

**MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER**

January 29, 2019

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual Chapter 1200, Appendix A, are being proposed to reflect recommendations approved on July 26, 2018 by the Drug Use Review (DUR) Board. The proposed changes include the addition of Eucrisa® to the existing prior authorization (PA) criteria for Topical Immunomodulators, the addition of new PA criteria for opioid cough preparations, new PA criteria for antihemophilia agents, revisions to the existing Hepatitis C (Anti-Hepatitis Agents and Hepatitis C direct acting antivirals) criteria, amendments to the existing PA for Kalydeco®, the addition of Trulance® to the existing Irritable-Bowel Syndrome Agents, the addition of new PA criteria for Symdeko®, existing Botulinum Toxin PA was relocated and revised from Chapter 600 to Chapter 1200, and the addition of new PA for compounded medications.

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 February 4, 2019.

MATERIAL TRANSMITTED

MTL N/A
MSM Ch 1200 – Prescribed Drugs

MATERIAL SUPERSEDED

MTL N/A
MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section M, (1)(b)(2) and (1)(e)	Topical Immunomodulators	Addition of prior authorization (PA) criteria for Eucrisa® to existing criteria for Topical Immunomodulators.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section Z	Opioids	Drug title updated to read, “Opioids, Opioid Containing Cough Preparations.” Addition of opioid cough preparations PA criteria to the existing Opioids criteria.
Appendix A, Section GG	Reserved	Title now reads “Antihemophilia Agents.” Addition of new PA criteria.
Appendix A, Section HH	Anti-Hepatitis Agents – Protease Inhibitor Agents	Title of section has been changed to now read, “Anti-Hepatitis Agents.” Removal of all PA criteria for Victrelis® and Incivek® (these drugs no longer exist). Language from Section UU was utilized to re-organize and re-write all Anti-Hepatitis Agents by drug name.
Appendix A, Section LL. (1)(c) and (d)	Kalydeco® (ivacaftor)	Amendments made to existing PA criteria which include: adding language so that (1)(c) reads, “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.” The listed gene mutations were removed. The following language was added to (1)(d), “The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a cystic fibrosis care center” and recertification request language was added (2).
Appendix A, Section UU	Hepatitis C direct acting antivirals	Title of section changed to “Reserved.” Removal of entire section. All language was utilized to re-organize and re-write all Anti-Hepatitis Agents criteria by drug name, which has been re-located to Section HH.
Appendix A, Section WW (1)(a), (2)(a), (2)(c)	Irritable-Bowel Syndrome Agents	Drug names were updated for consistency throughout and Trulance® criteria was added.
Appendix A, Section VVV	Symdeko® (tezacaftor/ ivacaftor)	Addition of new PA criteria.
Appendix A, Section WWW	Botulinum Toxin	Addition of new PA criteria.
Appendix A, Section XXX	Compounded Medications	Addition of new PA criteria.

DIVISION OF HEALTH CARE FINANCING AND POLICY

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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.

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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, 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 (Social Security Administration (SSA), Title 19, (g)(1)(A)).
- D. Section 1927 of the Social Security Act 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 Social Security Act 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 Social Security Act) 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

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programs to capture and report National Drug Codes (NDC) for outpatient drugs in order for the state to receive federal financial participation.

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1202 RESERVED

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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 Social Security Act (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 Pharmacy and Therapeutics (P&T) Committee. Reference Medicaid Operations Manual (MOM) Chapter 200 for the P&T bylaws. Pharmaceuticals not on the preferred drug list, but within drug classes reviewed by the P&T Committee, require prior authorization, unless exempt under NRS or federal law or excluded through recommendations of the P&T Committee or excluded by the DHCFP.

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- 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 P&T Committee 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 list of preferred prescription drugs and are not excluded under state plan or by NRS, are covered with an approved Standard Preferred Drug List Exception prior authorization until the P&T Committee 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 P&T Committee determines that there are no significant differences between drugs within specific classes based on clinical efficacy and safety, the DHCFP or its Quality Improvement Organization (QIO)-like vendor may consider cost in determining which drugs are selected for inclusion on the PDL.
- e. Due to the 76th Special Session and in accordance with Senate Bill (SB) 4, every therapeutic prescription drug that is classified as an anticonvulsant medication or antidiabetic medication that was covered by the Medicaid program on June 30, 2010 must be included on the PDL as a preferred drug. If a therapeutic prescription drug that is included on the list of preferred prescription drugs is prescribed for a clinical indication other than the indication for which it was approved as of June 30, 2010, the Committee shall review the new clinical indication for that drug in accordance with Section 1203 of this chapter.
- f. Due to the 76th Special Session and in accordance with SB 4, the P&T Committee must prefer atypical and typical antipsychotic medications that are prescribed for the treatment of a mental illness, anticonvulsant medications and antidiabetic medications for a patient who is receiving services pursuant to Medicaid if the patient:
 1. was prescribed the prescription drug on or before June 30, 2010, and takes the prescription drug continuously, as prescribed, on and after that date; and
 2. maintains continuous eligibility for Medicaid.

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Reference Appendix A for coverage and limitations of medications with special criteria.

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.

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2. Agents used to promote fertility.
3. Agents used for cosmetic purposes or hair growth.
4. Yohimbine.
5. Drug Efficacy Study and 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 in this section for more information on maintenance medications.

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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 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.
3. 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;

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- 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

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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 PA (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 Fee-for-Service (FFS) recipients. There are NO exceptions.

I. Immunizations

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

1. **Childhood Immunizations:** All childhood immunizations are covered without prior authorization under the Healthy Kids Program. Refer to MSM Chapter 1500, Healthy Kids Program, for more information on childhood immunizations.
2. **Adult Immunizations:** Adult immunizations such as tetanus, flu vaccine and pneumococcal vaccine are covered without prior authorization. For a list of covered adult immunizations, please reference the Physician's Fee Schedule under "Professional Rates" at: <http://www.dhcfp.nv.gov/RatesUnit.htm>
3. **Human Papillomavirus (HPV) Vaccine:** The quadrivalent HPV vaccine, the bivalent HPV vaccine and the 9-valent HPV vaccine (for both males and females) is covered for Medicaid eligibles age 19 years through 26 years, based on the US FDA approved indications. These may be accessed by following the link: <http://www.fda.gov/cber/products/gardasil.htm>. 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

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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 immunizations through the VFC Program. The DHCFP or Nevada Medicaid and NCU do not reimburse for vaccines included in the VFC Program.
 - c. Covered immunizations not included in the VFC Program will be reimbursable per the Nevada Medicaid and NCU Pharmacy Manual.
 - d. If the pharmacist administers the immunization, 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 PA if:
 - a. The requesting pharmacist has access to the recipient's medical records.

K. Dispensing Practitioners:

1. Must have a current Certificate of Registration through the Nevada State 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 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 Provider Type 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.

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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 (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

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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. Lock-in Program

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 and/or provider. This means that Medicaid will only pay for controlled substance prescriptions/medical services at a single pharmacy/provider.

1. Criteria that is evaluated by the DHCFP when determining if a recipient should be locked in to a specific pharmacy begins with the number of controlled substance prescriptions filled in 60 days.

If 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) then the clinical review continues with the following criteria:

- 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(s).

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2. 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.
3. Recipients (who are locked-in to one pharmacy) or their provider/prescriber can change their locked-in pharmacy at any time by contacting their Medicaid District Office.
4. Pharmacies may call the Technical Call Center for an override to the locked-in pharmacy if:
 - a. The locked-in pharmacy is out of stock.
 - b. The locked-in pharmacy is closed.
 - c. 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.

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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 generic 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.

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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 Social Security Act (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).

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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.

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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 PA" 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.

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6. Pharmacy Billing Process

a. NCPDP Standard Billing Units

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

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

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

PLEASE NOTE:

Ounces must be converted to ml (1 ounce = 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, Catapres-TTS comes in a box of four patches. If two of these boxes are dispensed, the quantity entered will be eight.

Inhalers and Aerosols: must be billed as either grams or ml, as specified by the manufacturer on the labeling. For example a 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.

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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 # 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 anithemophilic units dispensed (each). Prolastin must similarly be billed as the number of milligrams dispensed (each).

