-line therapy for histologic (Richter's) transformation to DLBCL; and

a. Used in combination with cyclophosphamide, doxorubicin, and vincristine-based regimens (excluding use with venetoclax) or as a component of oxaliplatin, fludarabine, cytarabine, and rituximab (OFAR).

9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

10. Adult B-Cell Lymphomas including, but not limited to, the following:

a. HIV-Related B-Cell Lymphoma

1. Disease is related to Burkitt lymphoma, DLBCL, HHV8-positive DLBCL (not otherwise specified), or primary effusion lymphoma (PEL), plasmablastic lymphoma

b. Burkitt Lymphoma

1. Used in combination with chemotherapy

2. DLBCL

3. Low-Grade (grade 1-2) or Follicular Lymphoma

4. Extranodal Marginal Zone Lymphoma (EMZL) of the Stomach and Nongastric Sites (Noncutaneous)

5. Nodal and Splenic Marginal Zone Lymphoma

6. High-Grade B-Cell Lymphomas

7. Mantle Cell Lymphoma

8. Histologic Transformation of Indolent Lymphomas to DLBCL

9. Post-Transplant Lymphoproliferative Disorders (PTLD) (B-Cell type)

c. Castleman Disease

1. Recipient has multicentric disease; or

2. Recipient has unicentric unresectable disease; and

a. Used as first-line therapy; or

b. Used as second-line therapy for relapsed, refractory, or progressive disease

11. Primary Cutaneous B-Cell Lymphomas

12. Pediatric Aggressive Mature B-Cell Lymphomas (Primary Mediastinal Large B-Cell Lymphoma, DLBCL, Burkitt Lymphoma, and Burkitt-like Lymphoma)

a. Recipient is at least six months of age; and

b. Used in combination with chemotherapy.

13. Hairy Cell Leukemia

a. Used as a single agent; and

1. Used for incomplete hematologic recovery or relapsed disease in recipients unable to receive purine analogs (i.e., cladribine or pentostatin); or

b. Used in combination with cladribine; or

c. Used in combination with pentostatin; and

1. Used for incomplete hematologic recovery or relapsed disease; or

d. Used in combination with vemurafenib; and

1. Used as initial therapy or for relapse ≥2 years after initial therapy in recipients with indications for treatment who are not candidates for purine analogs including recipients who are frail and those with active infection; or

2. Used for incomplete hematologic recovery or relapse within two years of full hematologic recovery consistent with complete response following initial treatment with cladribine or pentostatin; or

3. Used for progression after therapy for relapsed or refractory disease; and

e. Used in combination with venetoclax; and

1. Used for progression after therapy for relapsed or refractory disease; and

2. Recipient had disease resistance to BRAF inhibitor therapy

14. Histiocytic Neoplasms – Rosai-Dorfman Disease

a. Used as a single agent for nodal, immune-cytopenia, or immunoglobulin G4 (IgG4) diseases; and

1. Used for symptomatic unresectable unifocal disease; or

2. Used for symptomatic multifocal disease; or

3. Used for relapsed/refractory disease.

15. Pediatric Hodgkin Lymphoma

a. Recipient is ≤18 years of age; and

b. Recipient has nodular lymphocyte-predominant; and

c. Used in combination with cyclophosphamide, vinblastine, prednisone (CVbP); and

d. Used as primary treatment for stage IA or IIA disease (incomplete resection and non-bulky disease).

16. Chronic Graft versus Host Disease (cGvHD)

a. Recipient is post-allogeneic hematopoietic cell transplant (generally three or more months); and

b. Used as additional therapy in combination with systemic corticosteroids; and

c. Recipient has no response (e.g., steroid-refractory disease) to first-line therapy options; and

17. Hematopoietic Cell Transplantation

a. Used as conditioning for allogeneic transplant as part of a non-myeloablative regimen in combination with cyclophosphamide and fludarabine.

18. Management of Immunotherapy-Related Toxicities

a. Recipient has been receiving therapy with an immune checkpoint inhibitor; and

1. Recipient has encephalitis related to immunotherapy; and

a. Recipient is autoimmune-encephalopathy-antibody positive; or

b. Recipient has had limited to no improvement after seven to 14 days on high-dose corticosteroids with or without IVIG; or

2. Recipient has bullous dermatitis related to immunotherapy; and

a. Used as additional therapy for moderate (G2), severe (G3) or life-threatening (G4) disease; or

3. Recipient has moderate or severe steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) related to immunotherapy; and

a. Used for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids; or

4. Recipient has myasthenia gravis related to immunotherapy; and

a. Used as additional therapy for severe (G3-4) disease that is refractory to plasmapheresis or IVIG.

19. Non-Oncology Indications

a. Recipient is not on concurrent treatment with another CD20-directed therapy, biologic agents (e.g., TNF-inhibitor, IL-inhibitor, integrin receptor antagonist, T-cell co-stimulation modulator, etc.) targeted synthetic therapies (i.e., apremilast, abroticinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, etc.); and

20. Rheumatoid Arthritis (RA)

a. Physician has assessed baseline disease severity utilizing an objective measure/tool; and

b. Documented moderate to severe active disease; and

c. Used in combination with methotrexate unless the recipient has contraindication or intolerance; and

1. Recipient tried and failed at least three-month trial with one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.); or

2. Recipient is already established on biologic or targeted synthetic therapy for the treatment of RA; and

d. Previous failure with one or more TNF antagonists; and

e. Physician has assessed baseline disease severity utilizing an objective measure/tool; and

f. Recipient has not had treatment with rituximab in the previous four months.

21. Pemphigus Vulgaris

a. Recipient has a diagnosis of pemphigus vulgaris as determined by the following:

1. Recipient has one or more of the following clinical features:

a. Appearance of lesions, erosions, and/or blisters

b. Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)

c. Characteristic scarring and lesion distribution; and

b. Histopathologic confirmation by skin/mucous membrane biopsy; and

c. Positive direct immunofluorescence (DIF) microscopy result or presence of autoantibodies as detected by indirect immunofluorescence (IIF) or enzyme-linked immunosorbent assay (ELISA); and

d. Recipient has moderate to severe disease as assessed utilizing an objective measure tool (i.e., PDAI, PSS, ABSIS, etc.); and

e. Used in combination with glucocorticoids (e.g., prednisone, prednisolone, etc.); and

f. Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out.

22. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

a. Recipient is at least two years of age; and

b. Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone, etc.).

23. Thrombocytopenic Purpura

a. Diagnosis includes one of the following:

1. Primary thrombocytopenia or idiopathic (immune) thrombocytopenia purpura (ITP).

2. Evans syndrome; and

b. Recipient has previously failed or has a contraindication or intolerance to therapy with corticosteroids; and

c. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) $<30 \times 10^9$/L (30,000mm (3)); and

24. Thrombotic Thrombocytopenic Purpura (TTP)

a. Recipient has immune-mediated or acquired disease with ADAMTS13-deficiency; and

1. Used in combination with corticosteroids and therapeutic plasma exchange (TPE); or

2. Used as a single agent as prophylactic therapy for recipients in remission.

25. Multiple Sclerosis (MS)

a. Recipient must have a confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); and

b. Recipient has a diagnosis of a relapsing form of MS [i.e., RRMS, active SPMS, or CIS]

26. Autoimmune Hemolytic Anemia (AIHA)

a. Recipient has warm-reactive disease refractory to or dependent on glucocorticoids; or

b. Recipient has cold agglutinin disease with symptomatic anemia, transfusion-dependence and/or disabling circulatory symptoms.

