MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

May 30, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES Casey Angres (Jul 13, 2023 19:49 PDT)
CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to add new prior authorization criteria for Physician-Administered Drugs (PADs). The proposed changes include addition of new PAD-specific prior authorization criteria for Libtayo® (cemiplimab-rwlc), Ocrevus® (ocrelizumab), Opdivo® (nivolumab), Tecentriq® (atezolizumab) within the Anti-PD-1 Monoclonal Antibodies Section; addition of new PAD-specific prior authorization criteria for Eylea® (aflibercept), Lucentis®; Byooviz™; Cimerli™(ranibizumab), Susvimo® (ranibizumab) within the Anti-Angiogenic Opthalmic Agent Section; addition of new PAD-specific prior authorization criteria for SCIG (immune globulin): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify® within the Immunoglobulins Section; addition of new PAD-specific prior authorization criteria for Pemetrexed within the Antimetabolites Section; addition of new PAD-specific prior authorization criteria for Perjeta® (pertuzumab), Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma™; Ontruzant® (Trastuzumab); Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) within the HER2 Inhibitor Section; addition of new PAD-specific prior authorization criteria for Rituxan®, Truxima®, Ruxience™, Riabni™ (Rituximab), Rituxan Hycela® (rituximab and hyaluronidase human) within the CD20 Monoclonal Antibodies Section; addition of new PAD-specific prior authorization criteria for Soliris® (eculizumab), Ultomiris® (ravulizumab-cwyz) within the Selective Immunosuppressants Section; addition of new PAD-specific prior authorization criteria for Yervoy® (ipilimumab) within the Anti-CLTA-4 Monoclonal Antibodies Section.

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 5, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A	MTL N/A
MSM Chapter 1200 - Prescribed Drugs	MSM Chapter 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix B Section B	**Anti-PD-1 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Libtayo® (cemiplimab-rwlc), Ocrevus® (ocrelizumab), Opdivo® (nivolumab), Tecentriq® (atezolizumab).
Appendix B Section H	**Anti-Angiogenic Opthalmic Agent**	Created new section for PAD prior authorization criteria and quantity limits for Eylea® (aflibercept), Lucentis®; Byooviz™; Cimerli™ (ranibizumab), Susvimo® (ranibizumab).
Appendix B Section I	**Immunoglobulins**	Created new section for PAD prior authorization criteria and quantity limits for SCIG (immune globulin): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify®.
Appendix B Section N	**Antimetabolites**	Created new section for PAD prior authorization criteria and quantity limits for Pemetrexed. Deleted Section for Libtayo®.and placed it under Anti-PD-1 Monoclonal Antibodies Section.
Appendix B Section O	**HER2 Inhibitors**	Created new section for PAD prior authorization criteria and quantity limits for Perjeta® (pertuzumab), Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (trastuzumab); Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk).
Appendix B Section P	**CD20 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Rituxan®, Truxima®, Ruxience™, Riabni™ (rituximab) and Rituxan Hycela® (rituximab and hyaluronidase human).
Appendix B Section Q	**Selective Immunosuppressants**	Created new section for PAD prior authorization criteria and quantity limits for Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz).
Appendix B Section R	**Anti-CLTA-4 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Yervoy® (ipilimumab).
Appendix B Section S	**Miscellaneous Antineoplastics**	Created new section for PAD prior authorization criteria and quantity limits for Zynlonta® (loncastuximab tesirine-lpyl).

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, 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 prior authorization on any covered outpatient drug, providing the prior authorization 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 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 prior authorization and step therapy; and

3. create the Pharmacy and Therapeutics 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 SAA) 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. The DHCFP requires that pharmaceuticals are written, dispensed and prescribed in accordance with the Nevada State Board of Pharmacy regulations and enforcement.

1203.1 COVERAGE AND LIMITATIONS

A. Covered drugs are subject to prior authorization 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. 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.

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 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 (formerly known as the Pharmacy and Therapeutics (P&T) Committee). Reference Medicaid Operations Manual (MOM) Chapter 200 for the Silver State Scripts Board bylaws. Pharmaceuticals not on the PDL, but within drug classes reviewed by the Silver State Scripts Board, require prior

authorization, unless exempt under NRS or federal law or excluded through recommendations of the Silver State Scripts Board or excluded by the DHCFP.

a. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard Preferred Drug List Exception prior authorization until, or if, the Silver State Scripts Board adds the drug class to the PDL and reviews the product or evidence.

b. New Food and Drug Administration (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 Preferred Drug List Exception prior authorization until the Silver State Scripts Board can review the new evidence or drug.

c. Pharmaceuticals may require prior authorization due to step therapy protocols regardless of inclusion in the PDL.

d. If the Silver State Scripts Board determines that there are no significant differences between drugs within specific classes based on clinical efficacy, safety, and outcomes for patients, the 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 Preferred Drug List 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 a 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.

2. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms/aspx

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight loss.

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 Medicaid Drug Rebate Program. This listing is available on the Centers for Medicare and Medicaid Services (CMS) website at: http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp

   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 Medicaid Drug Rebate Program unless rated "1-A" by the FDA.

7. Agents used for impotence/erectile dysfunction.

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. Prior authorization 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 less than three 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; and

   h. Progesterone.

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 prior authorization will be allowed.

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

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 prior authorization (if required) will be necessary to get additional medication.

H. Nevada Check Up (NCU)

All coverage and limitation policies and rules, including any prior authorization 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 prior authorization. Reference Appendix A of this chapter.

1. Childhood vaccines: All childhood vaccines are covered without prior authorization 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 prior authorization. For a list of covered adult vaccines, please reference the Physician's Fee Schedule at: http://dhcfp.nv.gov/Resources/Rates/FeeSchedules/

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. These may be accessed by following the link: https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil. 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 Board of Pharmacy (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. The 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 Prior Authorizations

1. The DHCFP will allow pharmacists to submit a prior authorization 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 Board of Pharmacy. 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 prior authorization 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 Drug Utilization Review (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. Drug Utilization Review (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 the 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. The 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 the DHCFP's action.

c. The 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 period lasting 36 months. Utilizing the pharmacy lock-in criteria, the DHCFP

conducts a clinical review not less than a month prior 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 the 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 still appropriate or may be removed from lock-in status.

2. A written NOD is issued by the DHCFP 15 days prior 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 the 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 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 prior authorization 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 (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. Long Term Care (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 the 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 the 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 Provider Type 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 (NVPAD).

   a. COD(s) are billed utilizing the appropriate National Drug Code (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 the 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 for 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 assure 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 prior authorization 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, Opthalmic/Otic Solutions: must be billed by milliliters (mls). For example, if 560ml of guiafenesin is dispensed, the quantity entered will be 560.

PLEASE NOTE:

Ounces must be converted to ml (1 ounce = 30ml).
Liters must be converted to ml (1L = 1000ml).
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, Catapress-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 90mcg(microgram)/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 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. Anithemophilic 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 the DHCFP or QIO-like vendor.

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

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

3. All drugs subject to the SMAC and updates will be posted on the following website: http://www.medicaid.nv.gov/providers/rx/MACinfo.aspx

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

2. Prior authorization requests must be submitted on the appropriate Prior Authorization Request form. Pharmacy prior authorization forms can be found at the following web site: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. LTC drug claims are subject to prior authorization requirements.

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

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

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

5. An approved prior authorization 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 Notice of Decision 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 prior authorization edits will be processed at the individual ingredient level.

B. Long Term Care (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 LIMITATION

A. Proton Pump Inhibitors (PPIs)

Therapeutic Class: Proton Pump Inhibitors
Last Reviewed by the DUR Board: April 30, 2020

PPIs are subject to prior authorization 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 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. Prior Authorization Guidelines

1. Prior authorization approval will be for up to 12 months.

2. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

B. Pyrukynd® (mitapivat)

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

Pyrukynd® (mitapivat) is subject to prior authorization 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 less than 10g/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 100mg/day).

2. Recertification Request:

   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 greater than or equal to 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 greater than or equal to 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, LDH, haptoglobin).

c. Recertification will be approved for six months.

3. Prior authorization guidelines:

a. Prior authorization 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 prior authorization 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 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 prior authorization 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 ICD code for ADD with or without hyperactivity is documented on the prescription and transmitted on the claim.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

D. Growth Hormones
Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 28, 2022

Growth Hormones are subject to prior authorization 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 less than 16 years for male recipients or less than 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 less than 14 years; or

4. The recipient has a diagnosis of chronic renal insufficiency (<75 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 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 less than 16 years for male or less than 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. Prior Authorization Guidelines

a. Initial prior authorization 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; and

d. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m²; 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. Prior Authorization Guidelines:

a. Prior authorization 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 age 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. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification request 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. Prior Authorization 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 greater than 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 greater than or equal to two 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 greater than or equal to one 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 less than 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. Prior Authorization Guidelines:

   a. Prior authorization 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 prior authorization 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 prior authorization and OTC MAC limits.

2. Prior Authorization Guidelines:

   a. Prior Authorization 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 PRN dosing with short-acting opioids. Transdermal fentanyl is subject to prior authorization 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 mcg/hr at the initiation of opioid therapy. Therefore, patients must meet the following criteria in order to gain prior authorization approval:

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

b. Patient requires continuous opioid administration.

c. Prescribers are required to check the Nevada State BOPs 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 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. Prior Authorization Guidelines

a. Prior authorization approval will be given for 12 months.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 greater than 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. Prior Authorization Guidelines:

1. Prior authorization 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 prior authorizations 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 prior authorization, i.e. serum hemoglobin, within seven days of prior authorization 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 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 greater than or equal to 100 ng/mL (mcg/L) and transferrin saturation (TSAT) greater than or equal to 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 (CML, AML) 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 Request

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. Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

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

1. Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct) less than 30%.

d. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria.

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

1. Pediatric patients: Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

2. Adult patients: Hemoglobin (Hb) less than 11 g/dL and/or Hematocrit (Hct) less than 33%.

4. Prior Authorization Guidelines

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

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

I. Anti-Fungal Agents

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

Anti-Fungal Agents are subject to prior authorization 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 (Jublia® (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), and 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. Prior Authorization Guidelines

      1. Prior authorization 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 150mg oral fluconazole.

      5. Quantity Limit is four tablets.

   b. Recertification Request:

      1. Coverage is not renewable.

   c. Prior Authorization Guidelines:

      1. Prior Authorization 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 vulvoginal candidiasis with greater than or equal to three episodes of vulvovaginal candidiasis (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 Request:

1. Coverage is not renewable.

c. Prior Authorization Guidelines:

1. Prior Authorization will be for 12 weeks.

J. Benlysta® (belimumab)

Therapeutic Class: Benlysta® (belimumab)
Last Reviewed by the DUR Board: January 25, 2018

Benlysta® (belimumab) is subject to prior authorization 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

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

3. Documentation confirms that the recipient is autoantibody positive (i.e., anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA)); and

4. 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

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

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

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

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

b. Recertification Request (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. Prior Authorization Guidelines

   a. Prior authorization approvals will be for:

      1. Initial request: six months.

   b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization and quantity limitatons 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 less than two 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. Zolgesma®) 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 Request (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 2-point (or maximal score) increase in ability to kick; or

2. Improvement or maintenance of previous improvement of at least a 1-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 3-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 2-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 4-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 3-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. Zolgesma®) 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. Prior Authorization Guidelines:

1. Initial authorization will be approved for 12 months.

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

a. The recipient has been on therapy for less than 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. Prior Authorization Guidelines

a. Initial request will be approved for 12 months.

b. Recertification request 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 SMN 2; 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 less than or equal to 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. Prior Authorization Guidelines

1. Prior authorization approval is limited to once in a lifetime.

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: October 20, 2022

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Remicade® (infliximab)
Amevive® (alefacept)	Ilumya® (tildrakizumab)	Renflexis® (infliximab)
Arcalyst® (rilonacept)	Inflectra® (infliximab)	Siliq® (brodalumab)
Cimzia® (certolizumab pegol)	Kevzara® (sarilumab)	Simponi® (golimumab)
Consentyx® (secukinumab)	Kineret® (ankinra)	Simponi® ARIA™ (golimumab)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Skyrizi® (risankizumab-rzaa)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Stelara® (ustekinumab)
Humira® (adalimumab)	Otezla® (apremilast)	Taltz® (ixekizumab)
Xeljanz® (tofacitinib)		

Immunomodulator Drugs are subject to prior authorization 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. Each request meets the appropriate diagnosis-specific criteria (b-j).

   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 less than six 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 greater than or equal to six 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 greater than or equal to six 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 Rheumatoid Arthritis/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 18 years of age of older; 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.

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

2. 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.

1. 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. 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. Sulfasalzine

d. Azathioprine

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

4. 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. Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID):

1. The recipient has a diagnosis of NOMID.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

M. Topical Immunomodulators

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

Topical Immunomodulators drugs are a subject to prior authorization 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 greater than or equal to two years.

         b. Eucrisa® for mild to moderate, for ages greater than or equal to three months.

         c. Protopic® 0.03%; moderate to severe, for ages greater than or equal to two years.

         d. Protopic® 0.1%; moderate to severe, for ages greater than or equal to 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® (pimecrolims) or Protopic (tacrolimus)).

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

b. Recertification Request:

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

c. Prior Authorization Guidelines

   1. Prior authorization 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 prior authorization 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 DHCFP requires prior authorization approval for children and adolescents for the psychotropic therapeutic classes below and medication combinations considered to be polypharmacy. The 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 the 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. Prior authorization 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. Prior authorization 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 prior authorization 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 prior authorization 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 prior authorization 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 prior authorization requirement at the pharmacy POS if the correct ICD Code is written on the prescription and transmitted on the claim. Or the prior authorization 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.

3. Prior Authorization Guidelines

a. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization documenting a diagnosis of Post Herpetic Neuralgia/Neuropathy.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: January 19, 2023

Respirator and Allergy Biologics are subject to prior authorization 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 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 150mg or 300mg 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 nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]

4. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 intravenous infusion of 20 to 50 minutes every four weeks.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 greater than or equal to 150 cells/microliter; or

2. Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter 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., greater than 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 greater than or equal to six 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 request (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, long-acting beta-2 agonist [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. Prior Authorization Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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

c. The recipient is currently receiving corticosteroid therapy; and

d. 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).

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification request will be approved 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 greater than or equal to 12 years old; and

b. Recipient has a diagnosis of uncontrolled HES for greater than or equal to six months defined by both of the following:

1. History of greater than or equal to two flares over the past 12 months; and

2. Baseline (pre-treatment) blood eosinophil count greater than or equal to 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 Request:

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. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification will be given for 12 months.

f. Nucala® (mepolizumab) for treatment of Chronic Rhinosinusitis with Nasal Polyps

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

a. Recipient is greater than or equal to 18 years old.

b. Recipient has a diagnosis of Chronic Rhinosinusitis with Nasal Polyps (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 Request:

a. Recipient continues to meet above criteria; and

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

3. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification approval will be given for 12 months.

e. Fasenra® (benralizumab)

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

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

b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthamtic 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., greater than 500 mcg fluticasone propionate equivalent/day) and an 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)).

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

1. Pulmonologist; or

2. Allergy/Immunology specialist.

2. Recertification Request: 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, long-acting beta-2 agonist (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. Prior Authorization Guidelines:

a. Initial prior authorization will be for 12 months.

b. Recertification request will be for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

f. 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® (pimecromulus) 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 greater than or equal to 150 cells per microliter; 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 inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (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 Request:

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, long-acting beta-2 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 (budenoside/formoterol)

3. Prescribed by or in consultation with an allergist/immunologist/otolaryngologist/ENTs.

c. Diagnosis of Chronic Rhinosinusitis with Nasal Polyps

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

a. Recipient is at least 18 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 Request:

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 greater than or equal to 12 years old; and

b. Recipient weighs greater than or equal to 40 kg; 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 Request:

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

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

3. Prior Authorization Guidelines:

a. Prior authorization 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 greater than or equal to 18 years old; and

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

2. Recertification Request:

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

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

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for 12 months.

b. Recertification requests 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 prior authorization 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. Prior Authorization Guidelines

a. The prior authorization approval will be for three months.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

R. Toradol® (ketorolac tromethamine) tablets

Therapeutic Class: Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
Last Reviewed by the DUR Board: April 30, 2020

Toradal® is subject to prior authorization 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/IM therapy; and

   b. Oral treatment must not to exceed five days; and

   c. Oral treatment must not exceed 40 mg/day.

2. Prior Authorization Guidelines

   a. Initial request will be approved for up to five days.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization 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 prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.

         c. Prior authorization will NOT be given to patients with ischemic heart disease.

   b. Prior Authorization Guidelines:

      1. Approval for exceeding the quantity limits on triptans will be provided for a two-month period.

2. The prior authorization must be initiated by the prescriber. The approved prior authorization must be available if requested.

2. Calcitonin Gene-Related Peptide (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 greater than or equal to 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. Evail (amitriptyline) or Effexor (venlafaxine)

2. Depakote/Depakote ER (divalproex) or Topamax (topiramate)

3. One of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metroprolol; and

d. The medication will not be used in combination with any other CGRP Inhibitor.

2. Recertification Request:

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. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request 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 Request:

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. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request 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.

e. The medication will not be used in combination with any other CGRP inhibitor.

2. Recertification Request:

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. Prior Authorization Guidelines:

a. Initial request will be approved for three months.

b. Recertification request 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. Metroprolol; and

d. Medication will not be used in combination with any other CGRP inhibitor.

2. Prior Authorization 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 criterias are met and documented:

a. The recipient has a diagnosis of headahces 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 triptants (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 Request:

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. Prior Authorization 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 criterias 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 sumatriptain injection; and

d. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

2. Recertification Request:

   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. Prior Authorization 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 20ml 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. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Xopenex®

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.

b. Prior Authorization Guidelines

Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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.

2. Prior Authorization Guidelines

   a. Prior Authorization forms are available at:
      https://www.medicaid.nv.gov/providers/rx/rxforms/aspx

W. Doxepin Topical

Therapeutic Class: Other Topical Anti-Pruiritics
Last Reviewed by DUR Board: October 22, 2020

Doxepin Topical is subject to prior authorization 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. Prior Authorization Guidelines:

   a. Prior Authorization approval will be given for eight days.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 prior authorization 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 prior authorization is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

Serotonin Receptor Antagonists (5 HT3 Antiemetics)

1. Coverage and Limitations

   a. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses; or

   b. The recipient is receiving chemotherapy treatments more often than once a week; or

   c. The recipient has a diagnosis of Acquired Immune Deficiency Syndrome (AIDS) associated nausea and vomiting; or

   d. 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.

2. Prior Authorization Guidelines

   A prior authorization to override the quantity limits to allow for a 30-day fill for these drugs may be effective for up to six months.

Cannabinoid Antiemetics

1. Coverage and Limitations

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

   a. 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.

b. 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 Acquired Immune Deficiency Syndrome (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.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

Y. Synagis® (palivizumaub)

Therapeutic Class: Antiviral Monoclonal Antibodies
Last Reviewed by the DUR Board: January 22, 2015

Synagis® (palivizumab) injections are subject to prior authorization 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 prior authorization 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, coritcosteroids) 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. Prior Authorization Guidelines

   a. Prior authorization approval will be up to five doses per RSV season for recipients meeting criteria.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization:

      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. Prior Authorization 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 (greater than three 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. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. CDC Guidance:

a. http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

4. Opioid Containing Cough Preparations

a. The recipient must be 18 years of age or older.

b. Prior authorization approval will be for six months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

d. For references purposes, codeine and tramadol for children prior authorization criteria can also be found within this chapter in Section TTT.

5. 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 (greater than three 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. Prior Authorization Guidelines

1. Prior authorization approval will be for three months.

f. Prescribing Guidance:

1. CDC Guidance: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

2. HHS Opioids and Adolescents: https://www.hhs.gov/ash/oah/adolescent-development/substance-use/drugs/opioids/index.html

AA. Savella® (milnacipran)

Therapeutic Class: Fibromyalgia Agents: Serotonin-Norepinephrine Reuptake Inhibitor
Last Reviewed by DUR Board: July 23, 2020

Savella® (milnacipran) is subject to prior authorization.

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 prior authorization documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.

2. Prior Authorization Guidelines:

   a. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 of the following criteria are met and documented:

a. Prior authorization approval will be required for all prescriptions over 24 mg.

b. Requires diagnosis of opioid dependence.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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. Prior Authorization Guidelines

a. Prior authorization approval will be for 14 days.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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. Prior Authorization Guidelines

   a. Prior authorization approvals will be for six months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 prior authorization 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 (CrCL less than 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. Prior Authorization Guidelines

      1. Initial prior authorization 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, secondary-progressive MS 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® (cladrivine)

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:

a. The recipient has previously received treatment with alemtuzumab; and

b. 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. Prior Authorization 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., relapsing-remitting MS, secondary-progressive MS 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. Prior Authorization Guidelines

a. Prior authorization 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 Hepatitis B virus (HBV) prior to initiating treatment and does not have active disease (i.e., positive 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. Multiple Sclerosis

a. Recipient must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); and

b. Must be used as single agent therapy; and

1. Recipient has a 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 less than 65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of less than or equal to 6.5.

2. Recertification Request (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 expanded disability status scale (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 greater than or equal to one relapse, greater than or equal to two 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 less than 7.5.

3. Prior Authorization Guidelines

a. Initial prior authorization 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., relapsing-remitting MS, secondary-progressive MS 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 two 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. Prior Authorization Guidelines:

a. Prior authorization 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 multiple sclerosis (MS) (e.g., relapsing-remitting disease [RRMS]; active secondary progressive MS [SPMS]+, or clinically isolated syndrome [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 two of the following disease-modifying therapies for MS;

a. Avonex® (interferon beta-1a); or
b. Betaserone® (interferon beta-1b); or

c. Copaxone®/Glatopa® (glatiramer acetate); or

d. Tysabri® (natalizumab); or

e. Tefidera® (dimethyl fumarate); or

f. Aubagio® (teriflunomide); or

g. Gilenya® (fingolimod)

2. Recertification Request:

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, neurologist.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be given for 12 months.