Kits: defined as products with a 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)

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- 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 (PA) PROCEDURES

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

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2. PA requests must be submitted on the appropriate Prior Authorization Request form. Pharmacy PA 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 PA requirements.
4. The QIO-like vendor will process the PA request within 24 hours of receipt.
 - a. The requesting practitioner will be advised of the PA status (approval, denial, pending further information) within 24 hours of the receipt.
 - b. For PA 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 PA will be entered in the POS system prior to the dispensing of the medication. There may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).
6. The Nevada Medicaid QIO-like vendor will send all 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

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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.

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1204 HEARINGS

1204.1 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.*

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

A. Proton Pump Inhibitors (PPIs)

Therapeutic Class: Proton Pump Inhibitor

Last Reviewed by the DUR Board: April 24, 2014

Proton Pump Inhibitors (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. Coverage and Limitations

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

- a. Prior Authorization is not required for once per day treatment if the following criteria is met:
 1. The recipient is not on concomitant therapy of an H2 antagonist or sucralfate.
- b. Requests for PPIs exceeding once per day 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.

2. Prior Authorization Guidelines

Prior authorization approval will be for up to one year.

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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B. Bevyxxa® (betrixaban)

Therapeutic Class: Oral Anticoagulants

Last Reviewed by the DUR Board: January 25, 2018

Bevyxxa® (betrixaban) 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 prophylaxis of venous thromboembolism (VTE); and
2. The recipient must be 18 years of age or older; and
3. The recipient has received Bevyxxa® during hospitalization and will be continuing Bevyxxa® therapy following discharge from the hospital; and
4. The recipient is at risk for thromboembolic complications due to moderate or severe restricted mobility and has other risk factors of VTE; and
5. The recipient has not received a cumulative 42 days of Bevyxxa® therapy.

2. Prior Authorization Guidelines:

a. Prior Authorization approvals will be for:

1. Prior Authorization Request: Up to a total treatment duration of 42 days.

b. Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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C. Agents used for the treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD)

Therapeutic Class: ADHD/ADD Agents

Last Reviewed by the DUR Board: January 28, 2016

Agents for the treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (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 for medications will be given if the following criteria is met and documented:

a. General Criteria (Children and Adults)

1. Only one long-acting stimulant (amphetamine and methylphenidate products) may be used at a time, a 30-day transitional overlap in therapy will be allowed.
2. A diagnosis of ADD/ADHD or other FDA approved diagnosis.

b. ADD/ADHD Criteria (all requests for a diagnosis of ADD/ADHD)

1. The following criteria must be met and documented in the recipient's medical record prior to treatment with ADD/ADHD agents.
 - a. The decision to medicate for ADD or ADHD must be based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: school, home, work or with peers; and
 - b. Other treatable causes of ADD/ADHD have been ruled out.

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

1. The recipient is at least three years of age (shorting-acting stimulants) or at least six years of age (long-acting stimulants, long-acting alpha agonists, atomoxetine).
2. An initial evaluation or regular examination has been done within the past 12 months with the treating prescriber and medical notes documenting all of the following:
 - a. A physical evaluation;

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- b. A developmental history;
 - c. Any medical and/or psychological history, any history of the primary neurological diagnosis including any history of past psychiatric, psychological or neurological treatment for ADD/ADHD;
 - d. Any family history including: psychiatric diagnoses of ADD/ADHD, tic disorder, substance abuse disorder, conduct disorder, anxiety, etc., past or present, family stressors, crises, abuses or neglect and an interview with parent(s) or guardian(s);
 - e. A review of diagnostic symptoms of ADD/ADHD, presence or absence-child behavior checklist, development and context of symptoms and resulting impairment, (school, family, peers), possible alternate or comorbid psychiatric diagnosis;
 - f. School information, which should include standardized teachers rating scales, achievement tests, neuropsychological testing (if indicated) and speech and language evaluations.
- d. Adults (18 years or older)
- 1. An initial evaluation is documented in the recipient's medical record and must include: a complete psychiatric assessment (present and past), diagnostic symptoms of ADD or ADHD, history of development and context of symptoms and resulting impairment (academic achievement, learning disorder evaluation); and
 - 2. All of the following must be met and documented in the recipient's medical record:
 - a. A medical history, including medical or primary neurological diagnoses, any history of other psychiatric disorder(s) and the current treatment regimen;
 - b. A medication review to rule out other possible causes of symptoms (e.g. Phenobarbital, steroids);
 - c. Diagnostic symptoms of ADD and ADHD;
 - d. An assessment for possible alternate comorbid psychiatric diagnosis (especially: personality disorder, mood disorder, depression or mania, anxiety disorder, dissociative disorder, tic disorder including Tourette's disorder and substance abuse disorder): and

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- e. Any family history including diagnosis of ADD or ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder, mood disorder and anxiety disorder, possible family stressors, any history of abuse or neglect.

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 six 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 Attention Deficit Disorder 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>

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D. Growth Hormone

Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 25, 2013

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:

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

- a. Genotropin® (somatropin); Humatrope® (somatropin); Norditropin® (somatropin); Nutropin® (somatropin); Omnitrope® (somatropin); Saizen® (somatropin); Tev-Tropin® (somatropin):

1. Children (up to age 21, with open epiphyses and with remaining growth potential) must meet all of 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 third percentile for the patient's age and gender; or
2. 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
3. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and their height is at least two standard deviations below the mean or

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below the third percentile for the recipient's age and gender;
or

4. 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
5. 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 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), adrenocorticotrophic hormone (ACTH) or antidiuretic hormone (ADH).
2. Adults (age 21 years and older, with closed epiphyses, and no remaining growth potential) must meet all of 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

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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 of 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 of 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.

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b. Serostim® (somatropin)

Recipients must meet all of the following:

1. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and
2. The medication is indicated to increase lean body mass, body weight and physical endurance; and
3. The recipient is receiving and is compliant with antiretroviral therapy; and
4. 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
5. 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
6. 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.

c. Zorbtive® (somatropin)

Recipients must meet all of the following:

1. The recipient has a diagnosis of short bowel syndrome; and
2. The recipient is age 18 years or older; and
3. The medication is being prescribed by or following a consultation with a gastroenterologist; and
4. The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. Prior Authorization Guidelines:

- a. Prior Authorization approval will be 12 weeks for Serostim® (somatropin).
- b. Prior Authorization approval will be six months for initial authorization (for all somatropin products except for Serostim®).
- c. Prior Authorization approval will be one year for continuing treatment (for all somatropin products except Serostim®).

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- d. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

E. Over-the-Counter Medications

Last Reviewed by the DUR Board: N/A

Over-the-Counter (OTC) 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

Any more than two prescription requests for medications within the same therapeutic class will require prior authorization.

A Prior Authorization form must be submitted to the Nevada QIO-like vendor. The QIO-like vendor will request further information needed on a case by case basis to determine the necessity of the medication for the recipient.

Note: Insulin will be exempt from any prior authorization requirements.

Approval will be for a one month time limit.

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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F. Transdermal Fentanyl

Therapeutic Class: Analgesics, Narcotic

Last Reviewed by the DUR Board: January 22, 2015

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, nonsteroidal analgesics or PRN dosing with short-acting opioid.
- b. Patient requires continuous opioid administration.
- c. Prescribers are encouraged 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.

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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 Authorizations

Prior approval will be given for a 12 month time period.

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 25, 2013

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

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

- a. 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):

The recipient must meet all of the following:

1. The recipient is ≥ 18 years of age or ≥ 16 years of age if requesting fentanyl citrate transmucosal lozenge (Actiq®); and
2. The recipient has pain resulting from a malignancy; and
3. The recipient is already receiving and is tolerant to opioid therapy; and
4. The recipient is intolerant of at least two of the following immediate-release opioids: hydrocodone, hydromorphone, morphine or oxycodone.

2. Prior Authorization Guidelines

- a. Prior Authorization approval will be for six months.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)

Last Reviewed by the DUR Board: January 24, 2008

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

Recipients must meet one of the following criteria for coverage:

- a. Achieve and maintain hemoglobin levels within the range of 10 to 12 gm/dl in one of the following conditions:
 1. Treatment of anemia secondary to myelosuppressive anticancer chemotherapy.
 2. Treatment of anemia related to zidovudine therapy in HIV-infected patients.
 3. Treatment of anemia secondary to ESRD.
- b. 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®) does not have this indication.

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.

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

3. Prior Authorizations

Prior approval will be given for a one month period. Recent laboratory results are required for prior authorization, i.e. serum hemoglobin within seven days of prior authorization request.