27. Systemic Lupus Erythematosus (SLE)

a. Recipient has a confirmed diagnosis of SLE as evidenced by all of the following:

1. Confirmed SLE classification criteria score >10 (Note: must include clinical and immunologic domains criteria)

2. Anti-nuclear antibody (ANA) titer of >1:80 measured via IIF on human epithelial (HEp-2) cells (or an equivalent ANA positive test) at least once; and

b. Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K), British Isles Lupus Assessment Group 2004 (BILAG 2004) and/or Physician's Global Assessment (PGA) score); and

c. Recipient has failed to respond adequately to at least two standard therapies such as anti-malarials (i.e., hydroxychloroquine, chloroquine), corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, immunosuppressives (i.e., azathioprine, methotrexate, calcineurin inhibitors [cyclosporine, tacrolimus, voclosporin], oral cyclophosphamide, or mycophenolate); and

d. Recipient has moderate to severe active disease as defined by one of the following:

1. SLEDAI 2K score of >6

2. Disease activity with >2 systems with BILAG 2004 B scores

3. >1 system(s) with BILAG A score(s)

28. Lupus Nephritis (LN)

a. Recipient has disease that is non-responsive or refractory to standard first-line therapy (e.g., mycophenolate mofetil,

mycophenolic acid, cyclophosphamide, calcineurin inhibitors [e.g., tacrolimus, voclosporin, cyclosporine, etc.]); and

b. Used as a single agent or add-on therapy in combination with mycophenolate mofetil, mycophenolic acid, cyclophosphamide.

29. Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

a. Recipient has muscle-specific tyrosine kinase (MuSK)-antibody positive disease; and

b. Recipient is refractory to standard first-line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)

30. Complications of Transplanted Solid Organ (kidney, liver, lung, heart, pancreas) in Adult and Pediatric Recipients

a. Used for suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation; or

b. Used for treatment of antibody-mediated rejection of solid organ transplantation.

31. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has confirmed diagnosis based on the following:

1. Recipient is seropositive for aquaporin-4 (AQP-4) IgG antibodies; and

a. Recipient has at least one core clinical characteristic; and

b. Alternative diagnoses have been excluded (e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), MS, sarcoidosis, cancer, chronic infection, etc.); or

2. Recipient is seronegative for AQP-4 IgG antibodies or has unknown AQP-4-IgG status; and

a. Recipient has at least two core clinical characteristics occurring as a result of one or more clinical attacks; and

b. Recipient experienced all of the following:

1. At least one core clinical characteristic must be optic neuritis, acute myelitis with LETM, or area postrema syndrome

2. Fulfillment of additional MRI requirements for each area affected; and

c. Alternative diagnoses have been excluded (e.g., MOGAD, MS, sarcoidosis, cancer, chronic infection, etc.); and

b. Used as a single agent or in combination with immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate, etc.).

32. Antisynthetase Syndrome-Related Interstitial Lung Disease

a. Recipient has antisynthetase antibody positive disease (e.g., anti-Jo-1, -PL-7, -PL-12, -OJ, -EJ, etc.); and

b. Physician has assessed baseline disease severity utilizing an objective measure (i.e., baseline glucocorticoid use, pulmonary function testing [i.e., FVC%, total lung capacity (TLC%), diffusing capacity of the lungs for carbon monoxide (DLCO%)], or chest CT scan); and

c. Recipient has documented severe active disease; and

d. Recipient has recurrent or progressive disease despite treatment with glucocorticoids and/or other immunosuppressive agents (e.g., azathioprine, mycophenolate mofetil, cyclophosphamide, tacrolimus, etc.); and

e. Will be used in combination with glucocorticoids or other immunosuppressive agents (e.g., azathioprine, mycophenolate mofetil, cyclophosphamide, tacrolimus, etc.), unless the recipient has a contraindication or intolerance.

33. Idiopathic Membranous Nephropathy

a. Recipient has a documented diagnosis of idiopathic (primary) membranous nephropathy; and

b. Secondary causes of membranous nephropathy have been ruled out [e.g., infections, autoimmune diseases, malignancies, nutritional supplements (e.g., lipoic acid, etc.), NSAIDs, etc.]; and

1. Used as first-line therapy in recipient with any of the following moderate to high risk factors for progressive disease:

   a. Proteinuria >3.5 g/day and no decrease >50% after six months of therapy with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB); or

   b. eGFR <60 mL/min/1.73m2; or

   c. Proteinuria >8 g/d for >6 months; or

   d. Recipient has experienced serious complications of nephrotic syndrome (e.g., acute kidney injury, infection, thromboembolic events, etc.); or

2. Used for initial disease relapse following remission on first-line therapy with rituximab, a calcineurin inhibitor (e.g., tacrolimus, cyclosporine, etc.) or cyclophosphamide in combination with glucocorticoids; or

3. Used for treatment-resistance to first-line therapy with rituximab, a calcineurin inhibitor (e.g., tacrolimus, cyclosporine, etc.) or cyclophosphamide in combination with glucocorticoids; and

   a. Recipient has a stable eGFR; and

   b. Will be used in combination with a calcineurin inhibitor if previously treated with rituximab alone in the first-line setting; or

4. Used for disease recurrence following kidney transplant; and

   1. Recipient has proteinuria >1 g/d.

34. Pediatric Idiopathic Nephrotic Syndrome

   a. Recipient is 12 years of age or younger

   b. Recipient has symptomatic disease (i.e., nephrotic-range proteinuria and either hypoalbuminemia or edema when albumin level is not available)

c. Recipient has been diagnosed with one of the following:

1. Frequently relapsing nephrotic syndrome (FRNS) with at least four relapses per year or at least two relapses within six months of initial presentation

2. Steroid dependent nephrotic syndrome (SDNS) with two consecutive relapses during steroid tapering or within 14 days of cessation of therapy

3. Steroid resistant nephrotic syndrome (SRNS) with failure to achieve complete remission within a 4-6-week course of daily corticosteroids; and

d. Recipient has failed an adequate trial with at least one other steroid-sparing agent (e.g., cyclophosphamide, calcineurin inhibitor [e.g., tacrolimus, cyclosporine, etc.], mycophenolate mofetil, etc.)

35. IgG4-Related Disease

a. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., IgG4-RD Responder Index score, PGA, amount of glucocorticoid or other immunosuppressive use, incidence of disease flares, serum IgG4 level, etc.); and

b. Other conditions that mimic IgG4-related disease have been ruled out (e.g., malignancy, infection, other autoimmune disorders, etc.); and

c. Recipient has documented active disease; and

d. Documented failure or ineffective response to an adequate trial with glucocorticoids, unless there is a contraindication or intolerance to use.

b. Dosage Limits

1. Max units (per dose and over time) [HCPCS Unit]:

a. Oncology Indications

1. CLL/SLL:

a. Initial therapy:

1. Loading dose: 100 billable units x one dose

2. Subsequent doses: 130 billable units every 28 days x five doses per six months

b. Renewal therapy: 130 billable units every eight weeks.

2. ALL

a. 100 billable units twice weekly x 18 doses.

3. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma

a. Initial therapy: 100 billable units weekly x 12 doses

b. Renewal therapy: 400 billable units every six months

4. Central Nervous System (CNS) Cancers

a. Initial therapy: 190 billable units weekly x eight doses

b. Renewable therapy: 400 billable units every six months

5. Hairy Cell Leukemia

a. 100 billable units weekly x eight doses, 100 billable units every 14 days x eight doses, then 100 billable units every 28 days x four doses.

6. Histiocytic Neoplasms – Rosai-Dorfman Disease

a. 130 billable units weekly x six doses in a six-month period.

7. Pediatric Hodgkin Lymphoma

a. 100 billable units x three doses.

8. Chronic Graft Versus Host Disease (cGvHD)

a. 100 billable units weekly x 12 doses.

9. Hematopoietic Cell Transplantation

a. Initial dose: 100 billable units x one dose before transplant

b. Subsequent doses: 250 billable units x three doses after transplant.

10. All other oncology indications:

a. Initial therapy: 100 billable units weekly x eight doses per six months

b. Renewal therapy: 400 billable units every six months.

b. Non-Oncology Indications

1. Rheumatoid Arthritis (RA):

a. 100 billable units every 14 days x two doses in an 18-week period.