4. Primary Progressive Forms of Multiple Sclerosis (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 Request (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. Prior Authorization Guidelines

         a. Prior authorization 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 greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) greater than 19; and

      5. Recipient does not have a hematocrit greater than 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 less than 300 ng/dL (< 10.4 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 less than 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 changes in their physical Characteristics; and

b. Recipient is a female-to-male transsexual

c. Prior Authorization Guidelines:

1. Prior authorization approval with a diagnosis of hypogonadism will be given for one year.

2. Prior authorization approval with a diagnosis of gender dysphoria will be given for six months for recipients new to testosterone therapy; or

a. Prior authorization approval will be given to recipients continuing testosterone therapy without a current authorization on file for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Oral Testosterone Products

a. Hypogonadism:

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

   a. The recipient is greater than 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 hematocrit greater than 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 Request:

1. Recipient must continue to meet above criteria; and

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

d. Prior Authorization Guidelines:

1. Prior authorization 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 prior authorization 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 of 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. Prior Authorization Guidelines

c. Prior authorization approval will be given based on diagnosis.

1. For FMF and chronic gout: one year.

2. For acute gout: two months.

d. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

FF. Thrombin Inhibitors

Therapeutic Class: Thrombin Inhibitors
Last Reviewed by the DUR Board: January 22, 2015

Thrombin Inhibitors are subject to prior authorization 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 Prior Authorization documenting the recipient meeting all of the criteria above (1.) (a. and b.).

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for up to one year.

   b. Prior Authorization forms are available at:
      https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

GG. Antihemophilia Agents

Therapeutic Class: Antihemophilia Agents
Last Reviewed by the DUR Board: July 26, 2018

Antihemophilia Agents are subject to prior authorization 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 Prior Authorization 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 prior authorization will be required for any dose adjustment in excess of 5% (increase or decrease).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

HH. Anti-Hepatitis Agents

Therapeutic Class: Anti-Hepatitis Agents
Last Reviewed by the DUR Board: April 22, 2021

Anti-Hepatitis Agents are subject to prior authorization 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 and 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 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 hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (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. Prior authorization 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 hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (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. Prior authorization approval will be for 24 weeks.

d. Genotype 1, 2, 3, 4, 5 or 6 Ribavirin intolerance/ineligible or prior Sovaldi® (sofosbuvir) or NS5A-based treatment failure.

1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (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. Prior authorization 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 RNA is less than six million IU/mL

1. The recipient has a documented diagnosis of chronic hepatitis C 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 less than six million IU/mL must be submitted; and

d. Prior authorization approval will be for eight weeks.

c. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is greater than or equal to six million IU/mL

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 does not have cirrhosis; and

3. The recipient is treatment naïve; and

4. Medical records documenting pre-treatment HCV RNA greater than or equal to six million IU/mL must be submitted; and

5. Prior authorization approval will be for 12 weeks.

d. Genotype 1, treatment naïve with compensated 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. 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. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced without 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 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization approval will be for 24 weeks.

h. Genotype 1, 4, 5 or 6, decompensated cirrhosis or post-liver transplant

1. The recipient has a documented diagnosis of chronic hepatitis C 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. Prior authorization approval will be for 12 weeks.

i. Genotype 1,4, 5, or 6, decompensated cirrhosis, Ribavirin ineligible or prior failure of Sovaldi® or NS5A based regimen

1. The recipient has a documented diagnosis of chronic hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C genotype 1, 2, 3, 4, 5 or 6 (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. Prior authorization 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 hepatitis C genotype 1, 2, 3, 4, 5 or 6 (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. Prior authorization 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 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 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. Prior authorization 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior authorization approval will be for 12 weeks.

c. Genotype 3, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C 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 hepatitis C virus (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 less than 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. Prior authorization approval will be for 24 weeks.

d. Genotype 2, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C 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 hepatitis C 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 less than 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. Prior authorization approval will be for 12 weeks.

e. Genotype 1, without 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 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. Prior authorization approval will be for 12 weeks.

f. Genotype 1, with 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 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. Prior authorization approval will be for 12 weeks.

g. Genotype 1

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 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. Prior authorization approval will be for 12 weeks.

h. Genotype 3

1. The recipient has a documented diagnosis of chronic hepatitis C 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. Prior authorization 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 hepatitis C 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. Prior Authorization Guidelines:

         a. Prior authorization will be for 12 weeks.

         b. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

   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 hepatitis C 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. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

b. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 hepatitis C 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. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

b. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 hepatitis C 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 less than or equal to 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. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

b. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 hepatitis C genotype 1, 2, 3, 4, 5 or 6 (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 less than or equal to F2); and

2. Prior Authorization Guidelines:

   1. Prior authorization 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 hepatitis C 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. Prior Authorization Guidelines:

      1. Prior authorization approval will be for 12 weeks.

      2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 hepatitis C 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. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 PegIFN/RBV experienced, or PegIFN/RBV/protease inhibitor experienced, without NS5A polymorphisms

1. Approval will be given if all criterias are met and documented:

a. The recipient has a documented diagnosis of chronic hepatitis C 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. Prior Authorization Guidelines:

a. Prior authorization approval will be for 16 weeks.

b. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Genotype 1b, treatment naïve, or PegIFN/RBV experienced, or PegIFN/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 hepatitis C 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. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. Genotype 4, PegIFN/RBV experienced

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

1. The recipient has a documented diagnosis of chronic hepatitis C 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. Prior Authorization Guidelines:

1. Prior authorization approval will be for 16 weeks.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

II. Daliresp® (roflumilast)

Therapeutic Class: Phosphodiesterase-4 Inhibitors.
Last Reviewed by the DUR Board: October 17, 2019

Daliresp® (roflumilast) is subject to prior authorization 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 Chronic Obstructive Pulmonary Disease (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. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed by DUR Board: April 22, 2021

Hereditary Angioedema (HAE) agents are subject to prior authorization 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 estarase inhibitor), Orladeyo® (berotralstat) or Takhzyro® (ianadelumab-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. Prior Authorization Guidelines:

      1. Prior authorization approval will be approved for 12 months.

      2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Cinryze® (C1 esterase inhibitor) *, Firazyr® (icatibant), Ruconest® (C1 esterase inhibitor)

   Note: * off label use

   4. 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. Prior Authorization Guidelines:

1. Prior authorization approval will be approved for 12 months.

2. Prior authorization forms are available https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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. Prior Authorization Guidelines:

1. Prior authorization approval will be approved for 12 months.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 HAEattacks and

      6. One of the following:

         a. The recipient has trial and failure, contraindication, or intolerance to Ruconest®; or

         b. The recipient is 12 year of age or younger and there is documentation that the recipient has history of laryngeal attacks.

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be approved for 12 months.

      2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

KK. Incretin Mimetics

Therapeutic Class: Incretin Mimetics
Last Reviewed by the DUR Board: January 26, 2017
Previously reviewed by the DUR Board: July 26, 2012

Incretin Mimetics are subject to prior authorization 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. An ICD code for Type 2 Diabetes Mellitus is documented on the prescription and transmitted on the claim; or

   b. A prior authorization documenting a diagnosis of Type 2 Diabetes Mellitus has been submitted.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

LL. Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: January 27, 2022

Cystic Fibrosis (CF) Agents are subject to prior authorization 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 Request (the recipient must meet all the following criteria)

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

      3. Prior Authorization Guidelines:

         a. Initial request will be approved for 12 months.

         b. Recertification request will be for 12 months.

         c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

   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 cystic fibrosis 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. Prior Authorization Guidelines:

a. Prior authorization approvals will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 either a Pulmonolist 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 Request (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. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 Request:

a. The recipient must have documentation of a positive clinical response to Trikafta® therapy (e.g. improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations)

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

MM. Gimoti® (metoclopramide)

Therapeutic Class: Gastrointestinal Prokinetic Agents
Last Reviewed by the DUR Board: October 26, 2021
Gastrointestinal Prokinetic Agents are subject to prior authorization 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 (creatinine clearance [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., intramuscular) metoclopramide; or

      2. The recipient is NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications)

2. Recertification Request:

   a. Recipient continues to meet all initial authorization criteria; and

b. At least 2 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. Prior Authorization Guidelines:

a. Prior Authorization approval will be for two months

b. Recertification requests will be approved for two months

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors
Last Reviewed by the DUR Board: April 22, 2021

Platelet Inhibitors are subject to prior authorization 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 less than 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 less than 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. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

OO. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: January 19, 2023

Osteoporosis agents are subject to prior authorization 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 documented 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 documented 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 documented 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 FRAX (Fracture Risk Assessment Tool) 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® (abaoparatide); and

d. Treatment duration of Evenity® (romosozumab-aqqg) has not exceeded a total of 12 months during the recipient's lifetime.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be given for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

b. Prolia® (denosumab)

1. Criteria for Physician Administered Drugs (PAD)

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

1. Recipient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; and

2. Recipient must not have hypocalcemia; and

3. Coverage is provided in the following conditions:

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

b. Recipient must be at a high risk for fracture; and

c. Pregnancy ruled out prior to starting therapy in women of childbearing potential; and

2. For bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.

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

1. The recipient has a diagnosis of nonmetastatic prostate cancer; and

2. The recipient is undergoing androgen deprivation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar® (triptorelin), Vantas (histrelin), and Zoladex® (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

3. One of the following:

a. The recipient is 70 years of age or older; or

b. Both the following:

1. The recipient is less than 70 years of age; and

a. One of the following:

1. BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

2. Documented history of one of the following resulting from minimal trauma:

a. Vertebral compression fracture

b. Fracture of the hip

c. Fracture of the distal radius

d. Fracture of the pelvis

e. Fracture of the proximal numerous; and

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

1. The recipient is undergoing androgen depravation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar® (triptorelin), Vantas® (histrelin), and Zoladex® (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

2. The recipient has no evidence of metastases; and

3. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

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

1. The recipient has a diagnosis of breast cancer; and

2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex® [anastrozole], Aromasin® [exemestane], Femara® [letrozole]); and

3. One of the following:

a. The recipient's BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

b. Documented history of one of the following 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 humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g. alendronate)

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

1. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex® [anastrozole], Aromasin® [exemestane], Femara® [letrozole]); and

2. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. For Postmenopausal Osteoporosis or Osteopenia

a. Criteria for Physician Administered Drugs (PAD)

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

a. Recipient must be a woman; and

b. Recipient has a documented diagnosis of osteoporosis indicated by one or more of the following:

1. Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to negative two and a half and/or forearm DXA at the 33% (one-third) radius site; or

2. T-score less than or equal to negative one or low bone mass and a history of fragility fracture to the hip or spine; or

3. T-score between negative one and negative two and a half with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%; and

c. 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

d. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

b. Recertification Request:

1. Documentation that indicates the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. Glucocorticoid-Induced Osteoporosis

a. Criteria for Physician Administered Drugs (PAD):

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

a. Recipient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to greater than or equal to 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least six months; and

b. 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

c. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

6. Osteoporosis treatment and prevention in prostate cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

a. Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to negative one (or recipient meets the diagnostic criteria for osteoporosis above); and

b. Recipient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

7. Osteoporosis treatment and prevention in breast cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

a. Recipient must be receiving adjuvant aromatase inhibitor therapy for breast cancer.

b. Recertification Request:

1. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

c. 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 patient'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 greater than or equal to 5 mg/day for greater than or equal to three months; and

3. One of the following:

a. BMD T-score less than or equal to -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 humerous; 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 exceed a total of 24 months during the patient's lifetime.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

d. Tymlos® (abaloparatide)

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. 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. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

PP. Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations

Therapeutic Class: GnRH Antagonist and Combinations
Last Reviewed by DUR Board: October 22, 2020

GnRH Antagonist and Combinations are subject to prior authorization 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 Request (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. Prior Authorization Guidelines:

1. Prior authorization approval will be for six months.

2. Recertification approval will be for six months.

3. Prior Authorization forms are available at:

https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 Request:

      1. The recipient has documented improvement in menstrual bleeding; and

      2. Treatment duration will not exceed a total of 24 months.

   c. Prior Authorization Guidelines:

      1. Prior authorization approval will be for six months.

      2. Recertification approval will be for six months.

      3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

QQ. Spravato™ (esketamine)

Therapeutic Class: Miscellaneous Anti-Depressant
Last Reviewed by the DUR Board: July 25, 2019

Spravato™ (esketamine) is subject to prior authorization 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 treatment resistant depression as evidence of failure of two antidepressants; 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; and

      5. The medication must be prescribed by or in consultation with a psychiatrist; and

      6. The recipient must not have an aneurism or AV (arteriovenous) malformation.

   b. Approval will not be given for recipients who are currently pregnant or lactating and breastfeeding.

2. Recertification Request:

   a. In addition to the prior authorization criteria listed above (initial approval), the recipient must also have a positive clinical response to the medication treatment.

3. Prior Authorization Guidelines

   a. Initial prior authorization approval will be given for four weeks.

   b. Recertification authorization approval will be given for six months.

   c. Prior Authorization forms are available at:
      https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

RR. Omontys® (peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)
Last Reviewed by DUR Board: October 25, 2012

Omontys® (peginesatide) is subject to prior authorization 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. Prior Authorization Guidelines

   a. Prior authorization approval will be for one month.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 neuropenia 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. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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. Prior Authorization Guidelines

   a. Initial prior authorization approval will be for one year.

   b. Recertification approval will be for one year.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

UU. Aduhelm® (aducanumab-avwa)

Therapeutic Class: Alzheimer's Disease Agents
Last Reviewed by DUR Board: October 26, 2021

Aduhelm® is subject to prior authorization 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. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

      1. Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one the following;

         a. Diagnosis of mild cognitive impairment due to Alzheimer's disease; or

         b. Diagnosis of probable Alzheimer's disease dementia; and

      2. All of the following:

         a. 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

         b. Repeatable Battery for the Assessment of Neuropsychological (RBANS) score less than or equal to 85; and

         c. Mini-Mental State Examination score of 24-30; or

         d. Montreal Cognitive Assessment (MoCA) of 17 or above; and

   b. Documentation of beta-amyloid protein disposition, as evidenced by one of the following:

      1. Positive amyloid positron emission tomography (PET) scan; or

      2. Both of the following:

         a. Attestation that the patient does not have access to amyloid PET scanning; and

         b. Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., AB42 level, AB42:AB40 ratio); and

c. All of the following:

1. Recipient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less); and

2. Recipient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment; and

3. Recipient had no history of relevant brain hemorrhage, bleeding disorder, and cerebrovascular abnormalities in last six months; and

d. A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment to rule out other causes (e.g., stroke, small vessel disease, tumor); and

e. Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; and

f. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist, or other expert in the disease state.

2. Recertification Request:

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 recipientis benefitting from therapy as defined by both of the following:

a. Based on the 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 less than or equal to 85; and

3. Mini-Mental State Examination score of 24-30; and

2. Recipient has a follow-up brain MRI has been completed after the initiation of therapy to show one of the following:

   a. Both of the following:

      1. Less than ten new incident microhemorrhages; and

      2. Two or less focal areas of superficial siderosis; or

   b. If ten or more new incident microhemorrhages or greater than two focal areas of superficial siderosis are present then both of the following:

      1. Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances); and

      2. Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H); and

      3. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist.

3. Prior Authorization Guidelines

   a. Prior Authorization approval will be for six months.

   b. Recertification requests will be approved for six months.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization 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. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

WW. Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome Agents, Opioid-Induced Constipation Agents
Last Reviewed by the DUR Board: January 23, 2020

Functional Gastrointestinal Disorder Agents are subject to prior authorization 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 Idiopathic Constipation (CIC) 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 CIC; and

      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 sessosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada; and

      5. The maximum allowable dose for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2mg, once daily

         d. Trulance® (plecanatide): 2mg, once daily

   b. Prior Authorization Guidelines

      1. Prior authorization approval will be for one year.

      2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Irritable-Bowel Syndrome 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 Irritable-Bowel Syndrome 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 Irritable-Bowel Syndrome 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. Prior Authorization Guidelines

1. Prior authorization approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 less than 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 Request (the recipient must meet all criteria):

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

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be for six weeks.

b. Recertification approval will be 12 months.

c. Prior authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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. Prior Authorization Guidelines

1. Prior authorization approval will be for one year.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization 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 Prior Authorization form.

2. Prior Authorization Guidelines

   a. More than two fills of a quantity of 60 each, within six months requires an approved prior authorization documenting the reason to exceed the prescribing limit.

   b. Prior authorization approval will be for six months.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

YY. GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: April 26, 2018

GnRH Analogs are subject to prior authorization 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 prior authorization 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 is 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 less than 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 Disphoria:

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 is 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 is 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 is based on FDA-approved guidelines.

2. Prior Authorization Guidelines

   a. Prior authorization 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.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 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. Prior Authorization Guidelines:

      1. Prior authorization approval will be given in 12 months.

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: October 20, 2022

Narcolepsy Agents are subject to prior authorizations 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., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

c. Recertification Request:

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. Prior Authorization Guidelines:

1. Prior authorization approval will be given for 12 months.

2. Xyrem® (sodium oxybate)

a. The recipient has tried and failed on Provigil® (modafinil) or Nuvigil® (armodafinil); and/or

b. The recipient has a diagnosis of narcolepsy with cataplexy; and

c. The drug was prescribed by or in consultation with a neurologist or sleep specialist.

d. Prior Authorization Guidelines

1. Prior authorization approvals will be for 12 months.

3. 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 Request:

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

3. Prior Authorization Guidelines:

   a. Initial request will be approved for 12 months.

   b. Recertification request 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 Request (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. Prior Authorization Guidelines

a. Initial request will be approved for six months.

b. Recertification request 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. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

4. Xywav® (calcium, magnesium, potassium, and sodium oxybates)

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.

2. Recertification Request:

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. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request 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.

2. Recertification Request:

a. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request 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 prior authorizations 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 a 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 proton pump inhibitor (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. Prior Authorization Guidelines

a. Prior authorization approvals will be for one year.

b. Prior Authorization forms available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorizations 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 of the following criteria are met and documented:

   a. The requested drug is being used for a FDA approved indication; and

   b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate–release tablets.

2. Prior Authorization Guidelines

   a. Prior authorization approvals will be:

      1. Initial therapy: three months.

      2. Recertification: one year.

   b. Prior Authorization forms are available at:
      https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

DDD. Corlanor® (ivabradine)

Therapeutic Class: Cardiovascular Agent
Last Reviewed by the DUR Board: September 3, 2015

Corlanor® (ivabradine) is subject to prior authorization 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. Prior Authorization Guidelines

   a. The extent of prior authorization approvals will be based on the appropriate use for the individual agents.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 alirocumab (Praluent®)

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

         b. With evolocumab (Repatha®)

            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 LDL-C after therapy for at least the past three months was $\geq$ 100 mg/dL (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 ≥ 100 mg/dL (HeFH) or ≥ 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 Request (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. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification approval will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 prior authorization 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. Prior Authorization Guidelines

      1. Prior authorization 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. Prior Authorization Guidelines:

1. Prior authorization 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 prior authorization 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 the DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for three months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

HHH. Ileal Bile Acid Transporter (IBAT) Inhibitor (D7F))

Therapeutic Drug Class: Ileal bile acid transporter (IBAT) inhibitor (D7F)
Last Reviewed by the DUR Board: July 28, 2022

Ileal bile acid transporter (IBAT) inhibitor (D7F) drugs are subject to prior authorization 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 heaptic decompensation event; and

         c. Another concomitant liver disease; and

         d. An international normalized ratio (INR) greater than 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 Request:

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 [alanine aminotransferase (ALT), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension

c. Prior Authorization Guidelines:

1. Prior authorization 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 intravenous 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 Request:

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 [alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension.

c. Prior Authorization Guidelines:

1. Prior Authorization 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 prior authorization 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.

2. 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 Request:

a. Documentation of positive clinical response to therapy.

3. Prior Authorization Guidelines:

a. Initial prior authorization 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 Request:

a. Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality).

3. Prior Authorization Guidelines:

a. Initial Prior Authorization will be approved after six months.

b. Recertification will be approved after 12 months.

JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker
Last Reviewed by the DUR Board: October 26, 2021

Entresto® (sacubitril/valsartan) is subject to prior authorization 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 NYHA Class II to IV; and

b. The recipient has reduced left ventricular ejection fraction (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. Prior Authorization Guidelines:

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 prior authorization 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 medical necessity for the recipient to exceed the quantity limit (e.g., duration of chemotherapy cycle).

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for six months.

   b. Prior Authorization forms are available at:
      https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

LLL. Voquenza® Dual Pak® (vonoprazan and amoxicillin), Voquenza® Triple Pak® (vonoprazan, amoxicillin, and clarithromycin)

Therapeutic Drug Class: Qualified Infection Disease Product
Last Reviewed by DUR Board: October 20, 2022

Voquenza® Dual Pak® (vonoprazan and amoxicillin), Voquenza® Triple Pak® (vonoprazan, amoxicillin, and clarithromycin) are subject to prior authorization 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, cephalosporings, macrolides); and

   d. Treatment will not be used concurrently with rilpivrine-containing products; and

   e. For vonoprazan/amoxicillin/clarithromycin requests (Voquenza® 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 (Voquenza® 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, proton pump inhibitor-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 Request:

   a. Coverage is not renewable.

3. Prior Authorization Guidelines:

   a. Prior Authorization will be given for 14 days.

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: January 27, 2022

DMD agents are subject to prior authorization 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 Duchenne muscular dystrophy (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 milligrams per kilogram of body weight once weekly.

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

         a. The recipient has been on therapy for less than 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 30 milligrams per kilogram 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 milligrams per kilogram of body weight once weekly; and

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

b. Prior Authorization Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 milligrams per kilogram of body weight once daily.

b. Recertification request (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 milligrams per kilogram of body weight once daily.

c. Prior Authorization Guidelines:

1. Initial prior authorization approval will be approved for 12 months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 milligrams per kilogram of body weight infused once weekly.

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

1. One of the following:

a. All the following:

1. The recipient has been on therapy for less than 12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 milligrams per kilogram 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. Recipient experienced a benefit from therapy (e.g. disease amelioration compared to untreated patients); and

3. Recipient is tolerating therapy; and

4. Dose will not exceed 30 milligrams per kilogram 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. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 milligrams per kilogram of body weight infused once weekly.

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

1. One of the following:

   a. All of the following:

      1. The recipient has been on therapy for less than 12 months; and

      2. The recipient is tolerating therapy; and

      3. Dose will not exceed 80 milligrams per kilogram 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 milligrams per kilogram 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. Prior Authorization Guidelines:

      1. Initial authorization will be approved for six months.

      2. Recertification request will be approved for 12 months.

      3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 Dystrophy (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 milligrams per kilograms of body weight infused once weekly.