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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I. Anti-Fungal Onychomycosis

Therapeutic Class: Antifungal Agents

Last Reviewed by the DUR: September 3, 2015

Anti-Fungal Onychomycosis 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 agent is U.S. FDA approved for the treatment of onychomycosis (tinea unguium).
- b. And one of the following:
 1. The recipient is experiencing pain which limits normal activity; or
 2. The recipient's disease is iatrogenically-induced; or
 3. The recipient's disease is associated with immunosuppression; or
 4. The recipient has diabetes; or
 5. The recipient has significant peripheral vascular compromise.
- c. And the requested length of therapy is appropriate, based on the agent and infection location.
- d. And the drug and/or formulation-specific criteria is met:
 1. Terbinafine: no pre-existing liver disease.
 2. Itraconazole: The recipient does not have a diagnosis of heart failure and there is no evidence of ventricular dysfunction.
 3. Oral granules dosage form: clinical rationale documenting why the recipient cannot or should not use terbinafine tablets or itraconazole capsules.
- e. Topical dosage forms:
 1. Inadequate response after an appropriate length of therapy with ciclopirox 8% solution or an adverse reaction or contraindication to ciclopirox 8% solution; and

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- 2. Inadequate response after an appropriate length of therapy to either terbinafine tablets or itraconazole capsules or an adverse reaction or a contraindication to terbinafine tablets or itraconazole capsules or a clinical rationale why the recipient cannot use terbinafine tablets or itraconazole capsules.
- f. Onmel (itraconazole) tablets: Clinical rationale documenting why the recipient cannot or should not use terbinafine tablets or itraconazole capsules.
- 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:

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- 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>

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K. Regranex®

Therapeutic Class: Diabetic Ulcer Preparations, Topical
Last Reviewed by the DUR Board: July 17, 2008

Regranex® 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. Diagnosis of lower extremity diabetic ulcer(s); and
- b. Recipient must be age 16 years or older.

2. Prior Authorization Guidelines

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

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L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators

Last Reviewed by the DUR Board: January 25, 2018

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Stelara® (ustekinumab)
Amevive® (alefacept)	Kevzara® (sarilumab)	Xeljanz® (tofacitinib)
Arcalyst® (rilonacept)	Kineret® (ankinra)	
Cimzia® (certolizumab pegol)	Orencia® (abatacept)	
Consentyx® (secukinumab)	Remicade® (infliximab)	
Enbrel® (etanercept)	Siliq® (brodalumab)	
Entyvio® (vedolizumab)	Simponi® (golimumab)	
Humira® (adalimumab)	Simponi® ARIA™ (golimumab)	

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. Coverage and Limitations

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. 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 \leq six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

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hydroxychloroquine, leflunomide, minocycline and sulfasalazine);
or

- b. The recipient has had RA for \geq 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 \geq 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
 4. The recipient has had an inadequate response to any one of the DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, leflunomide, minocycline).
- 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.

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- 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 or 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.
 - 3. And the recipient has failed to adequately respond to conventional therapy (e.g. sulfasalazine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or
 - 4. The recipient has fistulizing Crohn's Disease.
- h. Ulcerative Colitis:
 - 1. The recipient has a diagnosis of moderate to severe ulcerative colitis; and
 - 2. The recipient is at an appropriate age, based on the requested agent:
 - a. Infliximab: Six years of age or older.

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- b. All others: 18 years of age or older.
- 3. And the recipient has failed to adequately respond to one or more of the following standard therapies:
 - a. Corticosteroids;
 - b. 5-aminosalicylic acid agents;
 - c. Immunosuppressants; and/or
 - d. Thiopurines.
- 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

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

Prior authorization approval will be for one year.

M. Topical Immunomodulators

Therapeutic Class: Topical **Immunomodulators**

Eucrisa® last reviewed by the DUR Board: July 26, 2018

Last Reviewed by the DUR Board: April 26, 2007

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

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

- a. Patient must have a therapeutic failure with the use of a topical steroid.
 - b. Patient has a documented diagnosis of Atopic Dermatitis:
 1. Elidel®: for mild to moderate, for ages \geq two years.
 2. **Eucrisa® for mild to moderate, for ages \geq two years.**
 3. Protopic® 0.03%; moderate to severe, for ages \geq two years.
 4. Protopic® 0.1%; moderate to severe, for ages \geq 18 years.
 - c. Not for chronic use.
 - d. Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.
 - e. **The recipient must have had therapeutic failure with the trial of a topical steroid of at least 14 days within the last six months for approval of Eucrisa®.**
 - f. Not recommended for use in immunocompromised patients.
2. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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N. Psychotropic Medications for Children and Adolescents

Therapeutic Class: Psychotropic Agents

Last Reviewed by the DUR Board: September 3, 2015

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 poly-pharmacy. 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

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- 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. Poly-pharmacy: Each psychotropic medication prescribed must be independently treating a specific symptom and/or diagnosis.
 1. Poly-pharmacy (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. Poly-pharmacy (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 poly-pharmacy 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 poly-pharmacy may be given for a medication to augment the effect of another psychotropic medication as long as the purpose of the poly-pharmacy 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 poly-pharmacy, all psychotropic medications must be utilized for a medically accepted indication as established by the FDA, and/or peer reviewed literature.
 - d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a prior authorization approval

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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 this 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:

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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O. Lidoderm 5% Patches®

Therapeutic Class: Topical, Local Anesthetics
Last Reviewed by the DUR Board: April 30, 2009

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.

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P. Monoclonal Antibody Agents

Therapeutic Class: Respiratory Monoclonal Antibody Agents

Fasenra® reviewed by DUR Board: April 26, 2018

Xolair® previously reviewed: October 19, 2017

Last Reviewed by the DUR Board: July 28, 2016

Xolair® (Omalizumab) 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

A. Xolair® (Omalizumab)

1. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies.
2. All of the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:
 - a. The recipient must be six years of age or older; and
 - b. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and
 - c. The prescriber must be either a pulmonologist or allergist/immunologist; and
 - d. The recipient must have had an inadequate response, adverse reaction or contraindication to inhaled, oral corticosteroids; and
 - e. The recipient must have had an inadequate response, adverse reaction or contraindication to a leukotriene receptor antagonist; and
 - f. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and
 - g. The recipient's current weight must be recorded; and
 - h. The requested dose is appropriate for the recipient's pre-treatment serum IgE and body weight (see Table 1).
3. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU); and

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- 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. The requested dose is:
 1. Initial therapy: 150 mg every four weeks or 300 mg every four weeks and clinical rationale for starting therapy at 300 mg every four weeks has been provided.
 2. Continuation of therapy: 150 mg or 300 mg every four weeks.
- 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 an appropriate age:
 1. Mepolizumab: 12 years of age or older
 2. Reslizumab: 18 years of age or older
 - d. And, the prescriber must be either a pulmonologist or allergist/immunologist; and

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- 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.

C. 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 antiasthmatic monoclonal antibodies; and
 - c. The recipient must have a diagnosis of severe asthma; and
 - d. Asthma is an eosinophilic phenotype as defined by a baseline blood eosinophil level greater than or equal to 300 cells per microliter; and
 - e. One of the following:
 - 1. Patient has had at least two 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.
 - f. 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 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

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2. One maximally-dosed combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)).
- g. 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. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
 1. Both an inhaled corticosteroid (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.
2. Prior Authorization Guidelines
 - A. Prior Authorization approval will be for 12 months.
 - B. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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				

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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 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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R. Toradol® (ketorolac tromethamine) tablets

Therapeutic Class: Nonsteroidal Antinflammatory Drugs, NSAIDS

Last Reviewed by the DUR Board: Not Available

The pharmaceutical Toradol® 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

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 is indicated only as continuation therapy to IV/IM therapy.
- b. Oral treatment is not to exceed five days.

2. Prior Authorization Guidelines

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

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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S. Anti-Migraine Medications

Therapeutic Class: Triptans

Last Reviewed by the DUR Board: September 21, 2006

Serotonin 5-HT₁ receptor agonists commonly referred to as “triptans” 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. Coverage and Limitations

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:

- a. 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
- b. 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.
 1. Recipient’s current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).
 2. 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.
 3. Prior authorization will NOT be given to patients with ischemic heart disease.

Approval for exceeding the quantity limits on triptans will be given for a two month time period.