2. Multiple Sclerosis (MS):

a. 100 billable units every 14 days x two doses every six months.

3. Pemphigus Vulgaris (PV):

a. Initiation: 100 billable units weekly x four doses in a 12-month period

b. Maintenance: 50 billable units every 16 weeks.

4. GPA(WG)/MPA:

a. Induction: 100 billable units weekly x four doses in a 20-week period

b. Initial Maintenance: 100 billable units x two doses in a six-month period

c. Subsequent Maintenance: 100 billable units every six months.

5. All other non-oncology indications:

a. 400 billable units every six-months.

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), HPV reactivation, serious infections (bacterial, fungal, or viral), cardiovascular adverse reactions (e.g., ventricular fibrillation, myocardial infarction, cardiogenic shock, cardiac arrhythmias), renal toxicity, bowel obstruction or perforation, etc.; and

4. Oncology Indications

   a. Recipient has not exceeded dosing or duration limits as defined in Section I, II, and V; and

5. Adult Acute Lymphoblastic Leukemia (ALL)

   a. Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, quantitative polymerase chain reaction (QPCR), or fluorescence in situ hybridization (FISH).

6. All Other Oncology Indications

   a. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

7. Non-Oncology Indications

   a. Rheumatoid Arthritis (RA)

      1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of recipient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more of a ≥20% improvement on the American College of

Rheumatology-20 (ARC20) criteria or improvement of disease severity on RAPID3 assessment]; and

2. Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the recipient has:

a. Shown an initial response to therapy; and

b. Received a minimum of one maintenance dose at the dose and interval specified below; and

c. Responded to therapy with subsequent loss of response

b. Thrombocytopenic Purpura (ITP or Evan's Syndrome)

1. Disease response as indicated by the achievement and maintenance of a platelet count of at least 50 x $10^9$/L and at least doubling the baseline platelet count

c. Thrombotic Thrombocytopenic Purpura (TTP)

1. Disease response as indicated by an increase in ADAMTS13 activity with a reduction in thrombotic risk

d. Multiple Sclerosis (MS)

1. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in ARR, development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, T25-FW, 9-HPT]

e. Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)

1. Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; and

2. Decreased frequency in the occurrence of major relapse (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)

f. Pemphigus Vulgaris

1. Recipient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; and

a. Disease response as indicated by one of the following:

1. Complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline

2. Recipient has not developed new lesions and established lesions begin to heal

b. For Relapses only:

1. Recipient previously achieved disease control; and

2. Recipient has the appearance of three or more new lesions a month that do not heal spontaneously within one week, or by the extension of established lesions

g. Autoimmune Hemolytic Anemia (AIHA)

1. Disease response as indicated by improvement in signs of anemia (e.g., dyspnea, fatigue, etc.); and

2. Recipient has had an improvement in laboratory values (e.g., hemoglobin, hematocrit, etc.), reduced transfusion needs, and/or reduced glucocorticoid use

h. Systemic Lupus Erythematosus (SLE)

1. Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:

a. Improvement in the SELENA-SLEDAI-2K; or

b. Reduction of baseline BILAG-2004 (e.g., from A to B or from B to C/D, and no BILAG-2004 worsening

in other organ systems, as defined by ≥2 new BILAG-2004 B or ≥ new BILAG-A); or

c. No worsening (<0.30 points increase) in PGA score; or

d. Seroconverted (negative)

i. Lupus Nephritis

1. Coverage may only be renewed in recipients experiencing a disease relapse (e.g., increased serum creatinine, increase in protein urine excretion, decrease in eGFR, etc.)

j. Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

1. Disease response as indicated by a decrease in the daily dose of corticosteroids and/or an improvement in signs and symptoms compared to baseline

k. NMOSD

1. Disease response as indicated by stabilization/improvement in any of the following:

a. Decrease in acute relapses or improvement of stability

b. Reduced hospitalizations

c. Reduction/discontinuation in plasma exchange treatments

d. Reduction/discontinuation of corticosteroids without relapse.

l. Antisynthetase Syndrome-Related Interstitial Lung Disease

1. Disease response as indicated by stabilization/improvement in any of the following:

a. Reduction or stabilization of glucocorticoid use from baseline

b. Improvement or stabilization of pulmonary function testing (i.e., improvement defined as >10%

increase in FVC%, TLC%, or DLCO%; stabilization defined as <10% decrease in FVC%, TLC%, or DLCO%)

c. Improvement or stabilization of chest CT score (improvement defined as >10% decrease in CT score, stabilization defined as a <10% increase in CT score)

m. Idiopathic Membranous Nephropathy

1. Recipient experienced beneficial disease response with improvement in symptoms and/or other objective measures compared to baseline (e.g., reduction in proteinuria, increase and/or normalization of serum albumin, improvement/stability of serum creatinine and/or eGFR, decrease in anti-PLA2R antibody levels, etc.); or

2. Recipient has resistant disease following first-line therapy with rituximab; and

a. Recipient has stable eGFR; and

b. Will be used in combination with a calcineurin inhibitor if previously treated with rituximab alone in the first-line setting

n. Pediatric Idiopathic Nephrotic Syndrome

1. Recipient previously achieved beneficial disease response from the prior course of therapy; and

2. Recipient is experiencing signs and symptoms of recurrent active disease necessitating additional doses (e.g., recurrence of nephrotic-range proteinuria with a dipstick >3+ [>300 mg/dL] for three consecutive days or urinary protein creatinine ratio [UPCR] ≥200 mg/mmol [≥2 mg/mg] on a spot urine sample on three consecutive days, with or without reappearance of edema in a child who had previously achieved complete remission)

o. IgG4-Related Disease

1. Recipient experienced beneficial disease response with improvement in involved organ-related symptoms and/or other objective measures compared to baseline (e.g.,

improvement in the IgG4-RD Responder Index score of >2 points, improvement in the PGA, reduction in glucocorticoid or other immunosuppressive use, reduction of disease flares, reduction in serum IgG4 level, etc.); and

2. Recipient meets one of the following:

a. Ongoing maintenance therapy is required due to recipient having a high-risk of relapse

b. Recipient is experiencing signs and symptoms of relapsed active disease necessitating an additional course of therapy.

d. PA Guidelines

1. Coverage will be provided for six months (12 months initially for pemphigus vulgaris) and may be renewed unless otherwise specified.

a. Maintenance therapy for oncology indications may be renewed for up to a maximum of two years, unless otherwise specified:

b. Adult ALL may be renewed for a maximum of 18 doses.

c. Mantle Cell Lymphoma may be renewed until disease progression or intolerable toxicity.

d. Hairy Cell Leukemia may be renewed for up to a maximum of 12 doses.

e. Induction/Consolidation of Pediatric B-Cell Acute Leukemia and Aggressive Mature B-Cell Lymphomas may not be renewed.

f. Pediatric Hodgkin Lymphoma may not be renewed.

g. Management of Immunotherapy-Related Toxicities:

1. Myositis/Myasthenia Gravis/Encephalitis may not be renewed.

2. Bullous Dermatitis may be renewed for a maximum of 18 months (four total doses).

h. Relapse therapy for Pemphigus Vulgaris must be at least 16 weeks past a prior infusion.

i. Chronic Graft Versus Host Disease (cGvHD) may be renewed for up to a maximum of 12 doses.

j. Hematopoietic Cell Transplantation (HCT) may not be renewed.

k. Lupus Nephritis and Pediatric Idiopathic Nephrotic Syndrome may be renewed only in recipient experiencing a disease relapse.

l. Complications of Transplanted Solid Organ may not be renewed.