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

1. Recipient is tolerating therapy; and

2. Dose will not exceed 30 milligrams per kilogram of body weight infused weekly; and

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

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

NNN. Qutenza® (capsaicin)

Therapeutic Class: Topical Neuropathic Pain Agents
Last Reviewed by the DUR Board: January 27, 2022

Qutenza® (capsaicin) is subject to prior authorization 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 history of failure or intolerance to over-the-counter capsaicin.

2. Recertification Request (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. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification request will be approved for three months.

   c. The Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

OOO. Movement Disorder Agents

Therapeutic Class: Movement Disorder Agents
Last Reviewed by the DUR Board: April 28, 2022

Movement Disorder Agents are subject to prior authorization 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. Prior Authorization Guidelines

         a. Initial prior authorization approval will be for 12 months.

         b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

   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 request:

a. Documentation of positive clinical response to therapy

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be for three months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Ingrezza® (valbenazine)

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

2. Initial request:

a. The recipient must have a diagnosis of severe tardive dyskinesia (TD);

b. The recipient must be 18 years of age or older; and

c. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and

d. One of the following:

1. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or

2. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.

b. Recertification Request:

1. Documentation of positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for three months.

2. Recertification will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

PPP. Brineura® (cerliponase alfa)

Therapeutic Class: Brineura® (cerliponase alfa)
Last Reviewed by the DUR Board: October 19, 2017

Brineura® (cerliponase alfa) is subject to prior authorization 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 request (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. Prior Authorization Guidelines

1. Initial prior authorization approval will be for four months.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 Request:

   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. Prior Authorization Guidelines:

   a. Initial authorization will be approved for one month.

   b. Recertification will be approved for six months.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

RRR. Livtencity® (maribravir)

Therapeutic Drug Class: Antivirals
Last Reviewed by DUR Board: October 20, 2022

Livencity® (maribravir) are subject to prior authorization 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 greater than or equal to 12 years of age; and

   b. Recipient must weigh greater than 35 kilograms (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 greater than or equal to 2,730 IU/mL in whole blood or greater than or equal to 910 IU/mL in plasma) in two consecutive assessments separated by greater than or equal to one day; and

   e. Recipient has current CMV infection that is refractory (documented failure to achieve greater than 1 log10 decrease in CMV deoxyribonucleic acid [DNA] level in whole blood or plasma after greater than or equal to 14 days treatment) to anti-CMV treatment agents (ganciclovir, valganciclovir, cidofovir, or foscarnet), even with documented genetic mutations associated with resistance; and

   f. Maribravir will not be coadministered with ganciclovir or valganciclovir; and

   g. Recipient will be monitored for clinically important drug interactions that could results in decreased therapeutic effect of maribravir.

2. Recertification Request:

   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 (greater than 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 maribravir.

3. Prior Authorization Guidelines:

   a. Prior authorization 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 prior authorization 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 greater than 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 MAOIs or other drugs that are potent inhibitors of MAOI (e.g., linezolid), opioid drugs (e.g., tramadol, meperidine, and related derivatives), selective norepinephrine reuptake inhibitors (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 Request:

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. Prior Authorization Guidelines:

1. Initial prior authorization 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, dolansetron, 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 Request:

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. Prior Authorization Guidelines:

1. Prior authorization 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 are subject to prior authorization 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/m²), 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 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/m²), 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 200mg/day and does not exceed a five-day supply.

2. Tramadol Extended Release (ER) will not be approved for children under 18 years of age and will reject at point of sale.

c. Prior Authorization Guidelines

1. Codeine, codeine with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

1. Prior authorization will be given for a one-month time period.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Tramadol, tramadol with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

b. Prior authorization will be given for a one-month time period.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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 prior authorization criteria exists, 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 a Food and Drug Administration (FDA) approved indication; or

2. One of the following:

a. Diagnosis is supported as a use of American Society of Health-System Pharmacists Drug Information (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 Prior Authorization 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. American Hospital Formulary Service (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. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

VVV. Cuvrior® (trientine tetrahydrochloride)

Therapeutic Drug Class: Copper Chelator
Last Reviewed by DUR Board: October 20, 2022

Cuvrior® (trientine tetrahydrochloride) is subject to prior authorization 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 greater than or equal to four); and

   c. Recipient is being treated with penicillamine for greater than or equal to one year at a stable dose and regimen for greater than or equal to four months, and recipient is tolerating penicillamine and adequately controlled (e.g., serum non-ceruloplasmin copper [NCC] level between greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour urinary copper excretion [UCE] of between levels greater than or equal to 100 and less than or equal to 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 3,000mg).

2. Recertification Request:

   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 greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour UCE levels greater than or equal to 100 and less than or equal to 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, central nervous system symptoms); and

   d. Recipient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity reactions, copper deficiency, iron deficiency).

3. Prior Authorization Guidelines:

   a. Prior authorization 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 prior authorization 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 Request (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. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

XXX. Compounded Medications

Last Reviewed by the DUR Board: January 24, 2019

Compounded medications are subject to prior authorization 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 prior authorization 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. Prior Authorization Guidelines

   a. Prior authorization approval will be for six months unless the provider requests for a shorter length of therapy.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

YYY. Antibiotics

Last Reviewed by the DUR Board: July 26, 2018

Antibiotic medications are subject to prior authorization 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	
cefdotoren	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 intravenous 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 intravenous 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. Prior Authorization Guidelines

a. Prior authorization approval will be for a single course.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. References

a. CDC Antibiotic Prescribing and Use in Doctor's Offices: https://www.cdc.gov/antibiotic-use/community/for-hcp/outpatient-hcp/index.html

b. CDC Improving Prescribing: https://www.cdc.gov/antibiotic-use/community/improving-prescribing/index.html

c. IDSA Guidelines: https://www.idsociety.org/practice-guidelines/#/score/DESC/0/+/

ZZZ. Oral Oncology Agents

Therapeutic Class: Oral Oncology Agents
Last Reviewed by the DUR Board: January 24, 2019

Oral oncology agents are subject to prior authorization 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 Request

   a. Documentation of a positive clinical response to the oral oncology treatment.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 prior authorization 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.

a. Coverage and Limitations

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

a. The recipient has a documented diagnosis of pulmonary arterial hypertension; 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 Pulmonary Arterial Hypertension
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. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: April 22, 2021

Anticonvulsants are subject to prior authorization 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 (10mg/kg twice daily); and

f. The medication will be used as adjunctive therapy (the recipient has been taking one or more antiepileptic drugs and has chart notes confirming the presence of at least four convulsive seizures per month).

2. Recertification Request

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. Prior Authorization Guidelines

a. Initial prior authorization will be for three months.

b. Recertification approval will be for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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 Request

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

c. Prior Authorization Guidelines

1. Initial prior authorization will be for six months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 and 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. Prior Authorization Guidelines:

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 Request:

1. The recipient has documentation of positive clinical response to Fintepla® therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 prior authorization 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 greater than or equal to 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 transthyretin (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/FAP (familial amyloidotic polyneuropathy) 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 greater than or equal to two 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 Request:

    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. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

DDDD. Oxervate® (cenegermin-bkbj)

Therpeutic Drug Class: Ophthalmic Human Nerve Growth Factor (Q25)
Last Reviewed by DUR Board: October 20, 2022

Oxervate® (cenegermin-bkbj) is subject to prior authorization 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 greater than or equal to two 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. Prior Authorization Guidelines:

    a. Prior authorization will be approved for eight weeks.

EEEE. Penicillamine

Therapeutic Class: Antirheumatics
Last reviewed by DUR Board: January 19, 2023

Penicillamine is subject to prior authorization 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.

   b. Recertification Request:

      1. Recipient continues to meet above criteria; and

      2. Recipient has demonstrated positive clinical response to therapy.

   c. Prior Authorization Guidelines:

      1. Initial approval will be given for 12 months.

      2. 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 Request:

      1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

3. Rheumatoid Arthritis

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

1. Recipient has diagnosis of severe, active rheumatoid arthritis; 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 Request:

1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. Prior Authorization 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 prior authorization 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 greater than or equal to 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 less than 30 ng/mL; and

c. serum corrected total calcium below 9.8 mg/d; and

4. Recipient has Chronic Kidney Disease (CKD) Stage 3 or 4

5. Recipient does not have CKD Stage 5 or end stage renal disease on dialysis

6. Recipient has a history of failure, contraindication, or intolerance to adequate trial of all of the following:

a. Calcitriol

b. Doxercalciferol

d. Paricalcitol

7. Medication is prescribed by or in consultation with nephrologist or endocrinologist.

b. Recertification Request:

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.

5. Prior Authorization 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: January 19, 2023

Relvyrio® (sodium phenylbutyrate/taurusodiol) is subject to prior authorization 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/taurusodiol)

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

1. Recipient is greater than or equal to 18 years of age; and

2. Recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

3. Recipient must have an adequate trial of riluzole for greater than or equal to eight weeks or contraindication to therapy; and

3. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R); and

4. Recipient does not require permanent assisted ventilation; and

5. Therapy prescribed by or in consultation with neurologist; and

b. Recertification Request:

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

2. 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. Recipient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure).

a. Prior Authorization Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be approved for six 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 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 HIV/AIDS are a covered benefit for Nevada Medicaid recipients. FDA approved antiretrovirals whose manufacturers participate in the federal Drug Rebate Program and are not DESI drugs, are covered.

4. DIABETIC SUPPLY PROGRAM

Diabetic Supplies are subject to prior authorization 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.

Prior authorization is required for preferred and non-preferred diabetic products (including insulin delivery system and Continuous Glucose Monitor [CGM] receivers and readers).

Preferred diabetic product information is found at:
https://www.medicaid.nv.gov/providers/rx/diabeticsupplies.aspx

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) 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 Diabetes Mellitus Type I 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 mg/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. Prior Authorization Guidelines

   a. Initial prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Recertification Request

   a. Recertification of prior authorization approval will be given if the recipient has documented positive clinical response to the product (including current HbA1C).

   b. Recertification prior authorization 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 Continuous Glucose Monitors (CGMs)

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

   a. Recipient must have a documented diagnosis of Diabetes Mellitus Type I 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. Prior Authorization Guidelines

a. Initial prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https/www.medicaid.nv.gov/providers/rx/rxforms.aspx

D. Non-Preferred Continuous Glucose Monitor (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

a. Pharmacy Services billing information including Billing Manual and Quantity Limits is available at: https://www.medicaid.nv.gov/providers/rx/billinginfo.aspx

*Blood Glucose monitors with special features (e.g. voice synthesizers) require a prior authorization. For special blood glucose monitors, a diagnosis and a statement from the physician documenting the impairment is required with a prior authorization.

5. PHYSICIAN ADMINISTERED DRUGS (PADs) REQUIRING PRIOR AUTHORIZATION AND/OR QUANTITY LIMITATIONS

A. Abraxane® (paclitaxel protein-bound particles)

Therapeutic Class: Taxane Chemotherapy
Last Reviewed by the DUR Board: N/A

Physician Administered Drugs (PAD) are subject to prior authorization 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. 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. Used a single agent or in combination with carboplatin in recipient with high tumor burden, rapidly progressing disease, and visceral crisis; and

b. Disease is HER2-negative; and

1. Disease is hormone receptor-negative; or

2. Disease is hormone receptor-positive, and recipient is refractory to endocrine therapy or has a visceral crisis; or

c. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; or

d. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease; or

3. May be substituted for paclitaxel or docetaxel if the recipient has experienced hypersensitivity reactions despite premedication, or the patient has contraindication 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 patients 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 combination with carboplatin and pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); and

a. Used in recipients with tumors that have negative actionable molecular biomarkers; and

b. Used in recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

2. Used in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2); and

a. Used in recipients with tumors that have negative actionable molecular biomarkers and PD-L1 greater than or equal to one percent; or

b. Used in recipients with tumors that have negative actionable molecular biomarkers and PD-L1 less than one percent; or

c. Used in recipients who are positive for one of the following molecular mutations: EFGR exon 20, KRAS G12C, BRAD V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

b. Used as subsequent therapy; and

1. Used as a single agent (if not previously given) in recipients with a PS 0-2; and

a. Used for first progression after initial systemic therapy; or

b. Used in combination with carboplatin and pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in recipients with PS score of 0-1; and

1. Used in recipients who are positive for one the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

2. Used in recipients who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; or

c. Used in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2); and

1. Used in recipients 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

2. Used in recipients who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or

L858R tumors, EGFR S7681, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; or

3. Used in recipients with PD-L1 expression-positive (greater than or equal to one percent) tumors that are negative for actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy.

d. Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal)

1. Recipient has recurrent or persistent disease; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); and

a. Used a single agent; and

1. Recipient has 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 relapse disease less than six months after complete remission from prior chemotherapy; or

2. Recipient has platinum-sensitive disease; and

a. Used for radiographic and/or clinical relapse greater than or equal to six months after complete remission from prior chemotherapy; or

b. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; and

1. Used for relapse greater than or equal to six months after complete remission from prior chemotherapy; or

3. Recipient has recurrent low-grade serous carcinoma; and

a. Used as a single agent for platinum-sensitive or platinum-resistant disease; or

b. Used in combination with carboplatin for platinum-sensitive disease 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 fluoropyrimide-based therapy; or

4. Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); or

5. Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy (metastatic disease only); or

b. Recipient has recurrent disease in the pancreatic operative bed or metastatic disease, post-resection; and

1. Used greater than or equal to six months after completion of primary therapy; or

2. Used less than six months from completion of primary therapy with a fluoropyrimidine-based regimen; or

c. Used as neoadjuvant therapy; and

1. Recipient has resectable disease with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); 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 ECOG PS 0-1; and

1. Used as first-line therapy; or

2. Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy.

f. Cutaneous Melanoma

1. Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; and

a. Used as subsequent therapy for disease progression; or

b. Used after maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.).

g. Uveal Melanoma

1. Used as a single agent for distant metastatic disease

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Used as a single agent therapy; and

2. 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

a. Recipient has endometroid adenocarcinoma; and

1. Used a primary treatment of disease not suitable for primary surgery; and

a. Recipient has suspected or gross cervical involvement (excluding recipients using a chemotherapy alone); or

b. Recipient has locoregional extrauterine disease; or

c. Recipient has distant metastases; or

2. Recipient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/de-differentiated carcinoma; and

a. Used for locoregional recurrence or disseminated metastases; or

b. Used as additional treatment of metastatic disease that is suitable for primary surgery; or

c. Used as primary treatment of metastatic disease that is not for primary surgery.

i. Hepatobiliary Adenocarcinoma (Intrahepatic /Extrahepatic Cholangiocarcinoma, Gallbladder)

1. Used in combination with gemcitabine for unresectable 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 subsequent therapy; or

b. Recipient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; and

1. Used as initial therapy; or

2. Used as subsequent therapy in recipient who previously received initial therapy with nivolumab with or without ipilimumab, pembrolizumab, or dostarlimab-gxly.

k. Kaposi Sarcoma

1. Used as subsequent 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

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

4. Disease has progressed on alternative first-line systemic therapy.

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., 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.

2. Dosing Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Abraxane® 100 mg powder for injection single dose vial: 9 vials per 21-day supply

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Kaposi Sarcoma

1. 300 billable units per 28 days

b. All other indications

1. 900 billable units per 21 days

3. Recertification Request:

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. 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: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count less than 1,500 cell/mm3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions (including anaphylactic reactions), etc.

4. PA Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be given for six months.

B. Anti-PD-1 Monoclonal Antibodies

Therapeutic Class: Anti-PD-1 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

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

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, 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

c. Recipient has metastatic or recurrent disseminated disease.

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

c. Metastatic or local bladder cancer recurrence post cystectomy

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.

4. 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.

5. 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; and

b. Recipient was previously treatment with a platinum-based regimen; or

2. Recipient has high-risk disease (i.e., prognostic score greater than or equal to seven or FIGO stage IV disease).

6. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as single-agent therapy; and

b. Recipient has recurrent or metastatic disease; and

c. Used as second-line treatment for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

b. Dosing Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Bavencio 200 mg/10mL single dose vial: 4 vials per 14 days

2. 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, hepatotoxicity, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE) when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

d. PA Guidelines:

1. Initial approval will be given for 6 months.

2. Recertification will be given for 6 months.

2. Imfinzi® (durvalumab)

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 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, etc.) unless otherwise specified; and

3. Non-Small Cell Lung Cancer (NSCLC)

   a. Recipient has a performance status (PS) of 0-1; and

      1. Used as a single agent; and

         a. Used as consolidation therapy: and

         b. Recipient has unresectable stage II-III disease; and

         c. Disease has not progressed after definitive chemoradiation; or

      2. Used in combination with tremelimuab-actl and platinum-based chemotherapy; and

         a. Used as first-line therapy for metastatic disease; and

         b. Recipient had no EGFR mutations or ALK genomic tumor aberrations.

4. Small Cell Lung Cancer (SCLC)

   a. Recipient has extensive stage disease (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.

5. Hepatobiliary Cancers

   a. Recipient has hepatocellular carcinoma (HCC); and

      1. Used a first-line therapy as a single agent; and

         a. Recipient has unresectable disease and is not a transplant candidate; or

         b. Recipient has liver-confirmed disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or

         c. Recipient has metastatic disease or extensive liver tumor burden; or

2. Used as first-line therapy in combination with tremelimumab-actl; and

a. Recipient has unresectable disease; and

b. Recipient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); and

1. Recipient has intermediate disease (i.e., multinodular, PS 0) and is not eligible for locoregional therapy; or

2. Recipient has advanced disease (i.e., portal invasion, regional lymph node metastasis, distant metastasis, PS 1-2); or

b. Recipient has biliary tract cancer (e.g., gallbladder cancer or intra-/extra- hepatic cholangiocarcinoma); and

1. Used in combination with cisplatin and gemcitabine; and

a. Used as primary treatment for unresectable, locally advanced, or metastatic disease; or

b. Used for recurrent disease greater than six months after surgery with curative intent and greater than six months after completion of adjuvant therapy.

b. Dosage Limits

1. Quantity Limits (max daily dose) [NDC Unit]:

a. Imfinzi 120 mg/2.4 mL single dose vial: four vials per 14 days

b. Imfinzi 500 mg/10 mL single dose vial: two vials per 14 days

2. Max Units (per dose and over time) [HCPCS Unit]:

a. NSCLC: 112 billable units (1,120 mg) every 14 days

b. SCLC: 150 billable units (1,500 mg) every 21 days x six disease, then 150 billable units (1,500 mg) every 28 days

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. Hepatocellular Carcinoma: 150 billable units (1,500 mg) every 28 days

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, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, pancreatitis, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; and

4. NSCLC (single-agent use)

a. Recipient has not exceeded a maximum of 12 months of therapy

5. Hepatobiliary Cancers

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-basis.

6. Continuation Maintenance Therapy for SCLC

a. Refer to Section III for criteria.

d. PA Guidelines:

1. Initial approval for Non-Small Cell Lung Cancer (single agent use) will be given for six months.

2. Recertification for Non-Small Cell Lung Cancer (single agent use) will be given for 12 months.

3. Initial approval for Non-Small Cell Lung Cancer (use in combination with tremelimumab-act] and platinum-based chemotherapy, Small Cell Lung Cancer and Hepatobiliary Cancers will be given for six months.

4. Recertification for Non-Small Cell Lung Cancer (used in combination with tremelimumab-act] and platinum-based chemotherapy, Small Cell Lung Cancer and Hepatobiliary Cancers will be for six months.

3. Libtayo® (cemiplimab-rwlc)

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 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, etc.), unless otherwise specified; and

3. Cutaneous Squamous Cell Carcinoma (cSCC)

a. Recipient has metastatic disease, locally advanced disease, unresectable disease, inoperable or incompletely resected regional disease, new regional disease, or local or regional recurrence; and

b. Used as a single agent; and

c. Recipient is not a candidate for curative surgery or curative radiation therapy.

4. Basal Cell Carcinoma

a. Recipient has previously been treated with a hedgehog pathway inhibitor (HHI) (e.g., vismodegib, sondegib, etc.)

b. Used as a single agent; and

1. Recipient has locally advanced disease; or

2. Recipient has local recurrence and is not a candidate for curative surgery or curative radiation therapy; or

3. Recipient has nodal, regional, or metastatic disease.

5. Non-Small Cell Lung Cancer (NSCLC)

a. Recipient has tumors that are negative for actionable molecular biomarkers; and

1. Used as first-line therapy in combination with platinum-based chemotherapy; and

a. Recipient has locally advanced disease and is not a candidate for surgical resection or definitive chemoradiation; or

b. Recipient has metastatic disease; or

2. 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. Recipient has tumors with high PD-L1 expression (Tumor Proportion Score [TPS] greater than or equal to 50%) as determined by an FDA-approved or CLIA compliant test; and

b. Used as a single agent; 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-rwlc.

b. Dosage Limits

1. Quantity Limits (max daily dose) [NDC Unit]:

a. Libtayo® 350 mg/seven mL single-dose vial: one vial per 21 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. 350 billable units (350 mg) every 21 days.

c. Recertification Request

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. 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 hematopoietic stem cell transplantation (HSCT), etc; and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

4. Ocrevus® (ocrelizumab)

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

1. Recipient is at least 18 years of age (unless otherwise specified); 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 HBsAg and anti-HBV tests); and

3. Recipient has had baseline serum immunoglobulins assessed; and

4. 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

5. Multiple Sclerosis

a. Recipient must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); and

b. Must be used as single agent therapy; 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 less than 65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of less than or equal to six and a half.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Ocrevus® 300mg single-dose vial: two vials in first two weeks, then two vials per six months.

2. 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 Dose

1. 600 billable units (300 mg) every six months.

c. Recertification Request

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

2. Recipient has not received a dose of ocrelizumab within the past five months; and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy malignancy, hypoegammaglobulinemia, immune-mediated colitis, etc.; and

4. 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 hypertensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), nine-hole peg test (nine-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 greater than or equal to one relapse, greater than or equal to two unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

5. PPMS

a. Recipient continues to be ambulatory, defined as an EDSS score of less than seven and a half.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

5. Opdivo® (nivolumab)

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

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, etc.), unless otherwise specified; and

3. Ampullary Adenocarcinoma

a. Recipient's disease is microsattelite instability-high (MSI-H) or mismatch repair deficient (dMMR); 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. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

1. Used for disease that progressed during or following platinum-containing chemotherapy 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; and

            a. Recipient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes

        5. Metastatic upper genitourinary (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 or atriall cystectomy; and

    c. Recipient is at high risk for disease recurrence.