2. Prior Authorization Guidelines

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

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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T. Tobacco Cessation Products

Therapeutic Class: Tobacco Cessation Agents

Last Reviewed by the DUR Board: Not Available

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.

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U. Xopenex® (Levalbuterol)

Therapeutic Class: Beta Adrenergic Agents

Last Reviewed by the DUR Board: July 26, 2012

Xopenex® 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

- a. Authorization only for recipients experiencing side effects on one other beta-adrenergic agent of any formulation.
- b. Authorization for patients whose cardiovascular status is considered to be in severe deteriorating condition.

2. Prior Authorization Guidelines

Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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W. Inhaled Anticholinergic Agents

Therapeutic Class:

Last Reviewed by the DUR Board:

Inhaled anticholinergic 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. General Criteria

- a. Only one inhaled anticholinergic agent may be used in a 30-day period.

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X. Antiemetics – Serotonin Receptor Antagonists (also known as 5-HT3 Antiemetics)

Therapeutic Class: Antiemetics, Antivertigo Agents

Last Reviewed by the DUR Board: October 28, 2010

1. Coverage and Limitations

5-HT3 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:

- 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 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.

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Y. Synagis® Palivizumab

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, corticosteroids) within six months to the start of RSV season; or
 2. The recipient has had a cardiac transplant; or
 3. The recipient is severely immunocompromised (solid organ or

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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Z. Opioids, Opioid Containing Cough Preparations

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

Last Reviewed by the DUR Board: October 27, 2016

Opioids and Opioid Containing Cough Preparations 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. Opioids will be covered without Prior Authorization (PA):

1. For initial prescriptions of seven days or less; and
2. For a total of 13 seven-day prescriptions in any rolling 12 month period; and
3. For prescriptions of 60 mg morphine equivalents or less per day.

b. Recipients currently on chronic opioid medications will not be subject to the seven-day requirement for an opioid(s) they have been receiving in the past 45 days.

c. 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

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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:
<http://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:
<http://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.

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AA. Savella® (milnacipran)

Therapeutic Class: Fibromyalgia Agents: Serotonin-Norepinephrine Reuptake Inhibitor
Last Reviewed by DUR Board: June 3, 2010

Savella® (milnacipran) is subject to prior authorization.

Coverage and Limitations

1. Diagnosis of Fibromyalgia:
 - a. If an ICD code for Myalgia and Myositis unspecified is documented on the prescription; or
 - b. Completion of a prior authorization documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.

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

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BB. Buprenorphine/Naloxone

Therapeutic Class: Narcotic Withdrawal Therapy Agents

Last Reviewed by the DUR Board: January 26, 2017

Previously reviewed by the DUR Board: April 28, 2017

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. To initiate therapy:

1. Buprenorphine/Naloxone will be covered without Prior Authorization (PA) approval for an initial prescription of seven days or less.

a. An ICD diagnosis related to opioid dependence must be written on the prescription and transmitted on the claim.

b. To re-initiate therapy:

1. Buprenorphine/Naloxone will be covered without PA approval to re-initiate therapy for a prescription of seven days or less for recipients with a gap in treatment.

a. An ICD diagnosis related to opioid dependence must be written on the prescription and transmitted on the claim.

c. Prior authorization approval is required to exceed the seven-day limit.

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

Nevada Medicaid encourages recipients to participate in formal substance abuse counseling and treatment.

a. The recipient is 16 years of age or older; and

b. The recipient has a diagnosis of opioid dependence; and

c. Requests for a diagnosis of chronic pain will not be approved; and

d. There is documentation the recipient has honored all of their office visits; and

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- e. The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique “X” DEA number; and
- f. All of the following are met:
 - 1. The recipient will not utilize opioids, including tramadol, concurrently with the requested agent; and
 - 2. If the recipient is currently utilizing an opioid, medical documentation must be provided stating the recipient will discontinue the opioid prior to initiation of buprenorphine or buprenorphine/naloxone.
- g. Requests for buprenorphine will be approved if one of the following is met:
 - 1. The recipient is a pregnant female;
 - 2. There is documentation that the recipient is breastfeeding an infant who is dependent on methadone or morphine;
 - 3. The recipient has had an allergy to a buprenorphine/naloxone; or
 - 4. The recipient has moderate to severe hepatic impairment (Child-Pugh B to C).
- d. Requests that exceed the quantity limit must meet all of the following:
 - 1. There is documentation in the recipient’s medical record that the requested dose is the lowest effective dose for the recipient; and
 - 2. The treatment plan has been provided.
- 2. 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>

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CC. Ampyra® (dalfampridine)

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
 Last Reviewed by the DUR Board: July 25, 2013

Ampyra® (dalfampridine) 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 for Ampyra® (dalfampridine) will be given if all of the following criteria are met and documented:

a. Ampyra® (dalfampridine)

The recipient must meet all of the following:

1. The recipient must have a diagnosis of Multiple Sclerosis; 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 >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.

2. Prior Authorization Guidelines

- a. Initial Prior Authorization approval will be for three months.
- b. Requests for continuation of therapy will be approved for one year.
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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DD. Androgel®, Androderm®, Testim® (Testosterone gel and transdermal system)

Therapeutic Class: Androgenic Agents

Last Reviewed by the DUR Board: July 22, 2010

Topical Androgens are subject to prior authorization.

1. Coverage and Limitations

Recipients must meet all of the criteria for coverage:

2. Criteria for approval

a. Recipient is a male;

b. Use is for the FDA Approved Indication:

Primary (congenital or acquired) or secondary (congenital or acquired) hypogonadism with an ICD code for hypogonadism;

c. The patient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used;

d. The patient 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) > 19;

e. The patient does not have a hematocrit > 50%;

f. The patient does not have untreated severe obstructive sleep apnea; and

g. The patient does not have uncontrolled or poorly controlled heart failure.

3. Prior Authorization Guidelines

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

b. Prior Authorization forms are available at:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>.

c. Length of authorization: one year.

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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

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- 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 \leq 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).

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2. Prior Authorization Guidelines:
 - a. Prior authorization approval will be given based on diagnosis.
 1. For FMF and chronic gout: one year.
 2. For Acute gout: two months.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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HH. Anti-Hepatitis Agents

Therapeutic Class: Anti-Hepatitis Agents

Last Reviewed by the DUR Board: July 26, 2018

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. Coverage and Limitations

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

a. **Daklinza® (daclatasvir) for genotype 1 or 3**

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or genotype 3 (submission of medical records e.g., chart notes, laboratory values); and
2. The medication is used in combination with Sovaldi® (sofosbuvir); and
3. 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.
4. The recipient has not failed a prior HCV NS5A-containing regimen (e.g., Daklinza); and
5. The medication must be prescribed by or in consultation with one of the following:
 - a. Hepatologist
 - b. Gastroenterologist
 - c. Infectious Disease Specialist

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- d. HIV Specialist (certified through the American Academy of HIV Medicine)
- 6. Prior authorization approval will be for 12 weeks.
- b. Epclusa® (sofosbuvir and velpatasvir)
 - 1. The following are required for all Epclusa® treatment:
 - a. The recipient is not receiving Epclusa® (sofosbuvir and velpatasvir) in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and
 - b. The medication must be 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)
 - 2. Genotype 1, 2, 3, 4, 5 or 6, without decompensated liver disease
 - a. 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
 - b. The recipient must not have decompensated liver disease; and
 - c. Epclusa® must be used alone; and
 - d. Prior authorization approval will be for 12 weeks.
 - 3. Genotype 1, 2, 3, 4, 5 or 6 with decompensated liver disease
 - a. 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
 - b. The recipient has decompensated liver disease; and
 - c. Epclusa® is being used in combination with Ribavirin; and

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- d. Prior authorization approval will be for 24 weeks.
- 4. Genotype 1, 2, 3, 4, 5 or 6 Ribavirin intolerance/ineligible or prior Sovaldi® (sofosbuvir) or NS5A-based treatment failure.
 - a. 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
 - b. The recipient has decompensated liver disease; and
 - 1. One of the following:
 - a. The recipient is Ribavirin intolerant or ineligible; or
 - b. Both of the following:
 - 2. 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
 - 3. Epclusa® is used in combination with Ribavirin®.
 - c. Prior authorization approval will be for 24 weeks.
- c. Harvoni® (ledipasvir/sofosbuvir)
 - 1. The following are required for all Harvoni® treatment:
 - a. The recipient is not receiving Harvoni® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and
 - b. The medication must be 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)
 - 2. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is less than six million IU/mL