2. Rituxan Hycela® (rituximab and hyaluronidase human)

a. Approval will be given if the following criteria are met and documented:

1. Recipient is at least 18 years of age; and

2. Recipient has received at least one full dose of a rituximab product by IV infusion prior to initiating therapy; and

3. Universal Criteria

a. Recipient does not have a severe, active infection; and

b. Recipient has been screened for the presence of HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and recipients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; and

c. Recipient is CD20 antigen expression positive; and

d. Rituxan Hycela will not be used with IV chemotherapy agents; and

e. Recipient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; and

4. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

5. B-Cell Lymphomas

a. Follicular Lymphoma (FL)

b. Diffuse Large B-Cell Lymphoma (DLBCL)

c. High Grade B-Cell Lymphomas

d. Extranodal Marginal Zone Lymphoma (EMZL) of the Stomach and Nongastric Sites (Noncutaneous)

e. Nodal and Splenic Marginal Zone Lymphoma

f. Mantle Cell Lymphoma

g. Histologic transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma (DLBCL)

h. Post-Transplant Lymphoproliferative Disorders (PTLD)

6. Castleman Disease

7. Hairy Cell Leukemia

8. Primary Cutaneous B-Cell Lymphoma

9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

10. Adult Hodgkin Lymphoma

a. Recipient has nodular lymphocyte predominant disease

b. Dosage Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

a. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL):

1. Initial Therapy:

a. 160 billable units every 28 days x five doses

2. Renewal Therapy: 160 billable units every eight weeks (maintenance treatment)

a. Hairy Cell Leukemia

1. 140 billable units weekly up to seven doses

2. 140 billable units every 14 days x seven doses, then 140 billable units every 28 days x four doses

b. Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma

1. Initial Therapy 140 billable units weekly (up to 18 doses)

c. Other indications:

1. Initial Therapy:140 billable units weekly up to 18 doses.

2. Renewal Therapy: 140 billable units every eight weeks (maintenance treatment).

c. Recertification Request

1. Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity or other administration reactions (i.e., local cutaneous reactions), TLS, severe mucocutaneous reactions, PML, HBV reactivation, serious bacterial, fungal, or viral infections, cardiac adverse reactions, renal toxicity, bowel obstructions or perforation, etc.; and

c. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. Recipient has not exceeded dosing or duration limits as defined in Sections I, II, and V.

d. PA Guidelines

1. Coverage will be provided for six months and may be renewed unless otherwise specified.

2. Maintenance therapy for Mantle Cell Lymphoma may be renewed until disease progression or intolerable toxicity

3. Hairy Cell Leukemia may be renewed up to a maximum of 11 doses.

4. Maintenance therapy for all other indications may be renewed for up to a maximum of two years.

Q. Selective Immunosuppressants

Therapeutic Class: Selective Immunosuppressants
Last Reviewed by the DUR Board: July 19, 2024

Selective Immunosuppressants are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Soliris® (eculizumab)

   a. Coverage is provided in the following conditions:

      1. Recipient is at least 18 years of age (unless otherwise specified); and

      2. Universal Criteria

         a. Recipient must be vaccinated against meningococcal infection (serogroups A, C, W, Y, and B) according to current Advisory Committee on Immunization Practices (ACIP) recommendations at least two weeks prior to initiation of therapy and will continue to revaccinate in accordance with ACIP recommendations (if urgent Soliris® therapy is indicated in a recipient who is not up-to-date with meningococcal vaccines according to ACIP recommendations, provide the recipient with antibacterial drug prophylaxis and administer the vaccines as soon as possible); and

         b. Recipient does not have an unresolved, serious systemic infection (e.g., Neisseria meningitidis, etc.); and

         c. Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, efgartigimod-hyaluronidase, ravulizumab, pegcetacoplan, satralizumab, tocilizumab, inebilizumab, rozanolixizumab, rituximab, zilucoplan, pozelimab, etc.).

      3. Paroxysmal Nocturnal Hemoglobinuria (PNH)

         a. Diagnosis must be accompanied by detection of PNH clones of at least 10% by flow cytometry diagnostic testing; and

            1. Recipient has at least two different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least two different cell lines (e.g., granulocytes, monocytes, erythrocytes); and

b. Recipient has laboratory evidence of significant intravascular hemolysis (i.e., lactate dehydrogenase (LDH) ≥1.5 x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):

1. Recipient has symptomatic anemia (i.e., hemoglobin <7 g/dL or hemoglobin <10 g/dL, in at least two independent measurements in a recipient with cardiac symptoms

2. Presence of a thrombotic event related to PNH

3. Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency pulmonary insufficiency/ hypertension)

4. Recipient is pregnant and potential benefit outweighs potential fetal risk

5. Recipient has disabling fatigue

6. Recipient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; and

c. Documented baseline values for one or more of the following (necessary for renewal): serum LDH, hemoglobulin level, packed RBC transfusion requirement, and history of thrombotic events; and

d. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

4. Atypical Hemolytic Uremic Syndrome (aHUS)

a. Recipient is at least two months of age; and

b. Recipient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); and

c. TTP has been ruled out by evaluating ADAMTS-13 level (i.e., ADAMTS-13 activity level ≥10%); and

d. Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out; and

e. Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ

transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis or known genetic defect in cobalamin C metabolism, etc.); and

f. Documented baseline values for one or more of the following (necessary for renewal): serum LDH, serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement; and

g. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

5. Generalized Myasthenia Gravis (gMG)

a. Recipient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and

b. Recipient has a positive serologic test for AChR antibodies; and

c. Recipient has had a thymectomy (Note: Applicable only to recipients with thymomas or non-thymomatous recipients who are 50 years of age or younger); and

d. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); and

e. Recipient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; and

1. Recipient had an inadequate response after a minimum one-year trial of concurrent use with two or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

2. Recipient required chronic treatment with plasmapheresis or plasma exchange (PE) or IVIG in addition to immunosuppressant therapy

f. Recipient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); and

g. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

6. NMOSD

a. Recipient has a confirmed diagnosis based on the following:

1. Recipient was found to be seropositive for AQP4 IgG antibodies; and

2. Recipient has at least one core clinical characteristics; and

3. Alternative diagnoses have been excluded (e.g., MS, sarcoidosis, cancer, chronic infection, etc.); and

b. Recipient has a history of at least two relapses in the last 12 months or three relapses in the 24 months, with at least one relapse in the last 12 months; and

c. Recipient has an EDSS of ≤7; and

d. Recipient is receiving concurrent corticosteroid therapy of 20 mg per day or less and those receiving immunosuppressive therapy (e.g., azathioprine, glucocorticoids, mycophenolate, etc.) are on a stable dose regimen; and

e. Recipient has not received therapy with rituximab or mitoxantrone in the last three months; and

f. Received has not received IVIG in the last three weeks; and

g. Recipient had an inadequate response, or has a contraindication or intolerance, to rituximab or inebilizumab (Uplizna®); and

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:
Soliris® 300 mg/30 mL single-dose vials

a. Loading Doses:

1. Three vials Days one, eight, 15, and 22; then four vials Day 29

b. Maintenance Doses:

1. Four vials every 14 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Indication: PNH

1. Loading Doses: 60 billable units Days one, eight, 15, and 22; then 90 billable units Day 29

2. Maintenance Dose: 90 billable units every 14 days

b. Indication: aHUS, gMG, NMOSD

1. Loading Doses: 90 billable units Day one, eight, 15, and 22; then 120 billable units Day 29

2. Maintenance Dose: 120 billable units every 14 days.

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.; and

3. PNH

a. Recipient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) or experienced a spontaneous disease remission or received curative allogeneic stem cell transplant; and

b. Disease response compared to pre-treatment baseline as indicated by one or more of the following:

1. Decrease in serum LDH

2. Stabilization/improvement in hemoglobin level

3. Decrease in packed RBC transfusion requirement (i.e., reduction of at least 30%)

4. Reduction in thromboembolic events.

4. aHUS

a. Disease response compared to pre-treatment baseline as indicated by one or more of the following:

1. Decrease in serum LDH

2. Stabilization/improvement in serum creatinine/eGFR

3. Increase in platelet count

4. Decrease in plasma exchange/infusion requirement.

5. gMG

a. Recipient experienced an improvement (i.e., reduction) of at least one-point from baseline in the MG-ADL total score; and

b. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline.