6. Bone Cancers

    a. Recipient has one of the following: Ewing sarcoma, chondrosarcoma (excluding mesenchymal chondrosarcoma), osteosarcoma, or chordoma; and

b. Recipient has tumor mutation burden-high (TMB-H) tumors [greater than or equal to 10 mutations/megabase (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.

7. 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. Recipient has 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 positive non-small cell lung cancer (NSCLC).

8. Pediatric Central Nervous System (CNS) Cancers

a. Recipient is less than or equal to 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 less than three years of age and used as a single agent; or

b. Recipient is greater than or equal to three years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide.

9. Cervical Cancer

a. Used as subsequent therapy as a single agent; and

b. Recipient has persistent, recurrent, or metastatic disease; and

c. Tumor expressed PD-L1 (e.g., CPS greater than or equal to one) as determined by an FDA-approved or CLIA-compliant test.

10. Colorectal Cancer

a. Recipient is at least 12 years of age; and

b. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

c. Used as a single agent or in combination with ipilimumab; and

1. Used as subsequent therapy for advanced or metastatic disease that progressed following treatment with one of the following:

a. Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy

b. Non-intensive therapy in recipients with an improvement in functional status; or

2. Used as primary treatment; and

a. Used as neoadjuvant therapy for clinical T4b colon cancer; or

b. Used as neoadjuvant therapy for resectable liver and/or lung metastases; or

c. Used if resection is contraindicated following neoadjuvant therapy for advanced, locally unresectable, or medically inoperable rectal cancer; or

d. Used for unresectable (or medically inoperable) or metastatic disease.

11. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipients' disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used as a single agent or in combination with ipilimumab; and

1. Used as subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin-irinotecan- and/or fluoropyrimidine-based therapy; or

2. Used as initial therapy for advanced or metastatic disease.

12. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

a. Used as first-line therapy; and

1. Recipient has esophageal squamous cell carcinoma (ESCC); 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

2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Used as subsequent therapy; and

1. Recipient has esophageal squamous cell carcinoma (ESCC); and

2. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; and

3. Used as a single agent; 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).

13. Gestational Trophoblastic Neoplasia

a. Used as 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; and

b. Recipient has previously treated with a platinum-based regimen; or

2. Recipient has high risk disease (i.e., greater than or equal to seven Prognostic score or stage IV disease).

14. Gastric Cancer

a. Recipient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; and

1. Used as first-line therapy in combination with fluoropyrimidine – and platinum containing chemotherapy.

15. 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 performance status 0-1; and

b. Used for one of the following:

1. Unresectable locoregional recurrence with prior radiation therapy (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

b. Recipient has unresectable, recurrent, persistent, or metastatic disease; and

c. Disease has progressed on or after platinum-containing chemotherapy.

16. Hepatocellular Carcinoma (HCC)

a. Used in combination with ipilimumab; and

b. Used as subsequent therapy for progressive disease; and

c. Recipient has Child-Pugh Class A hepatic impairment; and

1. Recipient was previously treated with sorafenib; or

2. Recipient has unresectable disease and is not a transplant candidate; or

3. Recipient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; or

4. Recipient has metastatic disease or extensive liver tumor burden.

17. Adult Classical Hodgkin Lymphoma (cHL)

a. Used as a single agent; and

1. Recipient has relapsed or progressive disease after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; or

2. Used for disease that is refractory to at least three prior lines of therapy or as palliative therapy in recipient greater than 60 years of age; and

a. Recipient has relapsed or progressive disease after autologous HSCT; or

b. Recipient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure or second-line chemotherapy; or

c. Recipient is post-allogeneic stem-cell transplant; or

b. Used in combination with brentuximab vedotin or ICE (ifosfamide, carboplatin, etoposide); and

1. Used as subsequent therapy (if not previously used) for relapse or refractory disease; and

a. Recipient has relapsed or progressive disease after autologous HSCT; or

b. Recipient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; or

c. Recipient is post-allogeneic stem-cell transplant.

18. Pediatric Classical Hodgkin Lymphoma (cHL)

a. Recipient is less than or equal to 18 years of age; and

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 re-induction therapy; and

2. Used as a single agent or in combination with brentuximab vedotin; or

3. 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 greater than one year, absence of extranodal disease or B symptoms at relapse).

19. Renal Cell Carcinoma (RCC)

a. Used in combination with ipilimumab for clear cell histology; and

1. Used as first-line therapy in recipients with poor or intermediate risk advanced, relapsed, or stage IV disease; or

2. Used as first-line therapy in recipients with favorable risk relapsed or stage IV disease; or

3. 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.

20. Malignant Peritoneal Mesothelioma (MPeM)

a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); or

b. Used in combination with ipilimumab as first-line therapy; and

1. Recipient has unresectable diffuse disease; or

2. Recipient has unresectable recurrent benign multicystic or well-differentiated papillary disease.

21. Malignant Pleural Mesothelioma (MPM)

a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); or

b. Used in combination with ipilimumab as first-line therapy; and

1. Recipient has stage IIIB or IV disease; or

2. Recipient has sarcomatoid or biphasic histology; or

3. Disease is medically inoperable or unresectable.

22. Cutaneous Melanoma

a. Used as first-line therapy for unresectable or metastatic disease; and

1. Used as a single agent or in combination with ipilumumab; or

b. Used as initial therapy for limited resectable disease; and

1. Used as single agent; and

a. Recipient has stage III disease with clinical satellite/in-transit metastases; or

b. Recipient has local satellite/in-transit recurrence; or

c. Used as subsequent therapy for unresectable or metastatic disease; and

1. 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 greater than three months after treatment discontinuation; and

a. Used as a single agent or in combination with ipilimumab; or

2. Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); and

a. Used as a single agent or in combination with ipilimumab if anti-PD-1 was not previously used; or

b. Used in combination with ipilimumab for recipients who progressed on single agent anti-PD-1 therapy; or

d. Used as adjuvant treatment as a single agent; and

1. Recipient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; or

2. Recipient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; or

3. Recipient has undergone TLND and/or complete excision of disease limited to nodal recurrence; or

4. Recipient has undergone complete resection of metastatic disease; or

5. Recipient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., stereotactic ablative therapy or complete resection) or systemic therapy.

23. Uveal Melanoma

a. Recipient has distant metastatic disease; and

b. Used as a single agent or in combination with ipilimumab.

24. Merkel Cell Carcinoma

a. Used as a single agent; and

1. Used as neoadjuvant treatment for regional, pathologic N+ disease; or

2. Used for primary or recurrent metastatic disseminated disease.

25. Non-Small Cell Lung Cancer

a. Used for resectable (tumors greater than or equal to four cm or node positive) disease; and

1. Used as neoadjuvant therapy in combination with platinum-doublet chemotherapy (e.g., cisplatin/carboplatin in combination with paclitaxel, pemetrexed, or gemcitabine); or

b. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediatinal 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 performance status (PS) zero to one have tumors that are negative for actionable molecular biomarkers and PD-L1 expression less than one percent

2. Recipients with a PS zero to one 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 greater than or equal to one percent) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

b. Used in combination with ipilimumab; or

c. 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 swuamous cell histology, etc.); or

2. Used as subsequent therapy; and

a. Used as a single agent; or

b. Used for one of the following:

1. Recipients with a PS 0-1 who are positive for one of the following molecular mutations 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 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

c. Used in combination with ipilimumab; or

d. Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

e. Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; or

3. Used as continuation maintenance therapy in combination with ipilimumab; and

a. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.

26. Small Bowel Adenocarcinoma

a. Recipient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used as a single agent or in combination with ipilimumab; and

1. Used as initial therapy; or

2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

27. Small Cell Lung Cancer (SCLC)

    a. Used as subsequent systemic therapy as a single agent; and

        1. Used for relapsed disease in recipients with a complete or partial response or stable disease after primary treatment (excluding use in recipients who progressed on maintenance atezolizumab or durvalumab at time of relapse); or

        2. Used for primary progressive disease.

28. 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.

29. Endometrial Carcinoma (Uterine Neoplasms)

    a. Used as a single agent; and

    b. Used as second-line therapy for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) recurrent or metastatic disease.

30. Vulvar Cancer

    a. Used as single agent; and

    b. Recipient has adenocarcinoma or squamous cell carcinoma; and

    c. Used as second-line therapy for HPV-related advanced, recurrent, or metastatic disease.

31. Pediatric Aggressive Mature B-Cell Lymphomas – Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

    a. Recipient is less than or equal to 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.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Opdivo® 40mg/four mL single-dose vial: two vials per 14 days

b. Opdivo® 100mg/10mL single-dose vial: three vials per 14 days

c. Opdivo® 120 mg/12mL single-dose vial: three vials per 14 days

d. Opdivo® 240 mg/24mL single-dose vial: four vials per 14 days.

c. Recertification Request

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. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe inf usion-related reactions, complications of allogeneic hematopoietic stem cell

transplantation (HSCT), severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis/hepatotoxicity, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), etc.; and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. For the following indications, recipient has not exceeded a maximum of two years of therapy:

a. Bone Cancer; or

b. Cervical Cancer; or

c. Esophageal Cancer (in combination with fluoropyrimidine- and platinum-containing chemotherapy or ipilimumab); or

d. Esophagogastric/Gastroesophageal Junction Cancer (in combination with fluoropyrimidine-and platinum-containing chemotherapy); or

e. Gastric Cancer; or

f. Malignant Pleural Mesothelioma; or

g. Malignant Peritoneal Mesothelioma; or

h. Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy); or

i. Renal Cell Carcinoma (in combination with cabozantinib); or

j. Vulvar Cancer.

5. Urothelial Carcinoma (adjuvant therapy)

a. Recipient has not exceeded a maximum of one year of therapy.

6. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy)

a. Recipient has not exceeded a maximum of one year of therapy.

7. Classical Hodgkin Lymphoma (in combination with brentuximab vedotin)

a. Recipient has not exceeded a maximum of twelve weeks of therapy.

8. Classical Hodgkin Lymphoma (in combination with ICE)

a. Recipient has not exceeded a maximum of six weeks of therapy.

9. Cutaneous Melanoma (re-induction therapy)

a. Refer to Section III for criteria (see Cutaneous Melanoma – Used for retreatment of disease as re-induction).

10. Merkel Cell Carcinoma (neoadjuvant therapy)

a. Recipient has not exceeded a maximum of two doses.

11. Non-Small Cell Lung Cancer (neoadjuvant therapy in combination with platinum-doublet chemotherapy)

a. Recipient has not exceeded a maximum of three cycles.

12. Non-Small Cell Lung Cancer (maintenance therapy)

a. Refer to Section III for criteria.

d. Prior Authorization Guidelines

1. Use in the treatment of Classical Hodgkin Lymphoma:

   a. In combination with brentuximab vedotin can be authorized up to a maximum of twelve weeks of therapy and may not be renewed; and

   b. In combination with ICE (ifosfamide, carboplatin, etoposide) can be authorized up to a maximum of six weeks of therapy and may not be renewed.

2. Neoadjuvant treatment of Merkel Cell Carcinoma can be authorized up to a maximum of two doses and may not be renewed

3. Neoadjuvant treatment of NSCLC in combination with platinum-doublet chemotherapy may be authorized for a maximum of three cycles and may not be renewed

4. Adjuvant treatment of the following indications may be renewed up to a maximum of one year of therapy:

   a. Cutaneous Melanoma

   b. Esophageal and Esophagogastric/Gatroesophageal Junction Cancer

   c. Urothelial Carcinoma.

5. The following indications may be renewed up to a maximum of two years of therapy:

   a. Bone Cancer

   b. Cervical Cancer

   c. Esophageal Cancer (in combination with fluoropyrimidine-and platinum-containing chemotherapy or ipilimumab)

   d. Esophagogastric/Gastroesophageal Junction Cancer (in combination with fluoropyrimidine-and platinum-containing chemotherapy)

   e. Gastric Cancer

   f. Malignant Pleural Mesothelioma

   g. Malignant Peritoneal Mesothelioma

   h. Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)

i. Renal Cell Carcinoma (in combination with cabozantinib)

j. Vulvar Cancer

6. Initial approval will be given for six months.

7. Recertification will be given for six months.

6. Tecentriq® (atezolizumab)

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

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, etc.); and

3. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

b. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma; or

2. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; or

3. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes); or

4. Primary carcinoma of the urethra that is stage T3-4 cN1-2 or cN1-2 with palpable inguinal lymph nodes; or

5. Metastatic upper genitourinary (GU) tract tumors; or

6. Metastatic urothelial carcinoma of the prostate; and

c. Used as first-line therapy in cisplatin-ineligible recipients; and

1. Recipient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible); or

2. Recipient has a PD-L1 expression of greater than or equal to five percent (PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to five percent of the tumor area) as determined by an FDA-approved or CLIA-compliant test.

4. Non-Small Cell Lung Cancer (NSCLC)

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; and

a. Used for tumors that are negative for actionable molecular markers and PD-L1 greater than or equal to 50% (PD-L1 stained greater than or equal to 50% of tumor cells [TC greater than or equal to 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to ten percent of the tumor area [IC greater than or equal to ten percent]), as determined by an FDA-approved test or CLIA-compliant test; and

1. Used as a single agent; or

b. Used for non-squamous disease in one of the following:

1. Recipients with PS 0-1 who have tumors that are negative for actionable molecular markers and PD-L1 less than one percent

2. Recipients with PD-L1 expression positive tumors (PD-L1 greater than or equal to one percent) that are negative for actionable molecular biomarkers

3. Recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); and

c. Used in combination with carboplatin, paclitaxel, and bevacizumab; or

d. Used in combination with carboplatin and albumin-bound paclitaxel; or

2. Used as subsequent therapy; and

a. Used as a single agent; or

b. Used for non-squamous disease in one of the following:

1. 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

2. Recipients with PS 0-1 who are positive for one of the following molecular mutations and received prior targeted therapy: EGFR exon 19 deletion or L858R tumors, EGFR S7681, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; and

c. Used in combination with carboplatin, paclitaxel, and bevacizumab; or

d. Used in combination with carboplatin and albumin-bound paclitaxel; 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

b. Recipient has stage II to IIIA disease; and

1. Used as a single agent; and

2. Used as adjuvant treatment following resection and previous adjuvant chemotherapy; and

3. Tumor expressed PD-L1 greater than or equal to one percent as determined by an FDA-approved test or CLIA-compliant test

5. Small Cell Lung Cancer (SCLC)

a. Recipient has extensive stage disease (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.

6. Hepatocellular Carcinoma (HCC)

a. Used as first-line therapy in combination with bevacizumab; and

b. Recipient has Child-Pugh Class A hepatic impairment; and

1. Recipient has unresectable or metastatic disease; or

2. Recipient has liver confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; or

3. Recipient has extensive liver tumor burden.

7. Malignant Peritoneal Mesothelioma (MPeM)

a. Used as subsequent therapy in combination with bevacizumab.

8. Cutaneous Melanoma

a. Recipient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; and

b. Recipient has unresectable or metastatic disease; and

c. Used as first-line therapy in combination with cobimetinib and vemurafenib.

9. Alveolar Soft Part Sarcoma (ASPS)

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

   b. Used as a single agent; and

   c. Recipient has unresectable or metastatic disease that is not curable by surgery.

b. Dosage Limits

   1. Quantity Limit (max daily dose) [NDC Unit]:

      a. Tecentriq® 1,200 mg single-use vial: one vial per 21 days.

      b. Tecentriq® 850 mg single-use vial: one vial per 14 days.

   2. Max Units (per dose and over time) [HCPCS Unit]:

      a. MPeM: 120 billable units every 21 days.

      b. All other indications: 168 billable units every 28 days.

c. Recertification Request

   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 S~~s~~ection 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: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis, etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

   4. Continuation Maintenance Therapy for NSCLC or SCLC

   5. NSCLC (adjuvant treatment)

      a. Recipient has not exceeded a maximum of twelve months of therapy

d. Prior Authorization Guidelines

   1. Initial approval will be given for six months.

2. Recertification will be given for six months.

3. Neoadjuvant therapy in NSCLC can be authorized up to a maximum of 12 months of therapy.

C. Beovu® (brolucizumab-dbll)

Therapeutic Class: Ophthalmic-Macular Degeneration
Last Reviewed by the DUR Board: N/A

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. 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. 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, pegaptanib, bevacizumab, faricimab-svoa, 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 age-related macular degeneration (AMD):

         a. Six 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. Diabetic Macular Edema (DME)

         a. Six 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 age-related macular degeneration (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. Diabetic Macular Edema (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

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) Age-Related Macular Degeneration (AMD)

1. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline corrected visual acuity (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 disease and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 16:

a. Decrease in BCVA of greater than or equal to five letters compared to baseline; or

b. Decrease in BCVA of greater than or equal to three letters due to neovascular AMD disease activity compared with week 12; or

c. Decrease in BCVA of greater than or equal to five letters and central subfield thickness greater than or equal to 75 microns compared with week 12; or

d. New or worsening intra-retinal cysts or fluid compared with week 12.

e. Diabetic Macular Edema (DME)

1. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA, etc.); and

2. Decreasing the interval or maintenance doses from 12-weeks to either 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 greater than or equal to five letters compared to baseline; and

b. Increase in central subfield thickness compared to baseline.

4. PA Guidelines:

a. Initial approval be given for 12 months.

b. Recertification will be approved for 12 months.

D. Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™ (bevacizumab)

Therapeutic Class: ANP -Human Vascular Endothelial Growth Factor Inhib Rec-MC Antibody
Last Reviewed by the DUR Board: N/A

Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™(bevacizumab) are subject to prior authorization 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, unless otherwise specified; and

   b. Universal Criteria

      1. Recipient has no recent history of hemoptysis (i.e., the presence of greater than or equal to 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., five-fluorouracil/five-FU or capecitabine) based regimen for intestinal type disease; and

         a. Used as first-line therapy for unresectable localized or metastatic disease or as subsequent therapy for disease progression; and

            1. Recipient has poor performance status (ECOG PS 2); or

            2. Recipient has good performance status (ECOG 0-1, with good biliary drainage and adequate nutritional intake) and received prior oxaliplatin-based therapy.

   d. Adult Central Nervous System (CNS) Cancers

      1. Used for symptom management related to radiation necrosis, poorly controlled vasogenic edema, or mass effect as single-agent short-course therapy; and

         a. Recipient has a diagnosis of one of the following CNS cancers

            1. Glioma (WHO Grade 1)

            2. Primary CNS Lymphoma

3. Meningiomas

4. Brain or Spine metastases

5. Medulloblastoma

6. Glioblastoma/Gliosarcoma

7. IDH-mutant Astrocytoma (WHO Grade 2-4)

8. IDH-mutant, 1p19q co-deleted Oligodendroglioma (WHO Grade 2 or 3)

9. Intracranial or Spinal Ependymoma (excluding subependymoma); or

2. Used for recurrent 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

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

3. Used as a single agent for progressive or recurrent Intracranial or Spinal Ependymoma (excluding subependymoma) after prior radiation therapy; or

4. Used as a single agent for recipients with surgically inaccessible recurrent or progressive Meningioma when radiation is not possible.

e. Cervical Cancer

1. Recipient has persistent, recurrent, or metastatic disease; and

a. Disease has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology; 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 (Combined Positive Score [CPS] greater than or equal to 1) as determined by an FDA-approved or CLIA compliant test; or

3. Recipient has small cell neuroendocrine carcinoma of the cervix (NECC); and

   a. Used as subsequent therapy; 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 expressed PD-L1 (Combined Positive Score [CPS] greater than or equal to one) as determined by an FDA-approved or CLIA compliant test.

f. Colorectal Cancer (CRC)

   1. Will not be used as part of adjuvant treatment; and

      a. Used in combination with a fluoropyrimidine (e.g., five-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; or

      b. 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

      c. Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease after progression on all available regimens.

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

2. Used as subsequent therapy for progression of advanced or metastatic disease; and

a. Used in combination with a fluoropyrimidine (e.g., five-fluorouracil/five-FU or capecitabine) or irinotecan-based regimen following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy; or

b. Used in combination with trifluridine and tipiracil after progression on all available regimens.