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- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient does not have cirrhosis; and
 - c. The recipient is treatment naïve; and
 - d. Medical records documenting pre-treatment HCV RNA less than six million IU/mL must be submitted; and
 - e. Prior authorization approval will be for eight weeks.
3. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is greater than or equal to six million IU/mL
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient does not have cirrhosis; and
 - c. The recipient is treatment naïve; and
 - d. Medical records documenting pre-treatment HCV RNA greater than or equal to six million IU/mL must be submitted; and
 - e. Prior authorization approval will be for 12 weeks.
 4. Genotype 1, treatment naïve with compensated cirrhosis
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and
 - c. The recipient is treatment naïve; and
 - d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - e. Prior authorization approval will be for 12 weeks.
 5. Genotype 1, treatment experienced without cirrhosis

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- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient does not have cirrhosis; and
 - c. One of the following:
 - 1. 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
 - 2. Both of the following:
 - a. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) except in combination with Olysio® (simeprevir); and
 - b. The medication is used in combination with Ribavirin.
 - d. Prior authorization approval will be for 12 weeks.
6. Genotype 1, Ribavirin eligible, treatment experienced and with compensated cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and
 - c. 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
 - d. The medication is used in combination with Ribavirin; and
 - e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

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- f. Prior authorization approval will be for 12 weeks.
7. Genotype 1, Ribavirin ineligible, treatment experienced and with compensated cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and
 - c. 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
 - d. The recipient is Ribavirin ineligible; and
 - e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - f. Prior authorization approval will be for 24 weeks.
8. Genotype 1, 4, 5 or 6, decompensated cirrhosis or post-liver transplant
- a. 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
 - b. One of the following:
 1. 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
 2. Both of the following:
 - a. The recipient is a liver transplant recipient; and
 - b. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - c. The medication is used in combination with Ribavirin; and
 - d. Prior authorization approval will be for 12 weeks.

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9. Genotype 1,4, 5, or 6, decompensated cirrhosis, Ribavirin ineligible or prior failure of Sovaldi® or NS5A based regimen
 - a. 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
 - b. 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
 - c. One of the following:
 1. The recipient is Ribavirin ineligible; or
 2. Both of the following:
 - a. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and
 - b. The medication is used in combination with Ribavirin; and
 - d. Prior authorization approval will be for 24 weeks
10. Genotype 4, treatment naïve or treatment experienced (peginterferon plus Ribavirin)
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and
 - b. One of the following:
 1. The recipient is treatment naïve; or
 2. One of the following:
 - a. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and is without cirrhosis; or
 - b. Both of the following:

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1. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and has compensated cirrhosis (Child-Pugh class A); and
 2. The medication is used in combination with Ribavirin; and
 - c. Prior authorization approval will be for 12 weeks.
11. Genotype 5 or 6, treatment naïve or treatment experienced (peginterferon plus Ribavirin)
- a. 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
 - b. One of the following:
 1. The recipient is treatment naïve; or
 2. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin; and
 - c. Prior authorization approval will be for 12 weeks.
- d. Mavyret® (glecaprevir/pibrentasvir)
1. The following are required for all Mavyret® treatment:
 - a. The recipient is not receiving Mavyret® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir)); and
 - b. The medication must be 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

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HIV Medicine)

2. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve without cirrhosis
 - 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 treatment naïve; and
 - c. The recipient is without cirrhosis; and
 - d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - e. Prior authorization approval will be for eight weeks.
3. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve with compensated cirrhosis
 - 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 treatment naïve; and
 - c. The recipient has compensated cirrhosis (Child-Pugh class A); and
 - d. Prior authorization approval will be for 12 weeks.
4. Genotype 1, treatment experienced (prior failure to an NS3/4A protease inhibitor), without decompensated cirrhosis
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. 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
 - c. The recipient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

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- d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and
 - e. Prior authorization approval will be for 12 weeks.
5. Genotype 1, treatment experienced (prior failure to an NS5A inhibitor), without decompensated cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and
 - c. 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
 - d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and
 - e. Prior authorization approval will be for 16 weeks.
6. Genotype 3, treatment experienced (interferon or Sovaldi® based regimen), without decompensated cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and
 - c. 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
 - d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

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- e. Prior authorization approval will be for 16 weeks.
7. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), without cirrhosis
- a. 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
 - b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and
 - c. 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
 - d. The recipient is without cirrhosis; and
 - e. Prior authorization approval will be for eight weeks.
8. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), with compensated cirrhosis
- a. 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
 - b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and
 - c. 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
 - d. The recipient has compensated cirrhosis (e.g., Child-Pugh class A); and
 - e. Prior authorization approval will be for 12 weeks.

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- e. Olysio® (simeprevir)
1. Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:
 - a. Both of the following:
 1. Diagnosis of chronic hepatitis C genotype 1a; and
 2. The recipient does not have the NS3 Q8K polymorphism; or
 - b. The recipient has a diagnosis of chronic hepatitis C genotype 1b; or
 - c. The recipient has a diagnosis of chronic hepatitis C genotype 4; and
 2. 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
 3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 4. The medication is used in combination with peginterferon alfa and Ribavirin; and
 5. 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)
 6. Genotype 1 without cirrhosis
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient is without cirrhosis; and
 - c. The medication is used in combination with Sovaldi® (sofosbuvir); and

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- d. Prior authorization approval will be for 12 weeks.
- 7. Genotype 1 with cirrhosis
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of medical records (e.g., chart notes, laboratory values documenting that the recipient has cirrhosis); and
 - c. The medication is used in combination with Sovaldi® (sofosbuvir); and
 - d. Prior authorization approval will be for 24 weeks.
 - e. Sovaldi® (sofosbuvir)
 - 1. The following is required for all Sovaldi® treatment:
 - a. The medication must be 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)
 - 2. Genotype 1 or 4, without decompensated liver disease
 - a. 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
 - b. The medication is used in combination with peginterferon alfa and Ribavirin; and
 - c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - d. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

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- e. Prior authorization approval will be for 12 weeks.
3. Genotype 3, without decompensated liver disease
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient must be 18 years of age or older; or
 - c. Both of the following:
 1. 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
 2. The recipient is 12 to 17 years of age; or both of the following:
 - a. The recipient weighs at least 35 kg; and
 - b. The recipient is less than 12 years of age; and
 - d. The medication is used in combination with Ribavirin; and
 - e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - f. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and
 - g. Prior authorization approval will be for 24 weeks.
 4. Genotype 2, without decompensated liver disease
 - 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 must be 18 years of age or older; or
 - c. Both of the following:
 1. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

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2. The recipient is 12 to 17 years of age; or both of the following:
 - a. The recipient weighs at least 35 kg; and
 - b. The recipient is less than 12 years of age; and
 - d. The medication is used in combination with Ribavirin; and
 - e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - f. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and
 - g. Prior authorization approval will be for 12 weeks.
5. Genotype 1, without cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The medication is used in combination with Olysio® (simeprevir); and
 - c. The recipient is without cirrhosis; and
 - d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - e. 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
 - f. Prior authorization approval will be for 12 weeks.
6. Genotype 1, with cirrhosis
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The medication is used in combination with Olysio® (simeprevir); and

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- c. The recipient has cirrhosis; and
- d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
- e. 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
- f. Prior authorization approval will be for 12 weeks.

7. Genotype 1

- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
- b. The medication is used in combination with Daklinza® (daclatasvir); and
- c. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and
- d. One of the following:
 - 1. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or
 - 2. Both of the following:
 - a. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and
 - b. The medication is used in combination with Ribavirin.
- e. Prior authorization approval will be for 12 weeks.