6. NMOSD

a. Disease response as indicated by stabilization and/or improvement in one or more of the following:

1. Neurologic symptoms as evidenced by a decrease in acute relapses, improvement of stability, or improvement in EDSS

2. Reduced hospitalizations

3. Reduction/discontinuation in plasma exchange treatments.

c. PA Guidelines

1. PNH and aHUS: Initial approval will be given for 12 months and may be renewed.

2. gMG and NMOSD: Initial approval will be given for six months and may be renewed annually thereafter,

2. Ultomiris® (ravulizumab-cwvz)

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age (unless otherwise specified); and

2. Confirmation that recipient does not have an unresolved serious Neisseria meningitidis infection prior to initiating therapy; and

3. Universal Criteria

a. Prescriber is enrolled in the Ultomiris® and Soliris® Risk Evaluation and Mitigation Strategy (REMS) program; and

b. Recipient must be vaccinated against meningococcal infection (serogroups A, C, W, Y, and B) according to current ACIP recommendations at least two weeks prior to initiation of therapy and will continue to be revaccinated in accordance with ACIP recommendations (Note: If urgent Ultomiris® therapy is indicated in a recipient who is not up-to-date with meningococcal vaccines according to ACIP recommendations, provide the recipient with antibacterial drug prophylaxis and administer these vaccines as soon as possible); and

c. Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, efgartigimod-hyaluronidase, eculizumab, pegcetacoplan, satralizumab, tocilizumab, inebilizumab, rozanolixizumab, rituximab, zilucoplan, pozelimab, etc.); and

4. PNH

a. Recipient is at least one month of age; and

b. Used as switch therapy; and

1. Recipient is currently receiving treatment with eculizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

c. Recipient is complement inhibitor treatment-naïve; and

1. Diagnosis must be accompanied by detection of PNH clones of at least 5% by flow cytometry diagnostic testing; and

a. Recipient has at least two different GPI protein deficiencies (e.g., CD55, CD59, etc.) within at least two different cell lines (e.g., granulocytes, monocytes, erythrocytes); and

b. Recipient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥1.5 x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):

1. Recipient has symptomatic anemia (i.e., hemoglobin <7 g/dL or hemoglobin <10 g/dL, in at least two independent measurements in a recipient with cardiac symptoms

2. Presence of a thrombotic event related to PNH

3. Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension)

4. Recipient is pregnant and potential benefit outweighs potential fetal risk

5. Recipient has disabling fatigue

6. Recipient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; and

c. Documented baseline values for one or more of the following (necessary for renewal); serum LDH, hemoglobin level, packed RBC transfusion requirement, and history of thrombotic events.

5. aHUS

a. Recipient is at least one month of age; and

b. Used as switch therapy; and

1. Recipient is currently receiving treatment with eculizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

c. Recipient is complement inhibitor treatment-naïve; and

1. Recipient shows signs of TMA (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); and

2. TTP has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level ≥10%); and

3. STEC-HUS has been ruled out; and

4. Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis or known genetic defect in cobalamin C metabolism, etc.); and

5. Documented baseline values for one or more of the following (necessary for renewal); serum LDH, serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement.

6. gMG

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with eculizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

b. Recipient is complement inhibitor treatment-naïve; and

1. Recipient is at least 18 years of age; and

2. Recipient has MGFA Clinical Classification of Class II to IV disease; and

3. Recipient has a positive serologic test for AChR antibodies; and

4. Recipient has had a thymectomy (Note: Applicable only to recipients with thymomas or non-thymomatous recipients who are 50 years of age or younger); and

5. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the QMG score, etc.); and

6. Recipient has a MG-ADL total score of ≥6; and

a. Recipient has had an inadequate response after a minimum one-year trial of concurrent use with two or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

b. Recipient required chronic treatment with plasmapheresis or PE or IVIG in addition to immunosuppressant therapy; and

7. Recipient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.).

7. NMOSD

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with eculizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

b. Recipient is complement inhibitor treatment-naïve; and

1. Recipient has a confirmed diagnosis based on the following:

a. Recipient was found to be seropositive for AQP4 IgG antibodies; and

b. Recipient has at least one core clinical characteristic (Note: some core clinical characteristics require both clinical and typical MRI findings); and

c. Alternative diagnoses have been excluded [e.g., MOGAD, MS, sarcoidosis, cancer, chronic infection, etc.]; and

2. Recipient has a history of at least one relapse in the last 12 months; and

3. Recipient has an EDSS of ≤7.0; and

4. Recipients who are receiving concurrent immunosuppressive therapy (e.g., corticosteroids, azathioprine, mycophenolate mofetil, methotrexate, tacrolimus, etc.) are on a stable dose regimen; and

5. Recipient has not received therapy with rituximab or mitoxantrone in the last three months; and

6. Recipient has not received IVIG in the last three weeks.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Ultomiris® 10 mg/mL – 30 mL SDV: 10 vials on day zero followed by 13 vials starting on day 14 and every eight weeks thereafter

b. Ultomiris® 100 mg/mL – 3 mL SDC: 10 vials on day zero followed by 13 vials starting on day 14 and every eight weeks thereafter

c. Ultomiris® 100 mg/mL – 11 mL SDV: three vials on day zero followed by three vials starting on day 14 and every eight weeks thereafter

d. Ultomiris® 245 mg/3.5 mL single-dose cartridge on-body delivery system: two on-body delivery systems weekly.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Ultomiris® IV

1. PNH/aHUS/gMG: 300 units on Day 0 followed by 360 units on Day 14 and every eight weeks thereafter

b. Ultomiris® SQ

1. PNH/aHUS: 49 units weekly.

c. Recertification Request

Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet the universal and other indication-specific relevant criteria identified in Section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious meningococcal infections (septicemia and/or meningitis), infusion-related reactions, other serious infections, etc.; and

3. PNH

a. Recipient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) or experienced a spontaneous disease remission or received curative allogeneic stem cell transplant; and

b. Disease response compared to pre-treatment baseline as indicated by one or more of the following:

1. Decrease in serum LDH

2. Stabilization/improvement in hemoglobin level

3. Decrease in packed RBC transfusion requirement (i.e., reduction of at least 30%)

4. Reduction in thromboembolic events.

4. aHUS

a. Disease response compared to pre-treatment baseline indicated by one or more of the following:

1. Decrease in serum LDH

2. Stabilization/improvement in serum creatinine/eGFR

3. Increase in platelet count

4. Decrease in plasma exchange/infusion requirement.

5. gMG

a. Recipient experienced an improvement (i.e., reduction) of at least one-point from baseline in the MG-ADL total score; and

b. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline

6. Switch therapy from eculizumab to ravulizumab

a. Refer to Section III for criteria

7. NMOSD

a. Disease response as indicated by stabilization/improvement in one or more of the following:

1. Neurologic symptoms as evidenced by a decrease in acute relapses, improvement of stability, or improvement in EDSS

2. Reduced hospitalization

3. Reduction/discontinuation in plasma exchange treatments

d. PA Guidelines

1. Initial approval will be given for 12 months and may be renewed.

R. Yervoy® (ipilimumab)

Therapeutic Class: Anti-CLTA-4 Monoclonal Antibodies
Last Reviewed by the DUR Board: January 16, 2025

Yervoy® (ipilimumab) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   Coverage is provided in the following conditions

   a. Recipient is at least 18 years of age, unless otherwise specified; and

   b. Ampullary Adenocarcinoma

      1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA compliant test; and

      2. Used in combination with nivolumab; and

         a. Used as first-line therapy for unresectable or metastatic intestinal type disease; or

         b. Used as subsequent therapy for disease progression.