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Used as single agent therapy for recurrent or metastatic disease that has progressed or prior cytotoxic chemotherapy; or

2. Used in combination with carboplatin and paclitaxel for advanced and recurrent disease; or

3. Used in combination with paclitaxel and carboplatin as adjuvant therapy; and

a. Recipient has advanced and recurrent stage III-IV endometroid adenocarcinoma.

i. Hepatocellular Carcinoma (HCC)

1. Used as first-line therapy in combination with atezolizumab; and

2. Recipient has Child-Pugh Class A disease; and

a. Recipient has unresectable or metastatic disease; or

b. Recipient has liver confined disease inoperable by performance status, comorbidity or with minimal or uncertain extrahepatic-disease; or

c. Recipient has extensive liver tumor burden.

j. Malignant Peritoneal Mesothelioma (MPeM)

1. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Recipient has unresectable diffuse disease; or

2. Recipient has unresectable recurrent benign multi-cystic or well-differentiated papillary disease; or

2. Used as subsequent therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Immunotherapy was administered as first-line treatment; or

b. Used in combination with atezolizumab.

k. Malignant Pleural Mesothelioma (MPM)

1. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Recipient has unresectable 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

b. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible); and

c. Immunotherapy was administered as first-line treatment.

l. Non-Squamous Non-Small Cell Lung Cancer (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 L858R mutations; or

2. Used for one of the following:

a. Recipients with a performance status (PS) less than or equal to one who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression less than one percent; or

b. PD-L1 expression positive tumors (PD-L1 greater than or equal to one percent) that are negative for actionable molecular biomarkers; or

c. Recipients with a PS less than or equal to one 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); 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 inhibitor

c. Atezolizumab, carboplatin, and paclitaxel; or

b. Used for subsequent therapy in recipients with a PS less than or equal to one; and

1. Used for one of the following:

a. EGFR exon 19 deletion or 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 greater than or equal to one percent) tumors that are negative for actionable molecular biomarkers with 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 who have EGFR exon 19 deletions or L858R mutations or ALK rearrangement positive tumors); or

c. Used as continuation maintenance therapy (bevacizumab must have been included in the recipients first-line chemotherapy regimen) in recipients who achieved a tumor response or stable disease after first-line systemic therapy; and

1. Used as a single agent; 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 metastases; 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

b. 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 niraparib; or

3. Used in combination with carboplatin and either gemcitabine, paclitaxel, or PEGylated 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, PEGylated liposomal doxorubicin, paclitaxel, or topotecan; or

c. Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in recipients who have received no prior chemotherapy; or

d. Used as maintenance therapy; and

1. Used following primary therapy including bevacizumab; and

a. Used as a single agent in recipients that are BRCA1/2 wild-type or unknown and homologous recombination (HR) proficient or status unknown (grade 2/3 endometrioid and high-grade serous histology only); or

b. Used in combination with Olaparib; and

1. Recipient is BRCA1/2 wild-type or unknown and HR deficient (grade 2/3 endometrioid and high-grade serous histology only), or

2. Recipient has a germline or somatic BRCA1/2 mutation (grade 2/3 endometrioid, high grade serous, clear cell, carcinosarcoma histology only), or

2. Used a single agent following recurrence therapy with chemotherapy plus bevacizumab for platinum-sensitive disease; or

3. Used in combination with paclitaxel and carboplatin for stable disease following neoadjuvant therapy as continued treatment (grade 2/3 endometrioid and high-grade serous histology only); or

e. Used as neoadjuvant therapy in combination with paclitaxel and carboplatin (grade 2/3 endometrioid and high-grade serous histology only); and

1. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; or

f. Used as adjuvant therapy in combination with paclitaxel and carboplatin; and

1. Recipient has pathologic stage II-IV disease; or

2. Used after interval debulking surgery (IDS) in recipients with a response or stable disease to neoadjuvant therapy (grade 2/3 endometrioid and high-grade serous histology only); and

a. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction.

n. Pediatric Central Nervous System (CNS) Cancers

1. Recipient is less than or equal to 18 years of age; and

2. Recipient has diffuse high-grade glioma; and

3. Used for palliation of recurrent or progressive disease (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant).

o. Renal Cell Carcinoma (RCC)

1. Used in combination with interferon alfa for metastatic disease; or

2. Recipient has metastatic or relapsed disease with non-clear cell histology; and

a. Used as a single agent; or

b. Used in combination with everolimus; or

c. Used in combination with erlotinib in recipients with advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC.

p. Small Bowel Adenocarcinoma

1. Recipient has advanced or metastatic disease; and

2. Used in combination with fluoropyrimidine-based regimen.

q. Soft Tissue Sarcoma

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 squamous cell carcinoma or adenocarcinoma; and

3. Recipient has unresectable, locally advanced, metastatic, or recurrent disease.

2. Dosage Limits

   a. Quantity Limit (max daily dose) [NDC Unit]:

      1. 100 mg/4 mL single-dose vial: three vials 21 days

      2. 400 mg/16 mL single-dose vial: four vials per 21 days

   b. Max Units (per dose and over time) [HCPCS Unit]:

      1. Oncology Indications (J9035/Q5107/Q5118/J999/Q5126):

         a. Small Bowel Adenocarcinoma/Ampullary Adenocarcinoma:

            1. 60 billable units per 14 days

         b. NSCLC, Cervical Cancer, HCC, Vulvar Cancer, MPM, & MPeM:

            1. 170 billable units per 21 days

         c. All other indications:

            1. 120 billable units per 14 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. 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: gastrointestinal perforations and fistulae, surgical/wound healing complications, necrotizing fasciitis, hemorrhage, arterial and venous thromboembolic events (ATE & VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, proteinuria, severe infusion-related reactions, ovarian failure, congestive heart failure (CHF), etc.; and

   d. Adult CNS Cancers – symptom management (short-course therapy):

      1. Coverage may not be renewed

e. Adult CNS Cancers – Oligodendroglioma, Glioblastoma, or Astrocytoma (in combination with carmustine, lomustine, or temozolomide):

1. Refer to Section III for criteria

f. Colorectal Cancer (after first-line bevacizumab-containing regimen):

1. Refer to Section III for criteria

g. MPM and MPeM (maintenance therapy):

1. Refer to Section III for criteria

h. Non-Squamous Non-Small Cell Lung Cancer (maintenance therapy or continuation therapy in combination with erlotinib):

1. Refer to Section III for criteria

i. Ovarian Cancer (maintenance therapy):

1. Refer to Section III for criteria

4. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. For Adult CNS Cancers (symptom management), coverage will be provided for 12 weeks and may not be renewed.

c. Recertification will be given for six months.

E. Darzalex® (daratumumab)

Therapeutic Class: Antineoplastic
Last Reviewed by the DUR Board: N/A

Darzalex® (daratumumab) are subject to prior authorization 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 and hyaluronidase-fihj, isatuximab, etc,); and

   c. Multiple Myeloma

      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. Lenalidomine 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 autologous stem cell transplant (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; 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. Cyclophosphamide and bortezomib; or

e. Selinexor; or

5. Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (bortezomic, 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 as single agent therapy; 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 patients.

d. Systemic Light Chain Amyloidosis

1. Used as single agent therapy; and

2. Used for the treatment of relapsed/refractory disease.

2. Dosage Limits

   a. Quantity Limit (max daily dose) [NDC Unit]:

      1. Darzalex® 100 mg single dose vial for injection: up to three vials per dose

         a. Weekly Weeks 1 to 8, then every two weeks 9-24, then every four weeks-week 25 onwards; or

      2. Darzalex® 400 mg single dose vial for injections: up to four vial per dose

         a. Weekly weeks one to eight, then every two weeks 9-24, then every four weeks – week 25 onwards; or

   b. Max Units (per dose and over time) [HCPCS Unit]:

      1. Up to 180 billable units per dose

         a. Weekly week one to eight, then every two weeks, week 9-24, then every four weeks – week 25 onwards.

   c. Max Units (per dose and over time) [HCPCS Unit]:

      1. Up to 180 billable units per dose

         a. Weekly week one to eight, then every two weeks, week 9-24, then every four weeks – week 25 onwards.

3. Recertification Request

   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. 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: severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia, etc.; and

   d. Multiple Myeloma

      1. Use for newly diagnosed disease in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

2. Use for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

3. 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).

4. Use for newly diagnosed disease in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

4. PA Guidelines:

a. Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

b. Use for newly diagnosed multiple myeloma 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 multiple myeloma 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 multiple myeloma in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

e. Initial approval will be given for six months.

f. 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: N/A

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

      1. Used in the treatment of newly diagnosed disease in recipients who are ineligible 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 recipients who are eligible for autologous stem cell transplant (ASCT) in combination with one of the following regiments:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. Bortezomib, thalidomide, and dexamethasone (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 nine-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 nine-24, then every four weeks Week 25 onwards.

3. Recertification Request

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. Multiple Myeloma

1. Used for newly diagnosed disease in combination with bortezomib, thalidomide and dexamethasone may not be renewed.

2. Used for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

3. 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).

4. 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 bortezomib, cyclophosphamide and dexamethasone (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 multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

d. Used for newly diagnosed multiple myeloma 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: N/A

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

   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 (6MWT), percent predicted forced vital capacity (FVC), joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ), and/or urinary glycosaminoglycan (uGAG); and

      2. Recipients 16 months to less than five years of age: spleen volume, liver volume, FVC, six-MWT, and/or urinary glycosaminoglycan (uGAG); and

   c. Universal Criteria

      1. Recipient does not have severe cognitive impairment; and

      2. 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® six mg/three mL vial: 10 vials per seven days.

   b. Max Units (per dose and over time) [HCPCS Unit]:

      2. 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 six-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 uGAG levels; or

      2. Recipients 16 months to less than five years of age: reductions in spleen volume and/or liver volume or stabilization/improvement in FVC and/or 6-MWT, and/or uGAG levels.

4. PA Guidelines:

   a. Initial approval will be given for 12 months.

   b. Recertification will be given for 12 months.

H. Anti-Angiogenic Ophthalmic Agents

Therapeutic Class: Anti-angiogenic ophthalmic agents
Last Reviewed by the DUR Board: N/A

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. 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 active intraocular inflammation; and

c. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., brolucizumab-dbll, ranibizumab, pegaptanib, bevacizumab, faricimab-svoa, etc.); and

d. Recipients best corrected visual activity (BCVA) is measured at baseline and periodically during treatment; and

e. Recipient has a definitive diagnosis of one of the following:

3. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

4. Macular Edema following Retinal Vein Occlusion (RVO)

5. Diabetic Macular Edema (DME)

6. Diabetic Retinopathy (DR)

b. Dosage Limit

1. Quantity Limit (max daily dose) [NDC Unit]:

a. 2 mg injection: one vial per eye every 28 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Diagnosis

1. Neovascular age-related macular degeneration (AMD)

a. MU for Initial Dosing

1. Four units every 28 days x three doses.

a. MU for Maintenance Dosing

1. Four units every 28-56 days.

2. Macular edema following retinal vein occlusion (RVO)

a. MU for Initial Dosing

1. Four units every 28 days.

a. MU for Maintenance Dosing

1. Four units every 28 days.

3. Diabetic Macular Edema (DME)/ Diabetic Retinopathy (DR)

a. MU for Initial Dosing

1. Four units every 28 days x five doses.

a. MU for Initial Dosing

1. Four units every 28-56 days.

c. Recertification Request:

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 and retinal detachments, increase in intraocular pressure, arterial thromboembolic events: and

3. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition.

d. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be given for 12 months.

2. Lucentis®; Byooviz™; Cimerli™ (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. 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 best corrected visual activity (BCVA) is measured at baseline and periodically during treatment; and

d. Recipient has a definitive diagnosis of one of the following:

1. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

2. Diabetic Macular Edema (DME) (Lucentis® and Cimerli™ Only)

3. Diabetic Retinopathy (DR) (Lucentis® and Cimerli™ Only)

4. Macular Edema following Rental Vein Occlusion (RVO)

5. Myopic Choroidal Neovascularization (mCNV).

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. 0.3mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days

b. 0.5mg 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 Age-related Macular Degeneration (AMD)/Macular Edema following Retinal Vein Occlusion (RVO)/Myopic Choroidal Neovascularization (mCNV)

1. Ten units every 28 days

b. Diabetic Macular Edema (DME)/Diabetic Retinopathy (DR) – (Lucentis and Cimerli Only)

1. Six units every 28 days.

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 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 the baseline best corrected visual acuity (BCVA), 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. Prior Authorization Guidelines

1. Initial approval will be given for three months for myopic choroidal neovascularization (mCNV).

2. Recertification will be given for three months for myopic choroidal neovascularization (mCNV).

3. Initial approval will be given for 12 months for all other indications

4. Recertification will be given for 12 months for all other indications.

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, pergaptanib, brolucizumab, bevacizumab, ranibizumab, faricimab-svoa, etc.) unless supplemental treatment is necessary (see below); 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 best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; and

3. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

a. Recipient has previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab).

b. Dosage and Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Susvimo® 100mg/mL solution for injection SDV: one vial per eye every 24 weeks.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Neovascular Age-related Macular Degeneration

1. 40 billable units (four mg) 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 the baseline best corrected visual acuity (BCVA), 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. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

I. Immune Globulins (immunoglobin)

Therapeutic Class: Immune Globulin
Last Reviewed by DUR Board: N/A

Immune Globulins (immunoglobulin) are subject to prior authorization 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. Approval will be given if all the following criteria are met and documented:

1. Baseline valyes for BUN and serum creatinine within 30 days of request; and

2. Primary immunodeficiency (PID)/Wiskott – Aldrich Syndrome

a. Such as: 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) [list not all inclusive].

1. Recipients IgG level is less than 200 mg/dL or 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; 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. Need for intravenous antibiotics to clear infections; or

7. Two or more deep-seated infections including septicemia; 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 less than 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 disease state:

b. To manage acute bleeding due to severe thrombocytopenia (platelet count less than 30 x 10(9)/L); or

c. To increase platelet counts prior to invasive surgical procedures such as splenectomy (platelet count less than 20 x 10(9)/L).

d. Authorization will be given for one month only and cannot be renewed.

e. Chronic Immune Thrombocytopenia (CIT)

1. The recipient is at increased risk for bleeding as indicated by a platelet count less than 30 x 10(9)/L; and

2. History of failure, contraindication, or intolerance to corticosteroids; and

3. Duration of illness greater than six months.

5. Chronic Inflammatory Demyelination Polyneuropathy (CIDP)

a. Recipient's disease course is progressive or relapsing and remitting for greater than two 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 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., INCAT, Medical Research Council (MRC muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

f. Initial approval 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., less than one month); and

c. Recipient has abnormal or absent deep tendon reflexes in upper or lower limbs; and

d. Recipient has diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; and

e. Approval will be granted for a maximum of two rounds of therapy within six weeks of onset.

f. Initial approval will be given for two months only and cannot be renewed.

7. Multifocal Motor Neuropathy

a. Recipient has progressive, focal, asymmetric limb weakness (without sensory symptoms) for greater than one 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, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

e. Initial approval will be given for three months.

8. HIV infected children: Bacterial control or prevention

a. Recipient age does not exceed 13 years of age; and

b. Recipients IgG level is less than 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. Initial approval will be valid for one course (one month) only and cannot be renewed.

10. Dermatomyositis/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. Must be used as part of combination therapy with other agents; and

g. Recipient has a documented baseline physical exam and muscular strength/function.

h. Initial approval will be given for three months.

11. Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas), and bone marrow transplant

a. Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation.

b. Treatment of antibody-mediated rejection of solid organ transplantation.

c. Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus).

12. Stiff-Person Syndrome

a. Recipient has anti-glutamic acid decarboxylase (GAD) antibodies; and

b. Recipient has failed at least two of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam; 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 bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; and

c. Recipients IgG level is less than 400 mg/dL.

d. Initial approval will be given for three months.

14. Kawasaki's Disease

a. Initial approval will be 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. Initial approval will be given through the delivery date only and cannot be renewed.

16. Neonatal Alloimmune Thrombocytopenia (NAIT)

a. Initial approval will be 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 Aquisita

6. Pemphigus Gestationis (Herpes gestationis)

7. Linear IgA Dermatotis; and

b. Recipient has severe disease that is extensive and debilitating; and

c. Diagnosis has been confirmed by biopsy; and

d. Recipient's disease is progressive; 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 Acute Lymphoblastic Leukemia (ALL)

a. Used for prevention of infection; and

b. Recipient's IgG level is less than 400 mg/dL.

19. Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia or Multiple Myeloma

a. Recipients IgG level is less than 200 mg/dL or 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; or

b. Two or more serious sinus infections within one year; or

c. Two or more months of antibiotics with little effect; or

d. Two or more pneumonias within one year; or

e. Recurrent or deep skin abscesses; or

f. Need for intravenous antibiotics to clear infections; or

g. 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.

20. Toxic Shock Syndrome

a. Initial approval be given 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, dostarlimab, 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. Stevens-Johnson Syndrome (SJS)

3. Toxic epidermal necrolysis (TEN)

4. Severe (G3-4) myasthenia gravis

5. Transverse myelitis

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 pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present

11. Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

22. Management of CAR T-Cell-Related Toxicity

a. Recipient has been receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, 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 less than 600 mg/dL and serious, persistent, or recurrent bacterial infections; or

a. Used as prophylactic therapy prior to receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagen autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

b. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels less than or equal to 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.

b. Dosage Limits

1. Dosing should be calculated using adjusted body weight if one or more following criteria are met:

a. Recipient's body mass index (BMI) is 30 kg/m(2) or more; or

b. Recipient's actual body weight is 20% higher than his or her ideal body weight (IBW).

c. Recertification Request:

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. Recipient meets the disease-specific criteria identified below:

5. Primary Immunodeficiency (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.

6. 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. Recipient is at a decreased risk of infection as a result of treatment necessitating continued therapy.

7. Chronic Immune Thrombocytopenia/ITP

   a. Disease response as indicated by the achievement and maintenance of a platelet count of greater than or equal to 30 x 10(9)/L and at least doubling the baseline platelet count.

8. 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, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

9. Guillain-Barre Syndrome (Acute Inflammatory polyneuropathy)

   a. May not be renewed.

10. 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, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

11. 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 less than 400 mg/dL.

12. Myasthenia Gravis

    a. May not be renewed.

13. Dermatomyositis/Polymyositis

    a. Recipient had an improvement from baseline on physical exam and/or muscular strength and function.

14. Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas), and bone marrow transplant

    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 is at a decreased risk of infection as a result of treatment necessitating continued therapy.

15. Stiff Person Syndrome

    a. Documented improvement from baseline on physical exam.

16. Allogeneic Bone Marrow or Stem Cell Transplant

    a. Patients IgG trough is less than 400 mg/dL.

17. Kawasaki's Disease

    a. May not be renewed.

18. Fetal Alloimmune Thrombocytopenia (FAIT)

    a. Authorization is valid through the delivery date only and cannot be renewed.

19. Neonatal Alloimmune Thrombocytopenia

    a. May not be renewed.

20. Auto-Immune Mucocutaneous Blistering Diseases

    a. Documented improvement from baseline on physical exam.

21. Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), or Multiple Myeloma

    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 is at a decreased risk of infection as a result of treatment necessitating continued therapy.

22. Toxic Shock Syndrome

    a. May not be renewed.

23. Management of Immune Checkpoint Inhibitor related Toxicity

    a. May not be renewed.

24. Management of CAR T-Cell-Related Toxicity

    a. Recipient is still receiving treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

    b. Recipient has serum IgG levels less than 600 mg/dL.

25. 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 ten percent 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.

d. Prior Authorization Guidelines:

1. Initial and renewal authorization periods vary by specific covered indication.

2. Unless otherwise specified, the initial approval will be given for six months.

3. Recertification will be approved for 12 months.

2. SCIG (immune globulin SQ): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify®

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

1. Baseline values for BUN and serum creatinine obtained within 30 days of request; and

2. Primary immunodeficiency (PID)/Wiskott-Aldrich Syndrome

a. Such as: 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 greater than or equal to two years old [HyQvia only: recipient must be greater than or equal to 18 years old]; and

2. Recipient's IgG level is less than 200 mg/dL or 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

2. Two or more serious sinus infections within one year

3. Two or more serious months of antibiotics within little effect

4. Two or more pneumonias within one year

5. Recurrent or deep skin abscesses

6. Need for intravenous antibiotics to clear infections

7. Two or more deep-seated infections including septicemia; 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. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Hizentra® Only]

a. Recipient must be greater than or equal to 18 years old; and

b. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, six-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 Chronic Lymphocytic Leukemia

a. Recipient's IgG level is less than 200 mg/dL or 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 abscesses

f. Need for intravenous antibiotics to clear infections

g. 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 Limits

1. Quantity Limits

a. Hizentra®

1. Dose/week: 46g

2. Dose/28 days: 184g

b. Gamunex®-C & Gammaked™

1. Dose/week: 24g

2. Dose/28 days: 96g

c. Gammagard Liquid

1. Dose/week: 24g

2. Dose/28 days: 96g

d. HyQvia

1. Dose/week: 17.5g

2. Dose/28 days: 69g

e. Cuvitru®

1. Dose/week: 23g

2. Dose/28 days: 92g

f. Cutaquig®

1. Dose/week: 24g

2. Dose/28 days: 96g

g. Xembify®

1. Dose/weel: 24g

2. Dose/28 days: 96g

2. Max Units (per dose and over time) [HCPCS Unit]:

a. Hizentra®

a. Billable units/28 days: 960 (PID)/1840 (CIDP)

b. Gamunex®-C & Gammaked™

1. Billable units/28 days: 192

c. Gammagard liquid

1. Billable units/28 days: 192

d. HyQvia

1. Billable units/28 days: 690

e. Cuvitru®

1. Billable units/28 days: 920

f. Cutaquig®

1. Billable units/28 days: 960

g. Xembify®

1. Billable units/28 days: 960

c. Recertification Request

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 hypersensitivity/anaphylaxis, thrombosis, aseptic meningitis syndrome, hemolytic anemia, hyperproteinemia, acute lung injury, etc.; and

3. BUN and serum creatinine obtained within the last six months and the concentration and rate of infusion have been adjusted accordingly; and

4. Primary immunodeficiency (PID)/Wiskott-Aldrich Syndrome

   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.

5. Chronic Inflammatory Demyelination Polyneuropathy (CIDP) [Hizentra® 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, Medical Research Council (MRC) muscle strength, six-MWT, Rankin, Modified Rankin, etc.); or

   b. Recipient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra®; and

      1. Recipient improved and stabilized on IVIG treatment; and

      2. Recipient was not receiving maximum dosing or Hizentra® prior to relapse.

6. Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia

   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 is at a decreased risk of infection as a result of treatment necessitating continued therapy.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification approval will be given for 12 months.

J. Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)

Therapeutic Class: Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)
Last Reviewed by DUR Board: N/A

Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1) are subject to prior authorization 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-gwly)

   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 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, etc.), unless otherwise specified; and

      3. Mismatch Repair Deficient (dMMR/Microsatellite Instability-High (MSI-H) Cancer

         a. Recipient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or CLIA-compliant test; and

         b. Used as a single agent; and

         c. Recipient has, but is not limited to, one of the following cancers:

            1. Endometrial Carcinoma

               a. Recipient does not have endometrial sarcoma (excluding carcinosarcoma); and

               b. Used for advanced or recurrent disease; and

               c. Disease has progressed on or following prior treatment with a platinum-containing regimen.

            2. Ampullary Adenocarcinoma

a. Used as subsequent therapy for recurrent or advance disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

3. Breast Cancer

a. Used for recurrent unresectable or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

4. Appendiceal Adenocarcinoma – Colon Cancer

a. Used as subsequent therapy for advanced or metastatic disease; and

b. Disease has progressed following treatment with oxaliplatin-, irinotecan- and/or fluropyrimidine-based therapy.

5. Colorectal Cancer (CRC)

a. Used as subsequent therapy for advanced or metastatic disease; and

b. Disease has progressed following treatment with oxaliplatin-, irinotecan- and/or fluoropyrimidine-based therapy.