8. Genotype 3

- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and
- b. The medication is used in combination with Daklinza® (daclatasvir); and

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- c. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and
- d. One of the following:
 - 1. The recipient is without cirrhosis and is not a liver transplant recipient; or
 - 2. Both of the following:
 - a. The recipient has cirrhosis (compensated or decompensated) and/or is a liver transplant recipient; and
 - b. The medication is used in combination with Ribavirin.
- e. Prior authorization approval will be for 12 weeks.
- g. Technivie® (ombitasvir, paritaprevir and ritonavir) for genotype 4
 - 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 without cirrhosis; or
 - b. The recipient has compensated cirrhosis; and
 - 3. The medication is used in combination with Ribavirin; and
 - 4. The recipient is not receiving Technivie® in combination with another HCV direct acting agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and
 - 5. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and
 - 6. The medication must be prescribed by or in consultation with one of the following:
 - a. Hepatologist
 - b. Gastroenterologist

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- c. Infectious Disease Specialist
 - d. HIV Specialist (certified through the American Academy of HIV Medicine)
7. Prior authorization approval will be for 12 weeks.
- h. Viekira Pak®, Viekira XR® (ombitasvir, paritaprevir, ritonavir tablets, dasabuvir tablets)
- 1. The following is required for all Viekira Pak®, Viekira XR® treatment:
 - a. The recipient has not experienced failure with a previous treatment regimen that includes HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and
 - b. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and
 - c. The medication must be 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)
 - 2. Genotype 1a or mixed genotype 1, without cirrhosis and without liver transplant
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient is without cirrhosis; and
 - c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - d. The medication is used in combination with Ribavirin; and

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- e. Prior authorization approval will be for 12 weeks.
3. Genotype 1a or mixed genotype 1, with cirrhosis and without liver transplant
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and
 - c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - d. The medication is used in combination with Ribavirin; and
 - e. Prior authorization approval will be for 24 weeks.
 4. Genotype 1b, without liver transplant
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
 - c. Prior authorization approval will be for 24 weeks.
 5. Genotype 1 (regardless of sub genotype), with liver transplant
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and
 - b. Submission of documentation that the recipient is a liver transplant recipient; 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
 - d. The medication is used in combination with Ribavirin; and
 - e. Prior authorization approval will be for 24 weeks.

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i. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

1. The following is required for all Vosevi® treatment:

- a. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and
- b. The recipient is not receiving Vosevi® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Zepatier® (elbasvir/grazoprevir)); and
- c. The medication must be 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)

2. Genotype 1, 2, 3, 4, 5 or 6; without decompensated cirrhosis, prior relapse to NS5A based regimen

- 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 relapser 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
- d. Prior authorization approval will be for 12 weeks.

3. Genotype 1a, without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor

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- 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. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and
 - c. Prior authorization approval will be for 12 weeks.
4. Genotype 3, without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and
 - c. Prior authorization approval will be for 12 weeks.
- j. Zepatier® (elbasvir/grazoprevir)
 1. The following is required for all Zepatier® treatment:
 - a. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and
 - b. The recipient is not receiving Zepatier® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and
 - c. The medication must be 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)
 2. Genotype 1a, treatment naïve, or PegIFN/RBV experienced or PegIFN/RBV/protease inhibitor experienced, without NS5A

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polymorphisms

- 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
 - e. Prior authorization approval will be for 16 weeks.
3. Genotype 1b, treatment naïve, or PegIFN/RBV experienced or PegIFN/RBV/protease inhibitor experienced
 - a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (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. Both of the following:

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- a. 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
 - b. The medication is used in combination with Ribavirin; and
 - c. Prior authorization approval will be for 12 weeks.
4. Genotype 4, treatment naïve
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient is treatment naïve; and
 - c. Prior authorization approval will be for 12 weeks.
5. Genotype 4, PegIFN/RBV experienced
- a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and
 - b. The recipient has had prior failure to peginterferon alfa plus Ribavirin; and
 - c. The medication is used in combination with Ribavirin; and
 - d. Prior authorization approval will be for 16 weeks.
2. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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II. Daliresp® (roflumilast)

Therapeutic Class: Phosphodiesterase-4 Inhibitors.

Last Reviewed by the DUR Board: July 26, 2012

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 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 severe Chronic Obstructive Pulmonary Disease (COPD) associated with chronic bronchitis; and
- e. The recipient has a history of COPD exacerbations.

2. Prior Authorization Guidelines:

- a. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents

Last Reviewed By DUR Board: July 25, 2013

Hereditary angioedema 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

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

a. Cinryze® (C1 esterase inhibitor)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and
2. The medication is being prescribed by or in consultation with an allergist or immunologist; and
3. The medication is being used as prophylaxis for hereditary angioedema attacks; and
4. The recipient has experienced an inadequate response or adverse event with an attenuated androgen (e.g. danazol, stanozolol) or antifibrinolytic (e.g. tranexamic acid, aminocaproic acid) agent or has a contraindication to all agents in these classes; and
5. The recipient routinely experiences more than one hereditary angioedema attack per month, or the recipient has a history of laryngeal attacks.

b. Berinert® (C1 esterase inhibitor), Kalbitor® (ecallantide) and Firazyr® (icatibant)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and
2. The medication is being prescribed by or in consultation with an allergist or immunologist; and
3. The medication is being used to treat acute hereditary angioedema attacks.

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2. Prior Authorization Guidelines:

- a. Initial Prior Authorization approval will be for six months.
- b. Prior Authorization requests for continuation therapy will be approved for one year.
- c. Prior Authorization forms are available at:
<http://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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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LL. Kalydeco® (ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent

Last Reviewed by the DUR Board: July 26, 2018

Kalydeco® (ivacaftor) 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 two years of age or older; and
- b. The recipient has a diagnosis of cystic fibrosis; 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 cystic fibrosis care center.

2. 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 Kalydeco® therapy.

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>.

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MM. Natroba® (spinosad)

Therapeutic Class: Topical Antiparasitics

Last Reviewed by the DUR Board: July 26, 2012

Natroba® (spinosad) is subject to prior authorization.

1. Coverage and Limitations

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

- a. The recipient has experienced an allergy or adverse event with a permethrin or pyrethrin-containing pediculicide product; or
- b. The recipient has experienced a treatment failure with a permethrin or pyrethrin-containing pediculicide product despite a full course of treatment (two applications); or
- c. The recipient has a contraindication to treatment with permethrin or pyrethrin-containing pediculicide product.

2. Prior Authorization Guidelines

- a. Prior authorization approval will be for the date of service only.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors

Last Reviewed by the DUR Board: January 23, 2014

Brilinta® (ticagrelor) and Effient® (prasugrel) 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. Brilinta® (ticagrelor)

1. The recipient has a diagnosis of Acute Coronary Syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and
2. The recipient does not have an active pathological bleed or history of intracranial hemorrhage; and
3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and
4. The recipient has been started and stabilized on the requested medication; or
5. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or
6. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

b. Effient® (prasugrel)

1. The recipient has a diagnosis of ACS (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and
2. The recipient does not have an active pathological bleed or history of transient ischemic attack or cerebral vascular accident (CVA); and
3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and

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4. The recipient has a history of percutaneous coronary intervention; and
 5. The recipient has been started and stabilized on the requested medication;
or
 6. The recipient has experienced an adverse event with or has an allergy or
contraindication to clopidogrel; or
 7. Another clinically appropriate rationale is provided for why clopidogrel
cannot be used.
2. 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>

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OO. Prolia® (Denosumab)

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)

Last Reviewed by DUR Board: October 25, 2012

Prolia® (Denosumab) 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. Postmenopausal Osteoporosis

1. The recipient has a T score \leq -2.5; and
2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture; and
3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.

b. Male Osteoporosis

1. The recipient has a T score \leq -2.5; and
2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture; and
3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.

c. Non-metastatic Prostate Cancer

1. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture;
2. The recipient is receiving treatment with androgen-deprivation therapy (e.g., anti-androgen or luteinizing hormone-releasing hormone agents);

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3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
- d. Breast Cancer
1. The recipient has a history of osteoporotic fracture or has multiple risk factors for fracture;
 2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane and letrozole);
 3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
2. 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>.

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PP. Forteo® (Teriparatide)

Therapeutic Class: Parathyroid/Bone Formation Stimulating Agent (Osteoporosis Agents)

Last Reviewed by DUR Board: October 25, 2012

Forteo® (Teriparatide) 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 been diagnosed with Postmenopausal Osteoporosis, or Glucocorticoid-Induced Osteoporosis, or the recipient is male and diagnosed with Primary or Hypogonadal Osteoporosis;
- b. The recipient has a T score of ≤ 2.5 ;
- c. The recipient has a history of osteoporotic fracture or has multiple risk factors for fracture;
- d. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate;
- e. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
- f. The total duration of treatment with this agent has not exceeded two years.

2. 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>.

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QQ. Cannabinoid Antiemetics

Therapeutic Class: Antiemetic

Last Reviewed by DUR Board: October 25, 2012

Cannabinoid 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.

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

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- 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>.