   c. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

      1. Used in combination with nivolumab; and

      2. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

         a. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

         b. Disease is refractory to standard therapies or there are no standard treatment options available

      3. Used as neoadjuvant therapy for resectable locoregionally advanced (Note: Only applies to Gallbladder Cancer); and

         a. Recipient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; or

b. Recipient has incidental finding on pathologic review (cystic duct node positive); or

c. Recipient has mass on imaging

d. Bone Cancer

1. Recipient has one of the following: Ewing sarcoma, Chondrosarcoma (excluding mesenchymal chondrosarcoma), Osteosarcoma, or Chordoma; and

2. Recipient has TMB-H tumors [≥10 mut/Mb] as determined by an FDA-approved or CLIA-compliant test; and

3. Used in combination with nivolumab; and

4. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

5. Recipient has no satisfactory alternative treatment options.

e. Central Nervous System (CNS) Cancer

1. Used for the treatment of brain metastases in recipients with BRAF non-specific melanoma; and

2. Used in combination with nivolumab or as a single agent; and

a. Used as initial treatment in recipients with small asymptomatic brain metastases; or

b. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

c. Used for recurrent limited brain metastases; or

d. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

f. Colorectal Cancer (CRC)

1. Recipient is at least 12 years of age; and

2. Recipient's disease is MSI-H/ dMMR disease or POLE/POLD1 mutation as determined by an FDA-approved or CLIA-compliant test; and

3. Used in combination with nivolumab (if candidate for intensive therapy); and

a. Used as subsequent therapy; and

1. Recipient has metastatic, unresectable, or medically inoperable disease; or

b. Used as primary or initial treatment; and

1. Used for isolated pelvic/anastomotic recurrence of rectal cancer; or

2. Recipient has T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; or

3. Recipient has metastatic, unresectable, or medically inoperable disease; or

c. Used as neoadjuvant therapy; and

1. Recipient has clinical T4b colon cancer (dMMR/MSI-H disease only); or

2. Recipient has resectable liver and/or lung metastases

g. Appendiceal Adenocarcinoma – Colon Cancer

1. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation as determined by an FDA approved or CLIA-compliant test; and

2. Used in combination with nivolumab (if candidate for intensive therapy); and

3. Used for advanced or metastatic disease; and

a. Used as primary or initial treatment; or

b. Used as subsequent treatment.

h. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

1. Used in combination with nivolumab; and

a. Used as first-line therapy; and

1. Recipient has SCC; and

a. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease.

2. Recipient has adenocarcinoma; and

a. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; and

b. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy; and

1. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

2. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

c. Used as neoadjuvant or perioperative therapy; and

1. Recipient has adenocarcinoma; and

2. Used as primary treatment for recipient who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; and

3. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test.

d. Used as induction systemic therapy for relieving dysphagia; and

1. Recipient has MSI-H or dMMR disease as determined by an FDA approved or CLIA-compliant test; and

2. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease

i. Gastric Cancer

1. Used in combination with nivolumab; and

2. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

a. Used as first-line or subsequent therapy; and

b. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; or

c. Used as neoadjuvant or perioperative therapy; and

1. Used as primary treatment prior to surgery for potentially resectable locoregional disease (cT2 or higher, any N) in recipients who are medically fit for surgery

d. Used as systemic therapy for early-stage disease; and

1. Recipient has endoscopic features suggestive of deep submucosal invasion including converging folds, irregular surface pattern, and ulceration in a large gastric mass with favorable histology; and

2. Recipient has completed an endoscopic resection.

j. Hepatocellular Carcinoma (HCC)

1. Used in combination with nivolumab; and

2. Used as subsequent therapy; and

a. Recipient was previously treated with sorafenib; or

b. Recipient has liver-confined, unresectable disease and is deemed ineligible for a transplant; or

c. Recipient has extrahepatic/metastatic disease and deemed ineligible for resection, transplant, or locoregional therapy.

k. Kaposi Sarcoma

1. Used in combination with nivolumab as subsequent therapy; and

2. Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

3. Disease progressed on or did not respond to first-line therapy; and

4. Disease progressed on alternate first-line therapy

l. Renal Cell Carcinoma (RCC)

1. Used in combination with nivolumab for clear cell histology; and

a. Used as first-line therapy in recipients with poor or intermediate risk advanced, relapsed, or stage IV disease; or

b. Used as first-line therapy in recipients with favorable risk relapsed or stage IV disease; or

c. Used as subsequent therapy in recipients with relapsed or stage IV disease.

m. Peritoneal Mesothelioma (PeM)

1. Used in combination with nivolumab; and

a. Used as subsequent therapy (if chemotherapy was administered first-line); or

b. Used as first-line therapy; and

1. Used as adjuvant treatment for medically operable disease, following CRS and HIPEC; and

a. Recipient has surgical or pathologic high-risk features; or

2. Recipient has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features; or

3. Recipient has disease recurrence after prior CRS and HIPEC if no previous adjuvant systemic therapy was given; or

n. Pleural Mesothelioma (PM)

1. Used in combination with nivolumab; and

a. Used as subsequent therapy (if chemotherapy was administered first-line); or

b. Used as first-line therapy; or

c. Used as induction therapy prior to surgical exploration

1. Recipient has clinical stage I disease and epithelioid histology

o. Cutaneous Melanoma

1. Used as first-line therapy for unresectable or metastatic disease; and

a. Recipient is at least 12 years of age; and

b. Used as a single agent or in combination with nivolumab; or

2. Used as subsequent therapy for unresectable or metastatic disease; and

a. Used after disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/ binimetinib, etc.); and

1. Used as a single agent in recipients at least 12 years of age if not previously used alone or in combination with anti-PD-1 therapy; or

2. Used in combination with nivolumab in recipient at least 12 years of age if not previously used or for recipients who progress on single agent anti-PD-1 therapy; or

3. Used in combination with pembrolizumab, if not previously used alone or in combination with anti-PD-1 therapy, for recipients who progress on single agent anti-PD-1 therapy; or

b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete or partial response or stable disease) and no residual toxicity from prior use, but subsequently have disease progression/relapse >3 months after treatment discontinuation; and

1. Used as single agent or in combination with anti-PD-1 therapy; and

2. Recipient has completed initial induction ipilimumab therapy (i.e., completion of four cycles within a 16-week period); or

3. Used as adjuvant therapy; and

a. Used as a single agent; and

1. Recipient has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy; or

2. Recipient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); and

a. Recipient has local satellite/in-transit recurrence and has NED after complete excision; or

b. Recipient has resectable disease limited to nodal recurrence following excision of the recurrence and therapeutic lymph node dissection (TLND); or

c. Recipient has oligometastatic disease and NED following metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or following systemic therapy followed by resection; or

b. Used in combination with nivolumab; and

1. Recipient has oligometastatic disease and NED following metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or following systemic therapy followed by resection

4. Used as neoadjuvant therapy; and

a. Used in combination with nivolumab; and

1. Recipient stage III disease; and

a. Used as primary treatment for clinically positive, resectable nodal disease; or

b. Used for limited resectable disease with clinical satellite/in-transit metastases; or

2. Recipient has limited resectable local satellite/in-transit recurrence; or

3. Recipient has resectable disease limited to nodal recurrence.

p. Uveal Melanoma

1. Used as a single agent or in combination with nivolumab; and

2. Recipient has metastatic or unresectable disease.

q. Merkel Cell Carcinoma

1. Used for M1 disseminated disease; and

2. Used as a single agent or in combination with nivolumab; and

3. Recipient progressed on anti-PD-L1 or anti-PD-1 therapy or anti-PD-L1 or anti-PD-1 therapy is contraindicated

r. Non-Small Cell Lung Cancer (NSCLC)

1. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

a. Used as first-line therapy; and

1. Used for one of the following:

a. Recipients with a PS 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 <1%

b. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)

c. PD-L1 expression positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

b. Used in combination with one of the following:

1. Nivolumab

2. Nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); or

c. Used as subsequent therapy; and

1. Used for one of the following:

a. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior target therapy: EGFR exon 19 deletion or L858R tumors, EGFR S7681, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement; or

b. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; and

2. Used in combination with one of the following:

a. Nivolumab

b. Nivolumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology

c. Nivolumab, paclitaxel and carboplatin for squamous cell histology; or

d. Used as continuation maintenance therapy in combination with nivolumab; and

1. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.

s. Small Bowel Adenocarcinoma (SBA)

1. Used in combination with nivolumab; and

2. Recipient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] as detected by an FDA or CLIA compliant test; and

a. Recipient has advanced or metastatic disease; or

b. Recipient has locally unresectable or medically inoperable disease; and

1. Used as primary treatment.

t. STS

1. Extremity/Body Wall, Head/Neck or Retroperitoneal/Intra-Abdominal

a. Used in combination with nivolumab; and

b. Used as subsequent therapy; and

1. Recipient has myxofibrosarcoma, UPS, dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; or

2. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

a. Recipient has no satisfactory alternative treatment options.

u. Pleomorphic Rhabdomyosarcoma

1. Used in combination with nivolumab; and

2. Used as subsequent therapy; and

v. Angiosarcoma

1. Used in combination with nivolumab

w. Gestational Trophoblastic Neoplasia

1. Used in combination with nivolumab; and

2. Recipient has multiagent chemotherapy-resistant disease; and

a. Recipient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); and

1. Recipient has recurrent or progressive disease; or

b. Recipient has high-risk disease (i.e., ≥7 Prognostic score or stage IV disease)

4. Recertification Request

Coverage may be renewed based upon the following criteria:

a. Recipient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe immune-mediated adverse reactions (e.g., colitis, hepatitis, dermatitis/rash, pneumonitis, nephritis/renal dysfunction, endocrinopathies, etc.), severe infusion-related reactions, complications of allogeneic HSCT, etc.; and

d. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

e. Coverage may not be renewed for the following indications:

    1. Ampullary Adenocarcinoma

    2. CRC (subsequent therapy)

    3. Appendiceal Adenocarcinoma (subsequent therapy)

    4. CNS Cancer (combination therapy with nivolumab)

    5. MSI-H/dMMR Gastric, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer

    6. Gastric Cancer

    7. HCC

    8. RCC

    9. Cutaneous Melanoma (first-line or subsequent therapy)

    10. Cutaneous Melanoma (neoadjuvant therapy in combination with nivolumab)

    11. Small Bowel Adenocarcinoma

    12. Uveal Melanoma

f. Cutaneous Melanoma (re-induction therapy)

1. Refer to Section III for criteria (see Cutaneous Melanoma – Used for the retreatment of disease as re-induction)

g. Non-Small Cell Lung Cancer (NSCLC) (continuation maintenance therapy).

1. Refer to Section III for criteria

5. PA Guidelines

a. Coverage will be provided for six months and may be renewed (unless otherwise specified).

b. The following indications may be authorized up to a maximum of 12 weeks of therapy (four doses) and may not be renewed (coverage may be extended to 16 weeks if four doses were not administered within the 12-week time frame)

1. Ampullary Adenocarcinoma

2. Colorectal Cancer (CRC) (neoadjuvant therapy or subsequent therapy)

3. Appendiceal Adenocarcinoma (subsequent therapy/disease progression)

4. CNS Cancer (combination therapy with nivolumab)

5. HCC

6. RCC

7. Cutaneous Melanoma (first-line or subsequent therapy)

8. Cutaneous Melanoma (adjuvant therapy in combination with nivolumab)

9. SBA

10. Uveal Melanoma

c. The following indications may be renewed up to a maximum of two years of therapy (18 doses):

1. Biliary Tract Cancer

2. Bone Cancer

3. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line therapy or induction therapy to relieve dysphagia for SCC

4. Kaposi Sarcoma

5. NSCLC

6. PeM (initial therapy)

7. PM (initial therapy)

d. Gastric Cancer

1. Coverage will be provided for a maximum of 12 weeks (two doses) and may not be renewed for neoadjuvant or perioperative therapy.

2. Coverage will be provided for a maximum of 16 weeks (three doses) and may not be renewed for early-stage disease following endoscopic resection, first-line therapy, or subsequent therapy.

e. MSI-H/dMMR, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancer

1. Coverage will be provided for a maximum of 12 weeks of therapy (two doses) and may not be renewed for neoadjuvant or perioperative therapy.

2. Coverage will be provided for a maximum of 16 weeks (three doses) and may not be renewed for induction therapy for relieving dysphagia, first-line therapy, or subsequent therapy.

f. Cutaneous Melanoma (single agent adjuvant treatment)

1. Coverage will be provided for six months and may be renewed for up to a maximum of three years of maintenance therapy (17 doses total [initial and maintenance doses combined]).

g. Cutaneous Melanoma (neoadjuvant treatment in combination with nivolumab)

1. Coverage will be provided for a maximum of six weeks of therapy (two doses) and may not be renewed.

h. Gallbladder Cancer (neoadjuvant treatment in combination with nivolumab)

1. Coverage will be provided for a maximum of six months of therapy (four doses) and may not be renewed.

S. Zynlonta® (loncastuximab tesirine-lpyl)

Therapeutic Class: Miscellaneous Antineoplastics
Last Reviewed by the DUR Board: July 18, 2024

Miscellaneous Antineoplastics are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented

   a. Recipient is at least 18 years old; and

   b. Universal Criteria

      1. Used as single agent therapy; and

      2. Recipient has not received prior anti-CD19 therapy, (e.g., tafasitamab, axicabtagene, tisagenlecleucel, etc.) or recipient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; and

      3. Recipient does not have active graft-versus-host disease; and

      4. Recipient has not had an ASCT within 30 days or allogeneic stem cell transplant (AlloSCT) with 60 days, prior to start of therapy; and

      5. Recipient does not have active CNS lymphoma (includes leptomeningeal disease); and

      6. Recipient does not have a clinically significant active infection (e.g., Grade 3 or 4 infections); and

      7. Recipient does not have any clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath); and

   c. B-Cell Lymphoma

      1. DLBCL not otherwise specified, DLBCL arising from low grade lymphoma, or HHV8 positive DLCBCL, not otherwise specified

         a. Recipient has received at least two prior lines of therapy; and

         b. Recipient has had no response or partial response or has relapsed, progressive, or refractory disease

      2. Histological Transformation of Indolent Lymphomas (follicular lymphoma or marginal zone lymphoma to DLBCL)

a. Recipient has no intention to proceed to transplant; and

b. Recipient has been previously treated with an anthracycline-based regimen; and

1. Used as additional therapy for partial response, no response, or progressive or relapsed disease following chemoimmunotherapy for histologic transformation after minimal or no prior therapy if the recipient has histologic transformation to DLBCL after minimal or no prior treatment; or

2. Recipient has received multiple lines of prior therapies including ≥2 chemoimmunotherapy regimens for indolent or transformed disease

3. Monomorphic PTLD

a. Used as third-line and subsequent therapy for B-cell type disease; and

b. Recipient has partial response, no response, relapsed, progressive, or refractory disease

2. Dosage Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Zynlonta® 10 mg powder for injection: two vials every 21 days for the first two doses followed by one vial every 21 days thereafter.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. B-Cell Lymphoma

a. Cycle 1-2

1. 230 billable units (17.25 mg) per each 21-day cycle

b. Subsequent Cycles

1. 115 billable units (8.63 mg) per each 21-day cycle.

3. Recertification Request

a. Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirement (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread.