6. Esophageal and Esophagogastric Junction Cancer

a. Used as subsequent therapy for recipients who are not surgical candidates or who have unresectable locally advanced, recurrent, or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

7. Gastric Cancer (adenocarcinoma)

a. Used as subsequent therapy for recipients with locoregional disease who are not surgical candidates or who have unresectable locally advanced, recurrent, or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

8. Occult Primary/Cancer of Unknown Primary (CUP)

a. Used in symptomatic recipients with performance status (PS) 1-2 or asymptomatic recipients with PS 0 and aggressive recurrent or advanced disease; and

b. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

c. Disease has progressed on or following prior treatment; and

d. Recipient has no satisfactory alternative treatment options; and

e. Recipient has one of the following:

1. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated.

2. Lung nodules or breast marker-negative pleural effusion.

3. Resectable liver disease.

4. Peritoneal mass or ascites with non-ovarian histology.

5. Retroperitoneal mass of non-germ cell histology in selected recipients.

6. Unresectale liver disease or disseminated metastases.

9. Ovarian, Fallopian Tube, and Primary Peritoneal Cancers

a. Recipient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Mullerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; and

1. Recipient has persistent, recurrent, or advanced disease; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); or

b. Recipient has Low-Grade Serous Carcinoma; and

1. Recipient has recurrent or advanced tumors.

10. Small Bowel Adenocarcinoma

a. Used for advanced or metastatic disease; and

1. Used for initial therapy in recipient with prior oxaliplatin exposure in the adjuvant treatment setting or with a contraindication to oxaliplatin; or

2. Used as subsequent therapy in recipients without prior oxaliplatin exposure in the adjuvant treatment setting and without a contraindication to oxaliplatin.

b. Dosage Limits

1. Administer 500 mg intravenously every three weeks for doses one through four, followed by subsequent doses of 1,000 mg every six weeks (dose five begins three weeks after the fourth dose) until disease progression or unacceptable toxicity.

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 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 hematopoietic stem cell transplantation (HSCT), etc.

d. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

2. Keytruda® (pembrolizumab)

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

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., cemiplumab, avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab-rmbw, etc.), unless otherwise specified; and

3. Anal Carcinoma

a. Recipient has metastatic squamous cell carcinoma; 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. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

1. Recipient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMBIC) defined as one of the following:

a. Persistent disease despite adequate BCG therapy

b. Disease recurrence after an initial tumor free state following an adequate BCG course of therapy

c. T1 disease following a single induction course of BCG therapy; and

d. Recipient has carcinoma in situ (CIS); and

e. 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

c. Metastatic or local bladder cancer recurrence post-cystectomy

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 genitourinary (GU) tract tumors

g. Metastatic urothelial carcinoma of the prostate; and

h. Used for disease that progressed during or following platinum-containing chemotherapy; or

i. Used as second-line treatment after chemotherapy other than a platinum; or

j. Used as first-line therapy in cisplatin-ineligible recipients; and

1. Recipient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible).

6. Triple-Negative Breast Cancer

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 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has high-risk early-stage disease; and

1. Used as neoadjuvant therapy in combination with chemotherapy; and

2. Used as adjugvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy.

7. Adult Central Nervous System (CNS) Cancer

a. Used as a single agent; and

b. Primary tumor is due to BRAF non-specific melanoma or PD-L1 positive non-small cell lung cancer (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.

8. Pediatric Central Nervous System (CNS) Cancers

a. Recipient is less than or equal to 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 less than three years of age and used as a single agent; or

b. Recipient is greater than or equal to three years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide.

9. Cervical Cancer

a. Recipient has persistent, recurrent, or metastatic disease; and

b. Tumor expressed PD-L1 (CPS greater than or equal to one) as determined by an FDA-approved or CLIA-compliant test; and

1. Used as a single agent; and

a. Disease has progressed on or after chemotherapy; or

2. Used in combination with chemotherapy.

10. Esophageal or Gastroesophageal Junction Cancer:

a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

1. Used in combination with platinum-and fluoropyrimidine-based chemotherapy; and

   a. Used as first-line therapy; or

2. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

   a. Used as first-line therapy for HER2-positive disease; and

   b. Recipient has adenocarcinoma; or

3. Used as a single agent; and

   a. Recipient has squamous cell carcinoma; and

      1. Tumor expresses PD-L1 (CPS greater than or equal to 10) as determined by an FDA-approved or CLIA compliant test; and

      2. Recipient progressed after one or more prior lines of systemic therapy.

11. Gastric Cancer

    a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

    b. Recipient has adenocarcinoma; and

    c. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

    d. Used as first-line therapy for HER2-positive disease.

12. Gestational Trophoblastic Neoplasia

    a. Used as a single agent or multiagent chemotherapy-resistant disease; and

       1. Recipient has intermediate placental site trophoblastic (PSTT) or epithelioid trophoblastic tumor (ETT); and

          a. Used for recurrent or progressive disease; and

          b. Recipient has previously treated with a platinum-based regimen; or

2. Recipient has high risk disease (i.e., greater than or equal to seven prognostic score or stage IV disease).

13. 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; and

b. Recipient has Very Advanced Head and Neck Cancer; and

1. Recipient has nasopharyngeal cancer; and

a. Recipient has a performance status 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 radiation therapy (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 locally advanced disease; and

1. Used as a single agent as first-line therapy in recipients with a performance status (PS) 3; and

2. Tumor expresses PD-L1 (CPS greater than or equal to one) 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 greater than or equal to one) 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 fluorouracil and a platinum chemotherapy agent or in combination with docetaxel and either carboplatin or cisplatin; and

a. Recipient has a performance status zero through one.

14. Hepatocellular Carcinoma (HCC)

a. Used as a single agent; and

b. Recipient was previously treated with sorafenib; and

c. Recipient has Child-Pugh Class A liver impairment (i.e., excluding Child-Pugh Class B and C).

15. Adult Classical Hodgkin Lymphoma (cHL)

a. Recipient has relapsed or refractory disease; and

1. Used as a single agent; or

2. Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin); or

b. Used as a palliative therapy in recipients greater than 60 years of age; and

1. Recipient has relapsed or progressive disease after high-dose therapy (HDT)/autologous stem cell transplantation (ASCT); or

2. Recipient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; or

3. Recipient is post-allogeneic stem-cell transplant.

16. Pediatric Classical Hodgkin Lymphoma

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 decreased in cardiac function.

17. Renal Cell Carcinoma (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

2. Recipient has a metastasectomy within one year of having undergone a nephrectomy for relapsed or stage IV disease; or

a. Recipient has non-clear cell histology; and

b. Used as single agent for relapsed or stage IV disease.

18. Cutaneous Melanoma

a. Used as first-line therapy as a single agent for unresectable or metastatic disease; or

b. Used as initial treatment of limited resectable disease; and

1. Used as a single agent; and

a. Recipient has stage III disease with clinical satellite/in-transit metastases; or

b. Recipient has local satellite/in-transit recurrence; or

c. Used as subsequent therapy for unresectable or metastatic disease after disease progression or maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafen/binimetinib, etc.); and

1. 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 with no residual toxicity) from prior anti-PD-1 therapy, but subsequently have disease progression/relapse greater than three months after treatment discontinuation; or

2. 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 with no residual toxicity) from prior combination ipilimumab/anti-PD-1 therapy, but subsequently have disease progression/relapse greater than three months after treatment discontinuation; or

d. Used as a single agent for adjuvant treatment; and

1. Recipient has stage IIB or IIC melanoma following complete restriction; 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 lymph node involvement and has undergone complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; or

c. Recipient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision; or

3. Recipient has local satellite/in-transit recurrence and has NED after complete excision; or

4. Recipient has undergone TLND and/or complete excision of disease limited to nodal recurrence; or

5. Recipient has oligometastatic disease and NED after receiving metastasis-directed therapy (e.g., stereotactic ablative therapy or complete resection) or systemic therapy.

19. Uveal Melanoma

a. Used as a single parent; and

b. Recipient has distant metastatic disease.

20. Merkel Cell Carcinoma (MCC)

a. Recipient is at least six months of age; and

b. Used as a single agent; and

1. Recipient has recurrent disease and both curative surgery and curative radiation therapy are not feasible; or

2. Recipient has recurrent locally advanced or metastatic disease.

21. Adrenal Gland Tumors

a. Recipient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); and

b. Used with or without mitotane.

22. Non-Small Cell Lung Cancer (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 greater than or equal to one percent) as determined by an FDA-approved or CLIA compliant test and with no EGFR or ALK genomic tumor aberrations; or

b. Used for stage IB (T2a greater than or equal to four centimeters), II, or IIIA disease; and

1. Used as adjuvant therapy as a single agent; and

2. Used following resection and platinum-based chemotherapy; or

c. 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 greater than or equal to one percent) tumors, as detected by an FDA-approved or CLIA compliant test, that are negative for actionable molecular biomarkers

2. Recipients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression less than one percent

3. Recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, 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 historlogy; 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 greater than or equal to one percent) 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 mutations and have received prior targeted therapy; EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719x-positive tumors, 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 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.

23. Primary Cutaneous Lymphomas

a. Used as a single agent; 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 III Mycosis Fungoides or stage IV Sezary Syndrome; or

2. 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; 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).

24. Small Cell Lung Cancer (SCLC)

a. Used as subsequent therapy as a single agent; and

1. Disease has relapsed following a complete or partial response or stable disease with primary treatment (excluding use in recipients who progressed on maintenance atezolizumab or durvalumab at time of relapse); or

2. Recipient has primary progressive disease.

25. Soft Tissue Sarcoma

a. Used as a single agent; and

1. Recipient has alveolar soft part sarcoma (ASPS); or

2. Recipient has cutaneous angiosarcoma; or

b. Used in combination with axitinib; and

1. Recipient has alveolar soft part sarcoma (ASPS).

26. 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; or

2. Recipient has unresectable, inoperable, or incompletely resected regional disease or new regional disease that is not curable by radiation therapy.

27. Extranodal NK/T-Cell Lymphomas

    a. Used as a single agent for relapsed or refractory disease; and

    b. Disease progressed following additional treatment with an alternative asparaginase-based combination chemotherapy regimen not previously used; and

    c. Participation in a clinical trial is unavailable.

28. Thymic Carcinoma

    a. Used as a single agent: and

        1. Used as first-line therapy for unresectable, locally advanced, or metastatic disease in recipients who are unable to tolerate first-line combination regimens; or

        2. Used as postoperative treatment in recipients who are unable to tolerate first-line combination regimens; or

        3. Used as second-line therapy for unresectable or metastatic disease.

29. Endometrial Carcinoma (Uterine Neoplasms)

    a. Recipient has advanced, recurrent, or metastatic disease that is mismatch repair proficient (pMMR) as determined by an FDA-approved or CLIA-compliant test or not microsatellite instability-high (MSI-H); and

    b. Disease has progressed following prior systemic therapy; and

    c. Used in combination with Lenvatinib.

30. Vulvar Cancer

    a. Used as a single agent; and

    b. Recipient has adrenocarcinoma or squamous cell carcinoma; and

    c. Recipient has advanced, recurrent, or metastatic disease; and

    d. Tumor expresses PD-L1 (CPS greater than or equal to one) as determined by and FDA-approved or CLIA-compliant test; and

    e. Used as second-line therapy for disease progression on or after chemotherapy.

31. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Cancer

    a. Recipient has at least six months of age; and

    b. Used as a single agent; and

    c. Recipient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA compliant test; and

    d. Pediatric recipients must not have a diagnosis of MSI-H central nervous system cancer; and

    e. Recipient has, but is not limited to, one of the following cancers:

        1. Colorectal Cancer

            a. Used for unresectable or medically inoperable, advanced, or metastatic disease; or

        2. Appendiceal Adenocarcinoma – Colon Cancer

            a. Used as initial therapy for advanced or metastatic disease; or

            b. Used as subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy.

        3. Pancreatic Adenocarcinoma

            a. Used as subsequent therapy for locally advanced or metastatic disease after progression; or

            b. Used for recurrent or metastatic disease after resection; or

            c. Used as first-line therapy for metastatic disease; or

            d. Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and no disease progression after at least four to six months of first-line therapy in recipients with good performance status (i.e., ECOG PS 0-1).

4. Bone Cancer (Ewing Sarcoma, Chordoma [chondroid or conventional histology], Chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or Osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma])

    a. Used for unresectable or metastatic disease that has progressed following prior treatment; and

    b. Recipient has no satisfactory alternative treatment options.

5. Gastric Cancer (Adenocarcinoma) or Esophageal/Gastrophageal Junction Adenocarcinoma or Squamous Cell Carcinoma

    a. Used as subsequent therapy for recipients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.

6. Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Cancers)

    a. Used for persistent or recurrent disease; and

    b. Recipients is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease).

7. Uterine Neoplasms (Endometrial Carcinoma)

    a. Used as second-line therapy for recurrent or metastatic disease; or

    b. Recipient has advanced disease that has progressed following prior systemic therapy in any setting and is not a candidate for curative surgery or radiation.

8. Penile Cancer

    a. Used as subsequent therapy for unresectable or metastatic disease that has progressed following prior treatment; and

    b. Recipient has no satisfactory alternative treatment options.

9. Vulvular Cancer

   a. Recipient has adenocarcinoma or squamous cell carcinoma; and

   b. Used as second-line therapy for advanced, recurrent, or metastatic diseae that progressed following prior treatment; and

   c. Recipient has no satisfactory alternative treatment options.

10. Testicular Cancer

   a. Used as third-line therapy

11. Hepatobiliary Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)

   a. Used as primary treatment for unresectable or metastatic disease; or

   b. Used for unresectable or metastatic disease that has progressed on or after prior treatment.

12. Vulvar Cancer

   a. Recipient has adenocarcinoma or squamous cell carcinoma; and

   b. Used as second-line therapy for advanced, recurrent, or metastatic disease.

13. Cervical Cancer

   a. Used as subsequent therapy for persistent, recurrent, or metastatic disease.

14. Small Bowel Adenocarcinoma

   a. Used for advanced or metastatic disease; and

      1. Used as initial therapy; or

      2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

15. Ampullary Adenocarcinoma

    a. Used as subsequent therapy for disease progression; or

    b. Used as first-line therapy for unresectable localized or metastatic disease.

16. Breast Cancer

    a. Used for recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

    b. Recipient has progressed following prior treatment; and

    c. Recipient has no satisfactory alternative treatment options.

17. Occult Primary/Cancer of Unknown Primary (CUP)

    a. Used in symptomatic recipients with PS one-two or asymptomatic recipients with PS 0 and aggressive disease; and

        1. Recipient has squamous cell carcinoma; and

            a. Recipient has multiple lung nodules; pleural effusion, or disseminated metastases; or

        2. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

            a. Recipient has one of the following:

                1. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated

                2. Lung nodules or breast marker-negative pleural effusion

                3. Resectable liver disease

4. Peritoneal mass or ascites with non-ovarian histology

5. Retroperitoneal mass of non-germ cell histology in selected recipients

6. Unresectable liver disease or disseminated metastases.

18. Very Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)

    a. Recipient has non-nasopharyngeal cancer; and

    b. Recipient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease

19. Prostate Cancer

    a. Recipient has castration-resistant metastatic disease; and

    b. Recipient will continue androgen deprivation therapy (ADT); and

    c. Recipient received prior docetaxel and prior novel hormone therapy (excluding recipients with visceral metastases).

20. Well-Differentiated Grade 3 Neuroendocrine Tumors

    a. Recipient has progressed following prior treatment and has no satisfactory alternative treatment options; and

        1. Recipient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55%], rapid growth rate, negative SSTR-based PET imaging); or

        2. Recipient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [less than 55%], positive SSTR-based PET imaging); or

a. Recipient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55%], rapid growth rate, negative SSTR-based PET imaging); or

b. Recipient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [less than 55%], positive SSTR-based PET imaging); and

1. Recipient clinically significant tumor burden or evidence of disease progression.

21. Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm)

a. Recipient has locoregional unresectable or metastatic disease; and

b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options.

32. Tumor Mutational Burden-High (TMB-H) Cancer

a. Recipient is at least six months of age; and

b. Recipient has solid tumors that are tumor mutational burden-high (TMB-H0 [greater than or equal to 10 mutations/megabase 9mut/Mb)] 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, but is not limited to, one of the following cancers:

1. Bone Cancer (Ewing Sarcoma, Chordoma [chondroid or conventional histology], Chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or

Osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma])

a. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

b. Recipient has no satisfactory alternative treatment options.

2. Breast Cancer

a. Recipient has recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

b. Recipient has progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

3. Cervical Cancer

a. Used as subsequent therapy for unresectable or metastatic disease; and

b. Recipient has progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

4. Gastric Cancer (Adenocarcinoma) or Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma

a. Used as subsequent therapy for recipients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.

5. Hepatobiliary Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)

a. Used for unresectable or metastatic disease that has progressed on or after prior systemic treatment.

6. Head and Neck Cancers

a. Salivary Gland Tumors

1. Used for recurrent metastatic disease in recipients with a PS zero to three; or

2. Used for unresectable locoregional recurrence or second primary with prior radiation therapy.

b. Cancer of the Nasopharynx

1. Used as subsequent therapy for oligometastatic or metastatic disease.

7. Thyroid Carcinoma

a. Anaplastic Carcinoma

1. Used as first- or second-line therapy for metastatic disease

b. Follicular Carcinoma, Papillary Carcinoma, Hurthle Cell Carcinoma

1. Recipient has progressive and/or symptomatic unresectable locoregional recurrent/persistent or metastatic disease not amenable to radioactive iodine (RAI) therapy.

c. Medullary Carcinoma

1. Recipient has unresectable locoregional or recurrent/persistent metastatic disease that is either symptomatic or progressing.

8. Uterine Neoplasms (Uterine Sarcoma [excluding low-grade endometrial stromal sarcoma], Endometrial Carcinoma)

a. Used as second-line therapy for unresectable or metastatic disease that progressed following prior treatment; and

b. Recipient has no satisfactory alternative treatment options.

9. Testicular Cancer

   a. Used as third-line therapy

10. Occult Primary/Cancer of Unknown Primary (CUP)

    a. Used in symptomatic recipients with PS one-two or asymptomatic recipients with PS zero and aggressive disease; and

       1. Recipient has squamous cell carcinoma; and

          a. Recipient has multiple lung nodules, pleural effusion, or disseminated metastases; or

       2. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

          a. Recipient has one of the following:

          b. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated

          c. Lung nodules or breast marker-negative pleural effusion

          d. Resectable liver disease

          e. Peritoneal mass or ascites with non-ovarian histology

          f. Retroperitoneal mass of non-germ cell history in selected recipients

          g. Unresectable liver disease or disseminated metastases.

11. Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Cancers)

    a. Used for persistent or recurrent disease; and

    b. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease).

12. Penile Cancer

    a. Used as subsequent therapy for unresectable or metastatic disease that has progressed on previously approved lines of therapy.

13. Prostate Cancer

    a. Used as subsequent therapy for unresectable or metastatic disease that has progressed on previously approved lines of therapy.

14. Well-Differentiated Grade 3 Neuroendocrine Tumors

    a. Recipient has progressed following prior treatment and has no satisfactory alternative treatment options; and

        1. Recipient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55 percent], rapid growth rate, negative SSTR-based PET imaging); and

        2. Recipient clinically significant tumor burden or evidence of disease progression.

15. Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm)

    a. Recipient has locoregional unresectable or mestastatic disease; and

    b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options.

16. Ampullary Adenocarcinoma

    a. Used as subsequent therapy for disease progression; or

    b. Used as first-line therapy for unresectable localized or metastatic disease.

17. Pancreatic Adenocarcinoma

    a. Used as subsequent therapy for locally advanced or metastatic disease after progression; or

    b. Used for recurrent or metastatic disease after resection; or

    c. Used as first-line therapy for metastatic disease; or

    d. Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and disease no progression after at least four to six months of first-line therapy in recipients with good performance status (i.e., ECOG PS zero to one).

18. Soft Tissue Sarcoma

    a. Recipient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), cutaneous angiosarcoma, or undifferentiated sarcoma; and

    b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options; and

        1. Used as subsequent therapy for advanced or metastatic Extremity/Body Wall, Head/Neck disease; or

        2. Used as subsequent therapy for recurrent unresectable or recurrent stage IV Retroperitoneal/Intra-Abdominal disease.

b. Dosage Limits

    1. Keytruda 100mg/four mL single use vial: 11 vials per 14-day supply.

c. Recertification Requests:

    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 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 hematopoietic stem cell transplantation (HSCT), etc.; and

4. For the following indications, recipient has not exceeded a maximum of twenty-four months of therapy:

   a. Adrenal Gland Tumors

   b. Anal Carcinoma

   c. Bladder Cancer/Urothelial Carcinoma

   d. Cervical Cancer

   e. Classical Hodgkin Lymphoma (cHL)

   f. CNS Cancer

   g. Cutaneous Melanoma (in combination with ipilimumab only)

   h. Cutaneous Squamous Cell Carcinoma (cSCC)

   i. Endometrial Carcinoma

   j. Esophageal/Gastroesophageal Junction Cancer

   k. Gastric Cancer

   l. Hepatocellular Carcinoma (HCC)

   m. Merkel Cell Carcinoma (MCC)

   n. MSI-H/dMMR Cancer

   o. Non-Small Cell Lung Cancer (NSCLC) (first-line or subsequent therapy)

   p. Primary Cutaneous Lymphomas

   q. Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

   r. Renal Cell Carcinoma (RCC) (first-line or subsequent therapy)

   s. Small Cell Lung Cancer (SCLC)

   t. Squamous Cell Carcinoma of the Head and Neck (SCCHN)

u. Thymic Carcinoma

v. Tumor Mutational Burden-High (TMB-H) Cancer

w. Triple Negative Breast Cancer (recurrent unresectable or metastatic disease)

x. Uveal Melanoma

y. Vulvar Cancer

z. Cutaneous Melanoma (adjuvant treatment)

1. Recipient has not exceeded a maximum of twelve months of therapy.

aa. NSCLC (adjuvant treatment)

1. Recipient has not exceeded a maximum of twelve months of therapy.

bb. Triple Negative Breast Cancer (neoadjuvant treatment)

1. Recipient has not exceeded a maximum of twenty-four weeks of therapy.

cc. Triple Negative Breast Cancer (adjuvant treatment)

1. Recipient has not exceeded a maximum of twenty-seven weeks of therapy.

dd. Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy)

1. Refer to Section III for criteria.

ee. Continuation Maintenance Therapy for NSCLC

1. Refer to Section III for criteria.

d. PA Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

K. Kadcyla® (ado-trastuzumab emtansine)

Therapeutic Class: Antineoplastic-Antibody Drug Conjugates (ADCs)
Last Reviewed by DUR Board: N/A

Kadcyla® (ado-trastuzumab emtansine) are subject to prior authorization 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. 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 human epidermal growth factor receptor 2 (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. Central Nervous System (CNS) Cancer

1. Recipient has human epidermal growth factor receptor two (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. Non-Small Cell Lung Cancer (NSCLC)

1. Recipient has ERBB2 (HER2) mutation positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. 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 human epidermal growth factor receptor 2 (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 radiation therapy (RT)

c. Unresectable second primary with prior RT.