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: April 28, 2016

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 neutropenia risk of $\geq 20\%$; 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

UU. **RESERVED**

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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

WW. Irritable-Bowel Syndrome Agents

Therapeutic Class: Irritable-Bowel Syndrome Agents

Trulance® last reviewed by the DUR Board: July 26, 2018

Last Reviewed by the DUR Board: July 28, 2016

Viberzi® last reviewed by the DUR Board April 28, 2016

Irritable-Bowel Syndrome 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. Coverage and Limitations

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

1. The recipient is 18 years of age or older; and
2. The requested agent is being prescribed based on FDA approved guidelines; and
 - a. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):
 1. For requests for **Amitiza® (lubiprostone)**, the recipient must be female.
 2. The requested dose is appropriate based on indication and age.
 - a. **Linzess® (linaclotide)**: 290 µg daily.
 - b. **Amitiza® (lubiprostone)**: 16 µg daily.
 - c. **Trulance® (plecanatide)**: 3 µg daily.
 - b. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):
 1. The medication is being prescribed by or in consultation with a gastroenterologist; and
 2. The requested dose is appropriate based on indication and age.
 - a. **Lotronex® (alosetron)**: 0.5 mg twice daily or 1 mg twice daily.

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- b. **Viberzi® (eluxadoline)**: 75 mg twice daily or 100 mg twice daily.
- c. **Xifaxan® (rifaximin)**: 550 mg three times a day for 14 days.

2. Prior Authorization Guidelines

- a. Prior authorization approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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. PA 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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

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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

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- c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rationale 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.
- 1. 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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ZZ. Vivitrol® (naltrexone)

Therapeutic Class: Opioid Dependence Agents

Last Reviewed by DUR Board: January 28, 2016

Vivitrol® (naltrexone®) 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 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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AAA. Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil)

Therapeutic Class: Narcolepsy Agents (non-stimulants)

Last Reviewed by DUR Board: April 23, 2015

Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil) 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. Provigil® (modafinil), and Nuvigil® (armodafinil):
 1. The recipient has a diagnosis of narcolepsy.
- b. Xyrem® (sodium oxybate):
 1. The recipient has tried and failed on Provigil® (modafinil) or Nuvigil® (armodafinil); and/or
 2. The recipient has a diagnosis of narcolepsy with cataplexy; and
 3. The drug was prescribed by or in consultation with a neurologist or sleep specialist.

2. Prior Authorization Guidelines

- a. Prior Authorization approvals will be for one year.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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BBB. Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine)

Therapeutic Class: Nonsteroidal Anti-inflammatory Drug/Anti-ulcer Agent Combinations

Last Reviewed by 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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CCC. Rayos® (prednisone delayed-release)

Therapeutic Class: Corticosteroid, Systemic
Last Reviewed by 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: Antilepemic Agent, PCSK9 Inhibitors

Last Reviewed by the DUR Board: January 28, 2016

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. Coverage and Limitations

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

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

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3. The LDL-C after therapy for at least the past three months was ≥ 100 mg/dL (HeFH) for ≥ 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.

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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. Prior Authorizaiton approvals will be for:
 1. Initial request: six months
 2. Recertification request: one year
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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FFF. Invega Trinza® (paliperidone palmitate)

Therapeutic Class: Second Generation (Atypical) Antipsychotic

Last Reviewed by the DUR Board: November 5, 2015

Invega Trinza® (paliperidone palmitate) 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 has a diagnosis of schizophrenia; and
- b. 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
- c. The recipient is 18 years of age or older; and
- d. The requested dose is one injection every three months.

2. Prior Authorization Guidelines:

- a. Prior Authorization approvals will be for one year.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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:

<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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HHH. Orkambi® (lumacaftor/ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent

Last Reviewed by the DUR Board: January 26, 2017

Previously reviewed November 5, 2015

Orkambi® (lumacaftor/ivacaftor) 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 cystic fibrosis; and
- b. The recipient is two years of age or older; and
- c. The recipient is homozygous for the F508del mutation in the 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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III. Hetlioz® (tasimelteon)

Therapeutic Class: Sedative Hypnotic

Last Reviewed by the DUR Board: January 28, 2016

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.

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of non-24-hour sleep-wake disorder; and
- b. The recipient is totally blind; and
- c. The medication is being prescribed by or in consultation with a sleep specialist; and
- b. The recipient had an adverse reaction, contraindication or an inadequate response (after at least four weeks of therapy) to a therapeutic dose of melatonin.

2. Prior Authorization Guidelines

- a. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker

Last Reviewed by the DUR Board: November 5, 2015

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 18 years 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 ACE or an 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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.
- d. And, 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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LLL. Opioid-Induced Constipation Agents

Therapeutic Class: Opioid-Induced Constipation Agents

Last Reviewed by the DUR Board: January 25, 2018

Opioid-induced constipation 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. Coverage and Limitations:

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

- a. The recipient is 18 years of age or older; and
- b. The requested medication is being used for an FDA approved indication; and
- c. The recipient must meet the following criteria:
 1. 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:
 - a. Bulk forming laxatives;
 - b. Osmotic laxatives;
 - c. Saline laxatives;
 - d. Stimulant laxatives
 - d. And, requests for methylnaltrexone bromide that exceed the quantity limit must meet all of the following criteria:
 1. The recipient has opioid-induced constipation in advanced illness, is receiving palliative care, and is not enrolled in the DHCFP's hospice program; and
 2. The requested dose is 0.15 mg/kg; and
 3. The recipient's current weight is >114 kg.

2. 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>

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MMM. Exondys 51® (eteplirsen)

Therapeutic Class: Exondys 51® (eteplirsen)

Last Reviewed by the DUR Board: August 24, 2017

Exondys 51® (eteplirsen) 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 of the following criteria are met and documented:

a. Initial request:

1. The recipient has a diagnosis of Duchenne muscular dystrophy (DMD); and
2. There is documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping; and
3. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and
4. The prescribed dose does not exceed 30 milligrams per kilogram of body weight once weekly.

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

1. The recipient has been on therapy for less than 12 months; and
2. The recipient has experienced clinically significant benefit; and
3. The recipient is tolerating therapy; and
4. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and
5. The medication is prescribed by or in consultation with a neurologist who has experience treating children, or all of the following:
 - a. The recipient has been on therapy for 12 months or more; and
 - b. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and
 - c. The recipient has experienced clinically significant benefit; and

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- d. The recipient is tolerating therapy; and
 - e. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and
 - f. The medication is prescribed by or in consultation with a neurologist who has experience treating children.
2. Prior Authorization Guidelines:
- a. Prior Authorization approvals will be for:
 - 1. Initial request: six months.
 - 2. Recertification request: one year.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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NNN. Spinraza® (nusinersen)

Therapeutic Class: Spinraza® (nusinersen)

Last Reviewed by the DUR Board: August 24, 2017

Spinraza® (nusinersen) 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 Spinal Muscular Atrophy (SMA), and
2. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA.

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

1. The recipient has been on therapy for less than 12 months; and
2. The recipient is maintaining neurological status; and
3. The recipient is tolerating therapy; and
4. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA, or all of the following:
 - a. The recipient has been on therapy for 12 months or more; and
 - b. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and
 - c. The recipient is maintaining neurological status; and
 - d. The recipient is tolerating therapy; and
 - e. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA.

2. Prior Authorization Guidelines:

a. Prior Authorization approvals will be for:

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1. Initial request: twelve months.
 2. Recertification request: continued use shall be reviewed at least every 12 months.
- b. The Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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000. Austedo® (deutetrabenazine)

Therapeutic Class: Austedo® (deutetrabenazine)

Last Reviewed by the DUR Board: January 25, 2018

Austedo® (deutetrabenazine) 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. Austedo® is indicated for the diagnosis of chorea associated with Huntington's disease or Tardive Dyskinesia.

1. Coverage and Limitations for Diagnosis of Chorea Associated with Huntington's Disease

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

a. Initial request:

1. The recipient must have a diagnosis of chorea associated with Huntington's disease; and
2. The recipient must be 18 years of age or older; and
3. The medication is prescribed by or in consultation with a neurologist; and
4. Prior authorization will not be approved for recipients who are suicidal or have untreated/inadequately treated depression, or hepatic impairment, or are currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.