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe effusion and edema (e.g., pleural effusion, pericardial effusion, ascites, peripheral edema, and general edema, etc.), myelosuppression, (e.g., neutropenia, thrombocytopenia, anemia, etc.), serious infections, severe cutaneous reactions (e.g., photosensitivity reaction, rash, erythema, etc.), etc.

4. PA Guidelines

a. Initial approval will be given for six months.

b. Recertification will be given for six months.

T. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: April 18, 2024

Osteoporosis agents are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

a. Evenity® (romosozumab-aqqg)

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. The recipient's Bone Mineral Density (BMD) T-score is -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. The recipient has document history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. The recipient has documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); or

c. Both the following:

1. The recipient has a BMD T-score between -1.0 and-2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. The recipient has a document history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. The recipient has a document trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

2. One of the following Fracture Risk Assessment Tool (FRAX) 10-year probabilities:

a. The recipient has a major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions.

b. The recipient has a hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. The recipient has a documented trial and failure, contraindication, or intolerance to one of the following:

1. Forteo® (teriparatide)

2. Tymlos® (abaloparatide); and

d. Treatment duration of Evenity® (romosozumab-aqqg) has not exceeded a total of 12 months during the recipient's lifetime.

2. PA Guidelines:

a. PA approval will be given for 12 months.

b. Prolia® and Jubbonti® (denosumab)

1. Criteria for PAD and Point of Sale (POS)

2. Prolia®

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

b. Universal Criteria

1. Recipient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; and

2. Recipients must not have hypocalcemia; and

3. Recipients with advanced kidney disease (i.e., eGFR <30 mL/min/1.73 m2 and including dialysis-dependent recipients) will be monitored for the presence of CKD mineral and bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1.25 (OH)2 vitamin D prior to decisions regarding denosumab treatment; and

4. Pregnancy is ruled out prior to administration in biological females of childbearing potential; and

5. Will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; and

3. Osteoporosis in Men and Women

a. Biological female recipient must be post-menopausal; and

b. Recipient must be at a high risk for fracture; and

c. Recipient has a documented diagnosis of osteoporosis indicated by one or more of the following:

1. T-score by DXA of ≤-2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; or

2. History of fragility fracture to the hip or spine, regardless of T-score; or

3. T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; and

a. History of fracture of proximal humerus, pelvis, or distal forearm; or

b. FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; and

d. Recipient has one of the following:

1. Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV such as alendronate, risedronate, ibandronate, or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and IV bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

4. Glucocorticoid-Induced Osteoporosis

a. Recipient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥2.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least three months; and

b. Recipient must be at an increased risk for fracture; and

1. Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and IV bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

5. Osteoporosis treatment and prevention in prostate cancer patients

a. Recipient must be receiving androgen deprivation therapy and

b. Recipient must be at a high-risk for fracture

6. Osteoporosis treatment and prevention in breast cancer recipients

a. Recipient must be receiving adjuvant aromatase inhibitor therapy for breast cancer.

c. Xgeva® and Wyost®

1. Coverage is provided in the following conditions:

a. Universal Criteria

1. Recipient will receive calcium and vitamin D as necessary to treat or prevent hypocalcemia (Note: excludes when use is for hypercalcemia of malignancy); and

2. Recipient must not have hypocalcemia; and

3. Will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; and

b. Prevention of skeletal-related events in recipients with MM or bone metastases from solid tumors.

1. Recipient is at least 18 years of age; and

a. Recipient must try and have an inadequate response, contraindication, or intolerance to at least a three-month trial of zoledronic acid, or

b. Recipient has metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC).

2. Giant Cell Tumor of the Bone

a. Recipient must be an adult or at least 12 years of age and skeletally mature; and

1. Disease is unresectable or surgical resection is likely to result in severe morbidity; or

2. Disease is localized, recurrent, or metastatic and

a. Used as a single agent; or

b. Used in combination with serial embolization and/or radiation therapy.

3. Hypercalcemia of malignancy

a. Recipient is at least 18 years of age; and

b. Recipient must have a diagnosis of cancer (malignancy); and

1. Recipient must have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven-day trial on previous therapy with IV bisphosphonates such as ibandronate or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to IV bisphosphonates such as ibandronate or zoledronic acid.

4. Systemic Mastocytosis

a. Recipient has osteopenia or osteoporosis and coexisting bone pain; and

b. Used as second-line therapy if the recipient is

1. Not responding to bisphosphonate therapy; or

2. Recipient is not a candidate for bisphosphonate therapy due to renal insufficiency.

c. PA Guidelines:

1. Coverage will be provided for 12 months and may be renewed.

5. Dosing Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Prolia® 60 mg/1 mL single-dose prefilled syringe: one syringe every six months.

2. Xgeva® 120 mg/1.7 mL single-dose vial:

a. Load: four vials for one 28-day cycle.

b. Maintenance: 1 vial monthly.

b. Max Units (per dose and over time) [NDC Unit]:

1. Prolia® – All indications:

a. 60 billable units every six months.

2. Xgeva® – Giant Cell Tumor of Bone and Hypercalcemia of Malignancy.

a. Loading Dose:
120 billable units on days 1, 8, 15, and 29.

b. Maintenance:
120 billable units every four weeks.

3. Xgeva® –Bone metastases from solid tumors, MM, and Systemic Mastocytosis.

a. 120 billable units every four weeks.

6. Recertification Request:

a. Coverage can be renewed based on the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain, etc.; and

b. Prolia® and Jubbonti®

1. Beneficial disease response as indicated by one or more of the following:

a. Absence of fractures.

b. Increase in bone mineral density compared to pretreatment baseline; and

2. Osteoporosis in Men and Women only:

a. After five years of treatment, Recipient will have a repeat DXA performed; and

1. Recipients with low-to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms.

3. Glucocorticoid-Induced Osteoporosis

a. After two years of treatment, recipient will have a repeat DXA performed; and

b. Recipients with low to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms.

c. Xgeva® and Wyost®

1. Beneficial disease response as indicated by the following:

a. MM or Bone metastases from solid tumors: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression).

b. Giant Cell Tumor of the Bone: stabilization of disease or decrease in size of tumor or spread of tumor.

c. Hypercalcemia of Malignancy: corrected serum calcium ≤11.5 mg/dL (2.9 mmol/L).

d. Systemic Mastocytosis: improvement or resolution of bone pain as compared to pretreatment baseline.

d. Forteo® (teriparatide)

1. For Postmenopausal Osteoporosis or Osteopenia, or Men with Primary or Hypogonadal Osteoporosis or Osteopenia at High Risk for Fracture

a. Approval will be given if all criteria are met and documented:

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia, or primary or hypogonadal osteoporosis or osteopenia; and

2. One of the following:

a. Both the following:

1. The recipient has a BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following

a. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Documented trial and failure, contraindication intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); or

b. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. Recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. Recipient has a documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

2. One of the following FRAX 10-year probabilities:

a. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

3. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during the recipient's lifetime.

2. For Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

a. Approval will be given if all criteria are met and documented:

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient has documented history of prednisone or its equivalent at a dose ≥5 mg/day for ≥3 months; and

3. One of the following:

a. BMD T-score ≤2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerus; and

4. Documented trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate); and

5. The recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during the recipient's lifetime.

3. PA Guidelines:

a. PA approval will be for 24 months.

e. Tymlos® (abaloparatide)

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of osteoporosis or osteopenia; and is one of the following:

1. Postmenopausal female at high risk for fracture or has failed or is intolerant to other available osteoporosis therapy; or

2. Male at high risk for fracture or has failed or is intolerant to other available osteoporosis therapy; and

b. One of the following:

1. Both the following:

a. BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate,

risedronate, zoledronic acid, Prolia® [denosumab]); or

2. Both the following:

a. Recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Recipient has a documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Both the following:

a. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during their lifetime.

2. PA Guidelines:

a. PA approval will be for 24 months.