2. Dosing Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Kadcyla 100 mg singe-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:

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: hepatotoxicity, pulmonary toxicity (i.e., interstitial lung disease, pneumonitis), thrombocytopenia, neurotoxicity, infusion-related and hypersensitivity reactions, hemorrhage, extravasation at infusion site, etc.; and

d. Left ventricular ejection fraction (LVEF) obtained within the previous 3 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).

L. Aranesp® (darbepoetin alfa)

Therapeutic Class: Recombinant Human Erythropoietins
Last Reviewed by DUR Board: January 19, 2023

Aranesp® (darbepoetin alfa) are subject to prior authorization 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 (unless otherwise specified); and

   b. Initiation of therapy Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct); 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 greater than or equal to 100 ng/mL (mcg/L) and transferrin saturation (TSAT) greater than or equal to 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. Endogenous serum erythropoietin level of less than or equal to 500 mUnits/mL; and

      2. Recipient has lower risk disease (i.e., defined by IPSS-R [Very Low, Low, Intermediate]); and

      3. Recipient has symptomatic anemia.

   e. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

      1. Endogenous serum erythropoietin level of less than 500 mUnits/mL.

   f. Anemia Due to Chemotherapy Treatment

      1. Recipient is receiving concomitant myelosuppressive chemotherapy; and

2. Recipient's chemotherapy 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 (Non-Dialysis Recipients)

1. Recipient at least one month of age.

2. Dosage Limits

a. Quantity Limits (max daily dose) [NDC Unit]

1. Aranesp 10 mcg prefilled syringe: one syringe up to every seven days

2. Aranesp 25 mcg vial or prefilled syringe: one vial or syringe up to every seven days

3. Aranesp 40 mcg vial or prefilled syringe: one vial or syringe up to every seven days

4. Aranesp 60 mcg vial or prefilled syringe: one vial or syringe up to every seven days

5. Aranesp 100 mcg vial or prefilled syringe: one vial or syringe up to every seven days

6. Aranesp 150 mcg prefilled syringe: one syringe up to every seven days

7. Aranesp 200 mcg vial or prefilled syringe: one vial or syringe up to every seven days

8. Aranesp 300 mcg vial or prefilled syringe: one vial or syringe up to every 14 days (MPN may be as frequent as every seven days)

9. Aranesp 500 mcg prefilled syringe: one syringe up to every 14 days

b. Max Units (per dose and over time) [HCPCS Unit]:

1. MDS (J0881 only): 500 billable units every 14 days

2. MPN (J0881 only): 300 billable units every seven days

3. CKD (Non-Dialysis Recipients):

a. Initial: 100 billable units every 14 days

b. Maintenance: 600 billable units every 28 days

4. Chemotherapy-induced: 600 billable units every 21 days

3. Recertification Requests:

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

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

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

d. 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

e. Anemia Due to Myelodysplastic Syndrome (MDS):

1. Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%

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

1. Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct) less than 30%

g. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria

h. Anemia Due to Chronic Kidney Disease (Non-Dialysis Recipients):

1. Pediatric recipients: Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%

2. Adult recipients: Hemoglobin (Hb) less than 11 g/dL and/or Hematocrit (Hct) less than 33%.

4. PA Guidelines:

a. Initial approval will be given for 45 days.

b. Recertification will be given for 45 days.

M. Colony Stimulating Factors

Therapeutic Drug Class: Colony Stimulating Factors
Last Reviewed by DUR Board: January 19, 2023

Colony Stimulating Factors are subject to prior authorization 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. Approval will be given if the following criteria are met and documented:

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 greater than 20%; or

b. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20% and one or more of the following co-morbidities:

1. Age is greater than or equal to 65 years receiving full dose intensity chemotherapy

2. Extensive prior exposure to chemotherapy

3. Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation

4. Persistent neutropenia (ANC less than or equal to 1000/mm(3))

5. Bone marrow involvement by tumor

6. Recipient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)

7. Recent surgery and/or open wounds

8. Poor performance status

9. Renal dysfunction (creatinine clearance less than 50 mL/min)

10. Liver dysfunction (elevated bilirubin greater than 2.0 mg/dL)

11. Chronic immunosuppression in the post-transplant setting, including organ transplant

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. Bone marrow transplantation (BMT) failure or engraftment delay

5. Peripheral blood progenitor cell (PBPC) mobilization and transplant

6. Wilms Tumor (Nephroblastoma)

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® six mg prefilled syringe: one syringe per 14 days

b. Neulasta® Onpro® kit: one kit per 14 days

c. Fulphila® six mg prefilled syringe: one syringe per 14 days

d. Udenyca® six mg prefilled syringe: one syringe per 14 days

e. Ziextenzo® six mg prefilled syringe: one syringe per 14 days

f. Nyvepria™ six mg prefilled syringe: one syringe per 14 days

g. Fylnetra® six mg prefilled syringe: one syringe per 14 days

h. Stimufend® six mg 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. 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, etc.

d. PA Guidelines:

1. Bone marrow transplantation (BMT) failure or engraftment delay: Coverage will be provided for one dose only and may not be renewed.

2. Peripheral blood progenitor cell (PBPC) mobilization and transplant: Coverage will be provided for one dose only and may not be renewed.

3. Initial approval will be given for four months.

4. Recertification will be given for four months.

N. Pemetrexed

Therapeutic Drug Class: Antimetabolites
Last Reviewed by DUR Board: N/A

Antimetabolites are subject to prior authorization 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. Primary Central Nervous System (CNS) Lymphoma

      1. Used as single agent: and

         a. Used as induction therapy in recipients unsuitable for or intolerant to high-dose methotrexate (MTX); or

         b. Used for relapsed or refractory disease.

   c. Malignant Peritoneal Mesothelioma (MPeM)

      1. Used as first-line therapy; and

         a. Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy for unresectable disease; or

         b. Used as a single agent or in combination with cisplatin or carboplatin (if cisplatin ineligible) for diffuse or recurrent disease; or

      2. Used as subsequent therapy; and

         a. Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; or

         b. Used as a single agent; and

            1. Pemetrexed was not administered first-line; or

            2. Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted.

d. Malignant Pleural Mesothelioma (MPM)

1. Used as induction therapy; and

a. Used in combination with cisplatin or carboplatin (if cisplatin ineligible) in recipients with epithelioid histology; or

2. Used as first-line therapy; and

a. Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy; or

b. Used as a single agent; or in combination with cisplatin or carboplatin (if cisplatin ineligible) for resected or recurrent disease; or

c. Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; or

1. Pemetrexed was not administered first-line; or

2. Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted.

e. Non-Squamous Non-Small Cell Lung Cancer (NS-NSCLC)

1. Used in combination with carboplatin or cisplatin-containing regimen; or

2. Used as single-agent therapy; 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 PD-L1 greater than one percent tumors that have negative actionable molecular biomarkers; or

2. Used as first-line therapy for PD-L1 less than or equal to one percent and tumors that have negative actionable molecular markers or BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon-14 skipping mutation, EGFR exon 20 mutation, KRAS G12C mutation, or RET rearrangement positive tumors; or

3. Used as subsequent therapy for first progression after initial systemic therapy; or

4. Used continuation or switch maintenance therapy in recipients who have achieved tumor response or stable disease following initial therapy.

f. Thymomas/Thymic Carcinoma

1. Used as a single agent; and

a. Used as first-line therapy or postoperative treatment in recipients who are unable to tolerate first-line combination regimens; or

b. Used as second-line therapy for unresectable or metastatic disease.

g. Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer)

1. Used as single-agent therapy; and

a. Recipient has recurrent or persistent disease; 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.

2. Dosage Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Alimta® 100mg 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 disodium 750mg powder for injection: two vials every 21 days

5. Pemetrexed disodium 1000mg powder for injection: two vials every 21 days

6. Pemetrexed disodium 100mg/four mL solution for injection: four vials every 21 days

7. Pemetrexed disodium 500mg/20mL solution for injection: four vials every 21 days

8. Pemetrexed disodium 1000mg/40mL solution for injection: two vials every 21 days.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. CNS Lymphoma and Ovarian Cancer: 230 billable units every 21 days

2. All other indications: 130 billable units every 21 days.

3. Recertification Request

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: myelosuppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal toxicity (CrCl less than 45 mL/min), bullous and exfoliative skin toxicity (e.g., Stevens-Johnson Syndrome/Toxic epidermal necrolysis), interstitial pneumonitis, radiation recall, etc.; and

c. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

d. MPeM and MPM

1. May not be renewed when used in combination with platinum therapy and bevacizumab.

e. Thymomas/Thymic Carcinoma

1. May not be renewed

4. Prior Authorization Guidelines

a. Initial approval will be given for six months

1. Thymomas/Thymic Carcinoma: Coverage will be provided for six 21-day cycles and may not be renewed

2. MPeM and MPM: Coverage will be provided for six 21-day cycles and may not be renewed when used in combination with platinum therapy and bevacizumab

b. Recertification will be approved for six months.

O. HER2 Inhibitors

Therapeutic Drug Class: HER2 Inhibitors
Last Reviewed by DUR Board: N/A

HER2 Inhibitors are subject to prior authorization 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. 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. 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. 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. Central Nervous System (CNS) Cancer

a. Used for the treatment of brain metastases in recipients with breast cancer; and

b. Used in combination with high-dose 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. Colorectal Cancer (CRC)

a. Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; and

b. Recipient has not previously received HER2-targeted therapy; and

1. Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting.

6. Appendiceal Adenocarcinoma – Colon Cancer

   a. Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; and

   b. Recipient has not previously received HER2-targeted therapy; and

      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 after at least one prior line of treatment in the advanced or metastatic disease setting.

7. Head and Neck Cancer

   a. Recipient has salivary gland tumors; and

   b. Used in combination with trastuzumab; and

   c. Recipient has recurrent disease with one of the following:

      1. Distant metastases; or

      2. Unresectable locoregional recurrence with prior radiation therapy (RT); or

      3. Unresectable second primary with prior RT.

8. Hepatobiliary Cancers

   a. Recipient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; and

   b. Used as subsequent treatment for progression on or after systemic treatment for unresectable or metastatic diseae; and

   c. 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

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. Left ventricular ejection fraction (LVEF) obtained within the previous three months as follows:

a. Neoadjuvant and adjuvant treatment of breast cancer: LVEF is greater than or equal to 50% OR LVEF has had an absolute decrease of less than 10% from baseline

b. All other indications: LVEF is greater than 45% OR LVEF is 40% to 45% and absolute decrease is less than 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. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months.

2. Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (trastuzumab)

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. 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 two (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

c. Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla®) or famtrastuzumab deruxtecan-nxki (Enhertu®); and

d. 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 locally advanced, node positive, or inflammatory disease; and

a. Used in combination with taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; or

b. Used as a single agent; or

c. Used in combination with pertuzumab; or

b. Used as neoadjuvant or preoperative therapy; and

1. Recipient has locally advanced, 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 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 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 third-line therapy and beyond

f. Lapatinib (without cytotoxic therapy) as third-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

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 is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic adenocarcinoma; and

b. Used as first-line therapy in combination with chemotherapy with or without pembrolizumab (excluding use in combination with DCF [docetaxel, carboplatin, and fluorouracil]).

6. Endometrial Carcinoma – Uterine Neoplasms

a. Used in combination with carboplatin and paclitaxel; and

b. Recipient has stage III/IV or recurrent uterine serous carcinoma.

7. Colorectal Cancer (CRC)

a. Recipient has RAS and BRAF wild-type (WT) disease; and

b. Used in combination with pertuzumab or lapatinib; and

c. Recipient has not previously received HER2-directed therapy; and

1. Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting.

8. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient has RAS and BRAF wild-type (WT) disease; and

b. Used in combination with pertuzumab or lapatinib; and

c. Recipient has not previously received HER2-targeted therapy; and

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 after at least one prior line of treatment in the advanced or metastatic disease setting.

9. Head and Neck Cancer

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 radiation therapy (RT)

3. Unresectable second primary with prior RT.

10. Hepatobiliary Cancers

a. Recipient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; and

b. Used as subsequent treatment for progression on or after systemic treatment for unresectable or metastatic disease; and

c. Used in combination with pertuzumab.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. 150 mg single-dose vial: six vials day one, then five vials every 21 days thereafter

b. 420 mg multiple-dose vial: three vials day one, then two vials every 21 days thereafter.

c. Recertification Request

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. 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: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, etc.), severe or febrile neutropenia, severe infusion-related reactions, etc.; and

4. Left ventricular ejection fraction (LVEF) obtained within the previous three months as follows:

a. LVEF is within the institutional normal limits, and has not had an absolute of greater than or equal to 16% from pre-treatment baseline; or

b. LVEF is below the institutional lower limits of normal and has not had an absolute decrease of greater than or equal to ten percent from pre-treatment baseline.

5. Breast Cancer (neoadjuvant and adjuvant therapy)

a. Recipient has not exceeded a maximum of 52 weeks of treatment (total 18 cycles).

d. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months

a. Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of 52 weeks of treatment [18 cycles]

3. Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)

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. 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 two HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

c. Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyl®) or famtrastuzumab deruxtecan-nvki (Enhertu); and

d. Therapy will not be used in combination with intravenous chemotherapy agent; and

e. Therapy will not be used in combination with trastuzumab (or any of its biosimilar products [e.g., Ogivri®, Kanjiti®, Trazimera®, Herzuma®, Ontruzant®]) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo®); and

3. Breast Cancer

a. Used as adjuvant therapy; and

1. Used as a single agent following anthracycline-based therapy; or

b. Used for metastatic disease; and

1. Used a single agent in recipients who have received one or more prior chemotherapy regimens for metastatic disease.

b. Dosage Limits

1. Quantity Limits (max daily dose) [NDC Unit]:

a. Herceptin Hylecta (600 mg trastuzumab/10,000 units hyaluronidase) single-dose: one vial every 21 days.

2. Max Units (per dose and over time) [HCPCS Unit]:

a. 60 billable units every 21 days.

c. Recertification Request

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: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis), neutropenia, severe administration-related reactions (e.g., hypersensitivity, anaphylaxis), etc.; and

4. Left ventricular ejection fraction (LVEF) within the previous three months as follows:

   a. LVEF is within the institutional normal limits, and has not had an absolute decrease of greater than 16% from pre-treatment baseline; or

   b. LVEF is below the institutional lower limits of normal, and has not had an absolute decrease of greater than or equal to 10% from pre-treatment baseline; and

5. Breast Cancer (adjuvant treatment)

   a. Recipient has not exceeded a maximum of 52 weeks of therapy.

d. Prior Authorization Guidelines

1. Initial approval will be given six months.

2. Recertification will be given six months.

   a. Adjuvant therapy may be authorized for a total of fifty-two weeks.

P. CD20 Monoclonal Antibodies

Therapeutic Class: Antirheumatic, CD20 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

CD20 Monoclonal Antibodies are subject to prior authorization 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. Approval will be given if the following criteria are met and documented

      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 hepatitis B (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

         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-negative (Ph-) disease; and

            1. Used for induction/consolidation treatment; and

a. Used in combination with a regimen containing an anthracycline and vincristine; or

2. Used for relapsed/refractory treatment; and

a. Used in combination with MOpAD regimen (methotrexate, vincristine, pegaspargase, dexamethasone).

6. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from lymphomas; and

1. Rituximab will be administered intrathecally; or

b. Recipient has primary CNS lymphoma; and

1. Used as a component of induction therapy in combination with a methotrexate-containing regimen, temozolomide, lenalidomide, or as a single agent; or

2. Used as a component of consolidation therapy in combination with a methotrexate-containing regimen; or

3. Used for relapsed or refractory disease as a single agent, or in combination with either temozolomide, lenalidomide, or high-dose methotrexate.

7. Adult Hodgkin Lymphoma

a. Recipient has nodular lymphocute-predominant disease.

8. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/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 less than 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 one of the following:

a. Alemtuzumab

b. 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 diffuse large B-cell lymphoma; and

a. Used in combination with cyclophosphamide, doxorubicin, and vincristine-based regimens or as a component of OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab).

9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

10. Adult B-Cell Lymphomas

a. AIDS-Related B-Cell Lymphoma

1. Disease is related to Burkitt lymphoma, diffuse large B-cell lymphoma (DLBCL), HHV8-positive DLBCL (not otherwise specified), or primary effusion lymphoma (PEL)

b. Burkitt Lymphoma

1. Used in combination with chemotherapy

c. Castleman Disease

1. Recipient has multicentric disease; or

2. Recipient has unicentric disease; and

a. Used as second-line therapy for relapsed or refractory disease; or

b. Used for unresectable disease or symptomatic disease after incomplete resection

d. Diffuse Large B-Cell Lymphoma

e. Low-Grade (grade 1-2) or Follicular Lymphoma

f. Gastric & Non-Gastric (Noncutaneous) MALT Lymphoma

g. High Grade B-Cell Lymphomas

h. Mantle Cell Lymphoma

i. Nodal & Splenic Marginal Zone Lymphoma

j. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma

k. Post-Transplant Lymphoproliferative Disorder (PTLD) (B-Cell Type).

11. Primary Cutaneous B-Cell Lymphomas

12. Pediatric Aggressive Mature B-Cell Lymphomas (Primary Mediastinal Large B-Cell Lymphoma, Diffuse Large B-Cell Lymphoma, 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 less than complete responses or relapsed disease in recipients unable to receive purine analogs (i.e., cladriine or pentostatin); or

b. Used in combination with cladribine; or

c. Used in combination with pentostatin; and

1. Used for less than complete response or relapsed disease; or

d. Used in combination with vemurafenib; and

1. Used for less than complete response or relapsed disease; or

2. Used for progression after relapsed or refractory 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 less than or equal to 18 years of age; and

b. Recipient has nodular lymphocyte-predominant; and

c. Used in combination with CVbP (cyclophosphamide, vinblastine, prednislone); 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 stem cell transplant (generally three or more months); and

b. Used as additional therapy in combination with corticosteroids; and

c. Recipient has no response (e.g., steroid-refractory disease) to first-line therapy options; and

d. Recipient must try and have an inadequate response, contraindication, or intolerance to at least a three-month trial of ibrutinib.

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 (e.g., cemiplimab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, ipilumamb, dostarlimab, nivolumab/relatlimab-rmbw, etc.); and

1. Recipient has non-viral 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 pulse-dose methylprednisolone with or without intravenous immunoglobulin (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 myalgias or myositis, or life-threatening steroid-refractory myositis related to immunotherapy; 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 TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); and

20. Rheumatoid Arthritis (RA)

    a. Documented moderate to severe active disease; and

    b. Used in combination with methotrexate unless the recipient has contraindication or intolerance; and

    c. Recipient tried and failed at least three-month trial with one oral disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.); and

    d. Previous failure with one or more preferred TNF antagonists at least one of which should be a self-injectable; 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 one or more of the following clinical features:

        1. Appearance of lesions, erosions and/or blisters

        2. Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)

        3. 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 Granulmatosis) 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. Recipient has previously failed or has a contraindication or intolerance to therapy with corticosteroids; and

b. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30 x 109/L (30,000mm (3)); and

c. Diagnosis includes one of the following:

1. Primary thrombocytopenia or Idiopathic (Immune) thrombocytopenia purpura (ITP).

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24. Thrombotic Thrombocytopenic Purpura (TTP)

a. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30x109/L (30,000/mm(3)); and

b. 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. 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.

26. Lupus Nephritis

    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]); and

    b. Used as a single agent or add-on therapy in combination with mycophenolate mofetil, mycophenolic acid, cyclophosphamide.

27. 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.)

28. 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.

29. 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., multiple sclerosis, 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. Dissemination in space (greater than or equal to two different core clinical characteristics)

3. Fulfillment of additional MRI requirements, as applicable

c. Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); and

b. Used as a single agent or in combination with immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate, etc.).

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Rituxan® 100mg/10mL injection: 12 vials per 28-day supply

b. Rituxan® 500mg/50mL injection: eight vials per 28-day supply

c. Truxima® 100mg/10mL injection: 12 vials per 28-day supply

d. Truxima® 500mg/50mL injection: eight vials per 28-day supply

e. Ruxience® 100mg/10mL injection: 12 vials per 28-day supply

f. Ruxience® 500mg/50mL injection: either vials per 28-day supply

g. Riabni™ 100mg/10mL injection: 12 vials per 28-day supply

h. Riabni™ 500mg/50mL injection: eight vials per 28-day supply.

2. Max units (per dose and over time) [HCPCS Unit]:

a. Oncology Indications

1. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Leukemia (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. Hairy Cell Leukemia

b. 100 billable units weekly x eight doses.

4. Histiocytic Neoplasms – Rosai-Dorfman Disease

a. 130 billable units weekly x six doses in a six-month period.

5. Pediatric Hodgkin Lymphoma

a. 100 billable units x three doses.

6. cGVHD

a. 100 billable units weekly x eight doses.

7. 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.

8. All other oncology indications:

a. Initial therapy: 100 billable units weekly x eight doses per six months

b. Renewal therapy: 100 billable units x four doses per six months.

b. Non-Oncology Indications

1. Rhematoid Arthritis (RA):

a. 100 billable units every 14 days x two doses in a 16-week period.

2. Pemphigus Vulgaris:

a. Initiation: 100 billable units weekly x four doses in a 12-month period

b. Maintenance: 50 billable units every 16 weeks.

3. GPA(WG)/MPA:

a. Induction: 100 billable units weekly x four doses in a four-month period

b. Initial Maintenance: 50 billable units x two doses in a six-month period

c. Subsequent Maintenance: 50 billable units every six months.