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. Documentation of positive clinical response to Austedo® therapy.
2. Recertification will not be approved for recipients who are suicidal or have untreated/inadequately treated depression, or hepatic impairment, or are currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.

c. Prior Authorization Guidelines

1. Initial prior authorization approval will be for 12 months.
2. Prior authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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2. Coverage and Limitations for Diagnosis of Tardive Dyskinesia

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

a. Initial Request:

1. The recipient must have a confirmed diagnosis of Tardive Dyskinesia; and
2. The recipient must be 18 years of age or older; and
3. At least 60 days of stable (drug, dose) neuroleptic medication exposure (either typical or first-generation antipsychotic agents, atypical or second-generation antipsychotic agents or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis); and
4. Presence of involuntary athetoid or choreiform movements lasting at least 30 days; and
5. Must be prescribed by, or in consultation with, a neurologist or psychiatrist; and
6. The recipient must have one of the following:
 - a. Persistent symptoms of tardive dyskinesia despite a trial dose reduction, tapering or discontinuation of the offending medication; or
 - b. The recipient is not a candidate for trial dose reduction, tapering or discontinuation of the offending medication.

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

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 Austedo® therapy.
2. Prior Authorization Guidelines
 - a. Initial prior authorization approval will be for three months.
 - b. Prior authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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 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

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- 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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QQQ. Ingrezza® (valbenazine)

Therapeutic Class: Ingrezza® (valbenazine)

Last Reviewed by the DUR Board: October 19, 2017

Ingrezza® (valbenazine) 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 tardive dyskinesia (TD) confirmed by the most current edition of Diagnostic and Statistical Manual of Mental Disorders (DSM), and the following:
 - a. At least 60 days of stable (drug, dose) neuroleptic medication exposure (either typical or first generation antipsychotic agents (such as, chlorpromazine, haloperidol or fluphenazine), atypical or second-generation antipsychotic agents (such as, clozapine, risperidone, olanzapine, quetiapine or aripiprazole, or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis (such as, prochlorperazine, promethazine or metoclopramide)); and
 - b. The presence of involuntary athetoid or choreiform movements lasting at least 30 days.
1. The recipient must be 18 years of age or older; and
2. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and
3. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or
4. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.

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:

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- A. Documentation of positive clinical response to Ingrezza® therapy.

- C. Prior Authorization Guidelines
 - 1. Initial prior authorization approval will be for three months.
 - 2. Prior authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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RRR. Emflaza® (deflazacort)

Therapeutic Class: Emflaza® (deflazacort)

Last Reviewed by the DUR Board: October 19, 2017

Emflaza® (deflazacort) 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 Duchenne muscular dystrophy (DMD); and
2. The recipient must be five years of age or older; and
3. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:
 - a. Documentation of a confirmed mutation of the dystrophin gene; or
 - b. Muscle biopsy confirming an absence of dystrophin protein; and
4. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and
5. 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
6. The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

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. Documentation of positive clinical response to Emflaza® therapy (e.g., improvement or preservation of muscle strength); and

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- b. 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 for 12 months.
- 2. Prior authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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SSS. Xadago® (safinamide)

Therapeutic Class: Xadago® (safinamide)

Last Reviewed by the DUR Board: October 19, 2017

Xadago® (safinamide) 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 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 of "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 (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. Documentation of positive clinical response to Xadago® therapy; and
 - b. Documented continued Levodopa and/or other dopaminergic

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treatments.

C. Prior Authorization Guidelines

1. Initial prior authorization approval will be for three months.
2. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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

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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:
<http://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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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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

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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VVV. Symdeko® (tezacaftor/ivacaftor)

Last Reviewed by the DUR Board: July 26, 2018

Symdeko® (tezacaftor/ivacaftor) 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

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

a. Initial Request:

1. The recipient is 12 years of age or older; and
2. The recipient has a documented diagnosis of cystic fibrosis (CF); and
3. The medication must be prescribed by or in consultation with one of the following:
 - a. Pulmonologist
 - b. Specialist affiliated 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 cystic fibrosis 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 CF transmembrane conductance regulator (CFTR) gene as detected by FDA cleared cystic fibrosis mutation test or CLIA approved facility.

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

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria is met:
 - a. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

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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>

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WWW. Botulinum Toxin

Therapeutic Class: Neurotoxic Protein

Last reviewed by 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):

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- 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>.

XXX. Compounded Medications

Last Reviewed by the DUR Board: July 26, 2018

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. Compounded medications at or above \$200 will require a prior authorization; and
- b. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and
- c. 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
- d. If any prescription ingredients require prior authorization and/or step therapy, all drug specific criteria must also be met; and
- e. The compounded medication must not be used for cosmetic purpose; and
- f. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons; and
- g. 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

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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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>.

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2. MEDICATIONS WITH GENDER/AGE EDITS

A. Prenatal Vitamins

1. Payable only for female recipients.

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B. Oral/Topical Contraceptives

1. Payable only for female recipients.

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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. Transdermal 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 Identity Disorder will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

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D. Vitamins with Fluoride

1. Payable only for recipients up to age 21 years.

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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.

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4. BLOOD GLUCOSE TESTING

Nevada Medicaid and NCU participate in a Diabetic Supply Procurement Program. This program allows for the State to receive additional rebates for diabetic monitors and test strips. Effective March 1, 2009, diabetic monitors and test strips are covered for Nevada Medicaid and NCU from preferred manufacturers. Preferred manufacturers are listed in the pharmacy billing manual. This policy does not negatively impact freedom of choice for recipients. The providers billing for the service will continue to be all willing enrolled pharmacies.

Blood glucose monitors and testing supplies for home use require a prescription and are subject to quantity limitations. A recipient or their caregiver must specifically request refills of glucose supplies before they are dispensed. The provider must not automatically dispense a quantity of supplies on a predetermined regular basis, even if a recipient has “authorized” in advance.

For all items in excess of the limitations, a prior authorization must be obtained from the Nevada Medicaid QIO-like vendor.

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, and manufacturers’ invoice of cost is required with a prior authorization.

ICD codes for Diabetes Mellitus, Diabetes, gestational (in pregnancy) are only required for newly diagnosed diabetics who are receiving diabetic prescription medication, a glucometer or test strips for the first time, or for recipients who are new to Medicaid or transitioning from an MCO. For recipients with an ongoing diagnosis of diabetes and a history of Nevada Medicaid paid claims for diabetic prescriptions no ICD code is required.

Blood glucose monitors and related supplies are billed on the NCPDP Universal Claim Form (UCF) or on-line through the POS system with the correct NDC number, complete description, including brand name and package size. Reimbursement is Wholesale Acquisition Cost (WAC) plus 8% and handling and dispensing fee of \$1.54 per prescription.

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OptumRx AD HOC REPORTING SYSTEM
STANDARD THERAPEUTIC CLASSES

Standard Therapeutic	
Class	Description
00	MEDICAL SUPPLIES
01	ANTI-ULCER PREPS/GASTROINTESTI
02	EMETICS
03	ANTIDIARRHEALS
04	ANTISPASMODIC-ANTICHOLINERGICS
05	BILE THERAPY
06	LAXATIVES
07	ATARACTICS-TRANQUILIZERS
08	MUSCLE RELAXANTS
09	ANTIPARKINSON
10	CNS STIMULANTS
11	PSYCHOSTIMULANTS-ANTIDEPRESSAN
12	AMPHETAMINE PREPARATIONS
13	ALL OTHER ANTI OBESITY PREPS
14	ANTI HISTAMINES
15	BRONCHIAL DILATORS
16	COUGH PREPARATIONS/EXPECTORANT
17	COLD AND COUGH PREPARATIONS
18	ADRENERGICS
19	TOPICAL NASAL AND OTIC PREPARA
20	OPHTHALMIC PREPARATIONS
21	TETRACYCLINES
22	PENICILLINS
23	STREPTOMYCINS
24	SULFONAMIDES
25	ERYTHROMYCINS
26	CEPHALOSPORINS
27	OTHER ANTIBIOTICS
28	URINARY ANTIBACTERIALS
29	CHLORAMPHENICOL
30	ANTINEOPLASTICS
31	ANTIPARASITICS
32	ANTIMALARIALS
33	ANTIVIRALS
34	TB PREPARATIONS
35	TRIMETHOPRIM
36	CONTRACEPTIVES, NON-SYSTEMIC
37	VAGINAL CLEANSERS
38	GENERAL ANTIBACTERIALS AND ANT
39	DIAGNOSTICS

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