4. All other non-oncology indications:

a. 100 billable units weekly x four doses in a six-month period.

c. Recertification Request

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. 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), hepatitis B virus 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

3. Oncology Indications

   a. Recipient has not exceeded dosing or duration limits as defined in Section I, II, and V; and

4. Adult Acute Lymphoblastic Leukemia (ALL)

   a. Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

5. Hairy Cell Leukemia

   a. Coverage may not be renewed

6. Pediatric B-Cell Acute Leukemia and Aggressive Mature B-Cell Lymphomas (induction or consolidation therapy)

   a. Coverage may not be renewed

7. Pediatric Hodgkin Lymphoma

   a. Coverage may not be renewed

8. Chronic Graft-Versus-Host Disease (cGVHD)

   a. Coverage may not be renewed

9. Hematopoietic Cell Transplantation

   a. Coverage may not be renewed

10. Management of Immunotherapy-Related Toxicities

   a. Coverage for use in the treatment of myalgias/myositis/myasthenia gravis/encephalitis may not be renewed

   b. Coverage for use in bullous dermatitis: Recipient has not exceeded a maximum of 18 months of therapy (four total doses)

11. All Other Oncology Indications

    a. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor space

12. 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 greater than or equal to 20% improvement on the American College of Rheumatology-20 (ARC20) criteria]; 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 as necessary to reduce the risk for bleeding

    c. Thrombotic Thrombocytopenic Purpura (TTP)

        1. Disease response as indicated by an increase in ADAMTS13 activity with a reduction in thrombotic risk

    d. 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)

e. Pemphigus Vulgaris

1. Recipient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; and

a. Disease response as indicated by complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline; or

b. Recipient has not experienced continued development of new lesions and improvement in signs and symptoms of condition compared to baseline; or

1. For Relapses only: Recipient previously had active 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

f. Autoimmune Hemolytic Anemia (AIHA)

1. Disease response as indicated by improvement in anemia signs and symptoms (e.g., dyspnea, fatigue, etc.) as well as: improvement in laboratory values (Hb/Hct), reduced transfusion needs, and/or reduced glucocorticoid use

g. 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.)

h. 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

i. Complications of transplanted solid organ

1. Coverage may not be renewed

j. NMOSID

1. Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability reduced hospitalizations, reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months (12 months initially for pemphigus vulgaris)

2. Recertification will be given for six months

a. Maintenance therapy for oncology indications (excluding ALL, Hairy Cell Leukemia, Mantle Cell Lymphoma, induction/consolidation of Pediatric B-Cell Acute Leukemia/Aggressive Mature B-Cell Lymphomas, and Pediatric Hodgkin Lymphoma) may be renewed for up to a maximum of two years

1. ALL and Mantle Cell Lymphoma may be renewed until disease progression or intolerable toxicity (ALL may be renewed for up to a total of 18 doses)

2. Hairy Cell Leukemia may not be renewed

3. Induction/Consolidation of Pediatric B-Cell Acute Leukemia and Aggressive Mature B-Cell Lymphomas may not be renewed

4. Pediatric Hodgkin Lymphoma may not be renewed.

b. Management of Immunotherapy-Related Toxicities:

1. Myalgias/Myositis/Myasthenia Gravis/Encephalitis may not be renewed

2. Bullous dermatitis may be renewed for a maximum of 18 months (four total doses)

c. Relapse therapy for Pemphigus Vulgaris must be at least 16 weeks past a prior infusion

d. Chronic Graft-Versus-Host Disease (cGVHD) may not be renewed

e. Hematopoietic Cell Transplantation may not be renewed

f. Lupus Nephritis may be renewed only in recipients experiencing a disease relapse

g. 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. Universal Criteria

a. Recipient does not have a severe, active infection; and

b. Recipient has been screened for the presence of hepatitis B virus (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. Recipient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; and

e. Rituxan Hycela will not be used with intravenous chemotherapy agents; and

f. 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. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

4. B-Cell Lymphomas

   a. Follicular Lymphoma (FL)

   b. Diffuse Large B-Cell Lymphomas

   c. High Grade B-Cell Lymphomas

   d. Castleman Disease

   e. Gastric & Non-gastric MALT Lymphoma
   f. Mantle Cell Lymphoma

   g. Nodal and Splenic Marginal Zone Lymphoma

   h. Histologic transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma

   i. Post-transplant lymphoproliferative disorder (PTLD)

5. Hairy Cell Leukemia

6. Primary Cutaneous B-Cell Lymphoma

7. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

   a. Rituxan Hycela® 1,400mg/23,400 Units per 11.7 mL single-dose vial: four vials per 28-day supply

   b. Rituxan Hycela® 1,600mg/26,800 Units per 13.4 mL single-dose vial: one vial per 28-day supply.

2. Max Units (per dose and over time) [HCPCS Unit]:

   a. Follicular Lymphoma (FL):

      1. Relapsed-Refractory

         a. 1,400 mg/23,400 U (140 billable units) weekly up to seven doses

2. Previously Untreated

a. 1,400 mg/23,400 U (140 billable units) every 21 days x seven doses

b. 1,400 mg/23,400 U (140 billable units) every 21 days x seven doses

3. Non-progressing after first line CVP chemotherapy

a. 1,400 mg/23,400 U (140 billable units) weekly x three doses at six months intervals (up to a maximum of 15 doses).

b. Diffuse Large B-Cell Lymphoma (DLBCL);

1. 1,400 mg/23,400 U (140 billable units) every 14 or 21 days x seven doses

c. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

1. 1,600 mg/26,800 U (160 billable units) every 28 days x five doses

d. Hairy Cell Leukemia

1. 1,400 mg/23,400 U (140 billable units) weekly up to seven doses

e. Other indications:

1. 1,400 mg/23,400 U (140 billable units) weekly for x seven doses in a six-month period; or

2. 1,400 mg/23,400 U (140 billable units) every eight weeks (maintenance treatment).

c. Recertification Request

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 hypersensitivity or other administration reactions (i.e., local cutaneous reactions), tumor lysis syndrome (TLS), severe

mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiac adverse reactions, renal toxicity, bowel obstructions or perforation, etc.; and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. Recipient has not exceeded dosing or duration limits as defined in Sections I, II, and V.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months
2. Recertification will be given for six months

3. Maintenance therapy for mantle cell lymphoma may be renewed until disease progression or intolerable toxicity

4. Hairy Cell Leukemia may not be renewed

5. 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: N/A

Selective Immunosuppressants are subject to prior authorization 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. Approval will be given if the following criteria are met and documented:

1. Recipient is at least 18 years of age (unless otherwise specified); and

2. Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program; and

3. Universal Criteria

a. Recipient must be vaccinated with meningococcal disease at least two weeks prior to initiation of therapy and will continue to revaccinated according to current medical guidelines for vaccine use (if urgent Soliris therapy is indicated in an unvaccinated recipient, administer meningococcal vaccine(s) as soon as possible and provide recipients with two weeks of antibacterial drug prophylaxis); 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, ravulizumab, pegcetacoplan, satralizumab, inebilizumab, etc.).

4. 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. Demonstrate the presence of 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., LDH greater than or equal to one and a half 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 less than seven g/dL or hemoglobin less than 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 lactate dehydrogenase (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®).

5. 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. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (i.e., ADAMTS-13 activity level greater than or equal to ten percent); and

d. Shiga toxin E. coli related hemolytic uremic syndrome (STEC-UHS) 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 lactate dehydrogenase (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®).

6. 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 anti-acetylcholine receptor (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 greater than or equal to six; and

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 after a minimum one-year trial with two or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

1. Recipient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; and

h. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

7. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has a confirmed diagnosis based on the following:

1. Recipient was found to be seropositive for aquaporin-four (AQP4) IgG antibodies; and

2. Recipient has at least one core clinical characteristics; and

3. Alternative diagnoses have been excluded (e.g., multiple sclerosis, 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 Expanded Disability Status Score (EDSS) of less than or equal to seven (i.e., presence of at least limited ambulation with aid); 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 intravenous immune globulin (IVIG) in the last three weeks; and

g. Recipient had an inadequate response, or has a contraindication or intolerance, to rituximab or inebilizumab, and

h. Recipient will not concomitantly receive therapy with any of the following:

1. IL6-inhibitor (e.g., satralizumab); and

2. Anti-CD20-directed antibody (e.g., rituximab); and

3. Anti-CD19-directed antibody (e.g., inebilizumab).

b. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Loading Doses:

1. Three vials Days 1, 8, 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

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, thrombotic microangiopathy complications (TMA), etc.; and

3. Paroxysmal Nocturnal Hemoglobinuria (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 indicated by one or more of the following:

1. Decrease in serum LDG from pretreatment baseline Stabilization/improvement in hemoglobin level from pretreatment baseline

2. Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

3. Reduction in thromboembolic events.

4. Atypical Hemolytic Uremic Syndrome (aHUS)

a. Disease response indicated by one or more of the following:

1. Decrease in serum LDH from pretreatment baseline

2. Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline

3. Increase in platelet count from pretreatment baseline

4. Decrease in plasma exchange/infusion requirement from pretreatment baseline.

5. Generalized Myasthenia Gravis (gMG)

a. Recipient experienced an improvement (i.e., reduction) of at least three-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; or

b. Recipient experienced an improvement of at least five-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score.

6. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has stabilization and/or improvement of neurologic symptoms as evidenced by a decrease in acute relapses, EDSS, hospitalizations, or plasma exchange treatments.

c. Prior Authorization Guidelines

1. PNH and aHUS: Initial approval will be given for 12 months

2. PNH and aHUS: Recertification will be given for 12 months

3. gMG and NMOSD: Initial approval will be given for six months

4. gMG and NMOSD: Recertification will be given for six months.

2. Ultomiris® (ravulizumab-cwvz)

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

1. Recipient is at least one month of age (unless otherwise specified); and

2. Prescribed is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program; and

3. Universal Criteria

a. Recipients must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (If urgent Ultomiris® therapy is indicated in an unvaccinated recipient, administer meningococcal vaccine(s) as soon as possible and provide recipients with two weeks of antibacterial drug prophylaxis); and

b. Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, eculizumab, pegcetacoplan, satralizumab, inebilizumab, etc.); and

4. Paroxysmal Nocturnal Hemoglobinuria (PNH)

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with Soliris 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. Diagnosis must be accompanied by detection of PNH clones of at least five by flow cytometry diagnostic testing; and

a. Demonstrate the presence of 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., LDH greater than or

equal to one and a half 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 less than seven g/dL or hemoglobin less than 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 lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement, history of thrombotic events.

5. Atypical Hemolytic Uremic Syndrome (aHUS)

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with Soliris 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 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

2. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level greater than or equal to 10%); and

3. Shiga toxin E. Coli related hemolytic uremic syndrome (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 lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and dialysis requirement.

6. Generalized Myasthenia Gravis (gMG)

a. Used as switch therapy; and

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

2. Recipient is currently receiving treatment with Soliris 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 Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and

3. Recipient has a positive serologic test for anti-acetylcholine receptor (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 Quantitative Myasthenia Gravis (QMG) score, etc.); and

6. Recipient has a MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to six; 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.); and

8. Recipient had an inadequate response after a minimum of one-year trial with two or more immunosuppressive therapies (e.g., corticosteroids, plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

   a. Recipient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy.

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 – three 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 – 11mL SDV: three vials on day zero followed by three vials starting on day 14 and every eight weeks thereafter

   d. Ultomiris® 245 mg/3.5mL 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 zero followed by 360 units on Day 14 and every eight weeks thereafter

b. Ultomiris® SQ

1. PNH/aHUS: 49 units weekly.

c. Recertification Request

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, thrombotic microangiopathy (TMA) complications, etc.; and

3. Paroxysmal Nocturnal Hemoglobinuria (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 indicated by one or more of the following:

1. Decrease in serum LDH from pretreatment baseline Stabilization/improvement in hemoglobin level from pretreatment baseline

2. Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

3. Reduction in thromboembolic events.

4. Atypical Hemolytic Uremic Syndrome (aHUS)

a. Disease response indicated by one or more of the following:

1. Decrease in serum LDH from pretreatment baseline

2. Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline

3. Increase in platelet count from pretreatment baseline

4. Decrease in plasma exchange/infusion requirement from pretreatment baseline.

5. Generalized Myasthenia Gravis (gMG)

   a. Recipient experienced an improvement (i.e., reduction) of at least three-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; or

   b. Recipient experienced an improvement of at least five-points from baseline in Quantitative Myasthenia Gravis (QMG) total score.

6. Switch therapy from Soliris to Utomiris®

d. Prior Authorization Guidelines

1. Initial approval will be given for 12 months

2. Recertification will be given for 12 months.

R. Yervoy® (ipilimumab)

Therapeutic Class: Anti-CLTA-4 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

Yervoy® (ipilimumab) are subject to prior authorization 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.

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

1. Recipient is at least 18 years of age, unless otherwise specified; and

2. Ampullary Adenocarcinoma

a. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used in combination with nivolumab; and

1. Used as first-line therapy for unresectable or metastatic intestinal type disease; or

2. Used as subsequent therapy for disease progression.

3. Bone Cancer

a. Recipient has one of the following: Ewing sarcoma, chondrosarcoma (excluding mesenchymal chondrosarcoma), osteosarcoma, or chordoma; and

b. Recipient has tumor mutation burden-high (TMB-H) tumors [greater than or equal to 10 mutations/megabase (mut/mB)] as determined by an FDA-approved or CLIA-compliant test; and

c. Used in combination with nivolumab; and

d. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

e. Recipient has no satisfactory alternative treatment options.

4. Central Nervous System (CNS) Cancer

a. Used for the treatment of brain metastases in recipients with BRAF non-specific melanoma; and

b. Used in combination with nivolumab or as a single agent; 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. Recipients has recurrent limited brain metastases; or

4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

5. Colorectal Cancer (CRC)

a. Recipient is at least 12 years of age; and

b. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

c. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

d. Used in combination with nivolumab; and

1. Used as subsequent therapy for advanced or metastatic disease that progressed following treatment with one of the following:

a. Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy; or

b. Non-intensive therapy in recipients with improvement in functional status; or

2. Used as primary treatment; and

a. Used as neoadjuvant therapy for clinical T4b colon cancer; or

b. Used as neoadjuvant therapy of resectable liver and/or lung metastases; or

c. Used if resection is contraindicated following neoadjuvant therapy for advanced, locally unresectable, or medically inoperable rectal cancer; or

d. Used for unresectable (or medically inoperable) or metastatic disease.

6. Appendiceal Adenocarcinoma – Colon Cancer

   a. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

   b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

   c. Used in combination with nivolumab; and

      1. Used as subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy; or

      2. Used as initial therapy for advanced or metastatic disease.

7. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

   a. Recipient has esophageal squamous cell carcinoma (ESCC); and

   b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

   c. Used as first-line treatment with combination with nivolumab; and

   d. Recipient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease.

8. Hepatocellular Carcinoma (HCC)

   a. Used in combination with nivolumab; and

   b. Used as subsequent therapy for progressive disease; and

   c. Recipient has Child-Pugh Class A hepatic impairment; and

      1. Recipient was previously treated with sorafenib; or

      2. Recipient has unresectable disease and is not a transplant candidate; or

      3. Recipient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; or

      4. Recipient has metastatic disease or extensive liver tumor burden.

9. Renal Cell Carcinoma (RCC)

   a. Used in combination with nivolumab for clear cell histology; and

      1. Used as first-line therapy in recipients with poor or intermediate risk advanced, relapsed, or stage IV disease; or

      2. Used as first-line therapy in recipients with favorable risk relapsed or stage IV disease; or

      3. Used as subsequent therapy in recipients with relapsed or stage IV disease.

10. Malignant Peritoneal Mesothelioma (MPeM)

   a. Used in combination with nivolumab; and

      1. Used as subsequent therapy (if not administered first-line); or

      2. Used as first-line therapy; and

         a. Recipient has unresectable diffuse disease; or

         b. Recipient has unresectable recurrent benign multicystic or well-differentiated papillary disease.

11. Malignant Pleural Mesothelioma (MPM)

   a. Used in combination with nivolumab; and

      1. Used as subsequent therapy (if not administered first-line); or

      2. Used as first-line therapy; and

         a. Recipient has stage IIIB or IV disease; or

         b. Recipient has sarcomatoid or biphasic histology; or

         c. Disease is medically inoperable or unresectable.

12. Cutaneous Melanoma

   a. Used as first-line therapy for unresectable or metastatic disease in combination with nivolumab; or

   b. Used as initial therapy for limit resectable local satellite/in-transit recurrence; and

1. Used as a single agent; and

2. Recipient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); or

c. Used as subsequent therapy for unresectable or metastatic disease; and

1. Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); and

a. 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

b. Used in combination with nivolumab if not previously used or for recipients who progress on single agent anti-PD-1 therapy; or

c. 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

2. 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 greater than three months after treatment discontinuation; and

a. Used as single agent or in combination with anti-PD-1 therapy; and

b. Recipient has completed initial induction ipilimumab therapy (i.e., completion of four cycles within a 16 week period); or

d. Used a single agent for adjuvant therapy; and

1. Recipient has pathologic involvement of regional lymph nodes of more than one 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 no evidence of disease (NED) after complete excision; or

b. Recipient has undergone complete therapeutic lymph node dissection (TLND) and/or complete excision of nodal recurrence; or

c. Recipient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., stereotactic ablative therapy or complete resection) or systemic therapy.

13. Uveal Melanoma

a. Used as a single agent or in combination with nivolumab; and

b. Recipient has distant metastatic disease.

14. 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 for one of the following:

1. Recipients with a performance status (PS) zero to one who have tumors that are negative for actionable molecular biomarkers and PD-L1 less than one percent

2. Recipients with a PS zero to one 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)

3. PD-L1 expression positive (PD-L1 greater than or equal to one percent) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

b. Used in combination with nivolumab; or

c. Used in combination with 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

2. Used as subsequent therapy; and

a. Used for one of the following:

1. Recipients with a PS zero to one who are positive for one of the following molecular mutations 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

2. Recipients with a PS zero to one 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

b. Used in combination with nivolumab; or

c. Used in combination with nivolumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; or

d. Used in combination with nivolumab, paclitaxel and carboplatin for squamous cell histology; or

3. Used as continuation maintenance therapy in combination with nivolumab; and

a. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.

15. Small Bowel Adenocarcinoma (SBA)

a. Recipient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

c. Used in combination with nivolumab; and

1. Used as initial therapy; or

2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

B. Dosage Limits

1. Quantity Limit (max daily dose) [NDC Unit]:

a. Yervoy® 200mg/40mL injection:

1. Five vials per 84 days (initially up to five vials per 21 days x four doses)

b. Yervoy® 50mg/10mL injection:

1. Three vials per 84 days (initially up to three days per 21 days x four doses).

C. Recertification Request

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. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated reactions (e.g., colitis, hepatitis, dermatitis/rash, pneumonitis, nephritis/renal dysfunction, endocrinopathies, etc.), severe infusion reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; and

3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

4. Coverage may not be renewed for the following indications:

a. Colorectal Cancer (subsequent therapy/disease progression); or

b. Appendiceal Adenocarcinoma (subsequent therapy/disease progression)

c. CNS metastases from Melanoma (combination therapy with nivolumab)

d. Cutaneous Melanoma (first-line or subsequent therapy)

e. Hepatocellular Carcinoma

f. Renal Cell Carcinoma

g. Small Bowel Adenocarcinoma

h. Ampullary Adenocarcinoma

i. Uveal Melanoma

5. For the following indications, recipient has not exceeded a maximum of two years of therapy:

a. Bone Cancer

b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

c. Peritoneal Mesothelioma

d. Malignant Pleural Mesothelioma

e. Non-Small Cell Lung Cancer

6. Cutaneous Melanoma (re-induction therapy)

7. Cutaneous Melanoma (adjuvant treatment – maintenance therapy)

a. Recipient has not exceeded a maximum of three years of therapy

8. Non-Small Cell Lung Cancer (continuation maintenance therapy).

D. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months

3. The following indications may be authorized up to a maximum of twelve weeks of therapy and may not be renewed (coverage may be extended to 16 weeks if four doses were not administered within the 12-week time frame)

a. Colorectal Cancer (subsequent therapy/disease progression)

b. Appendiceal Adenocarcinoma (subsequent therapy/disease progression)

c. CNS metastases from Melanoma (combination therapy with nivolumab)

d. Cutaneous Melanoma (first-line or subsequent therapy)

e. Hepatocellular Carcinoma

f. Renal Cell Carcinoma

g. Small Bowel Adenocarcinoma

h. Ampullary Adenocarcinoma

i. Uveal Melanoma

4. The following indications may be renewed up to a maximum of two years of therapy:

a. Bone Cancer

b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

c. Malignant Peritoneal Mesothelioma

d. Malignant Pleural Mesothelioma

e. Non-Small Lung Cancer

5. Cutaneous Melanoma (adjuvant treatment)

a. Coverage will be provided for six months and may be renewed for up to a maximum of three years of maintenance therapy.

S. Zynlonta® (loncastuximab tesirine-lpyl)

Therapeutic Class: Miscellaneous Antineoplastics
Last Reviewed by the DUR Board: N/A

Miscellaneous Antineoplastics are subject to prior authorization 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. Recipient advised to minimize or avoid exposure to direct natural or artificial sunlight including exposure through glass windows; and

   C. Universal Criteria

      1. Used as single agent therapy; and

      b. Recipient has not received prior anti-CD19 therapy, (e.g., tafasitamab, CAR-T) or recipient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; and

      c. Recipient does not have active graft-versus-host disease; and

      d. Recipient has not had an autologous stem cell transplant (ASCT) within 30 days or allogeneic stem cell transplant (AlloSCT) with 60 days, prior to start of therapy; and

      e. Recipient does not have active CNS lymphoma (includes leptomeningeal disease); and

      f. Recipient does not have a clinically significant active infection (e.g., Grade 3 or 4 infections); and

      g. 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

   D. Large B-Cell Lymphoma

      1. Recipient has relapsed or refractory disease (includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma); and

      2. Recipient has received at least two prior lines of therapy.

2. Dosage Limits

   A. Quantity Limit (max daily dose) [NDC Unit]:

      1. Zynlonta® 10mg 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. Relapsed or Refractory B-Cell Lymphoma

         a. Cycle 1-2

            1. 230 billable units (17.25mg) per each 21-day cycle

         b. Subsequent Cycles

            1. 115 billable units (8.63mg) per each 21-day cycle.

3. Recertification Request

   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. 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), myelosuppression, infections, severe cutaneous reactions (e.g., photosensitivity, rash), etc.; and

   C. Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread.

4. Prior Authorization Guidelines

   A. Initial approval will be given for six months.

   B. Recertification will be given for six months.