MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

January 31, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES *Casey Angres* Casey Angres (Feb 22, 2023 09:22 PST)
MANAGER OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on October 20, 2022, by the Drug Utilization Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria for Vivjoa® (oteseconazole) within the Anti-Fungal Agents section; addition of new prior authorization criteria for Voquenza® Dual Pak® (Vonoprazan and amoxicillin), and Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin) within the new Qualified Infection Disease Product section; addition of new prior authorization criteria for Livtencity® (maribravir) in the Antivirals section; addition of new prior authorization criteria for Cuvrior® (trientine tetrahydrochloride) within the new Copper Chelator section; addition of new prior authorization criteria for Pyrukynd® (mitapivat) within the new Pyruvate Kinase Activators section; revisions to the existing Provigil® (modafinil) and Nuvigil® (armodafinil) for the treatment of Obtructive Sleep Apnea (OSA) within the Narcolepsy Agents section; addition of new prior authorization criteria for Kynmobi® (apomorphine) in the new Anti-Parkinson's Agents section; addition of new prior authorization criteria for Amvuttra® (Vutrisiran) within the new Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B) section; revisions to the existing immunomodulator drugs criteria; revision to the existing Topical Androgens and Gender Edits, which include the addition of new prior authorization for Oral testosterone products within the Hormones and Hormones Modifiers section; addition of new prior authorization for Oxervate® (cenegermin-bkbj) within the new Ophthalmic Human Nerve Growth Factor (Q25) section.

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

These changes are effective February 6, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section B	**Pyruvate Kinase Activators**	Added new prior authorization criteria for Pyrukynd® (mitapivat).
Appendix A Section I	**Anti-Fungal Agents**	Added new prior authorization criteria for Vivjoa® (oteseconazole).
Appendix A Section L	**Immunomodulator Drugs**	Updated existing immunomodulator drugs clinical criteria to requiring drugs to be prescribed for an FDA-approved indication or justification for off-label use. Removed Section L(1)(d)(4).
Appendix A Section DD	**Hormones and Hormone Modifiers**	Revised existing clinical criteria for Topical Androgens to include indication for gender dysphoria. Added new clinical criteria for oral testosterone products.
Appendix A Section AAA	**Narcolepsy Agents**	Updated existing clinical criteria to include diagnosis for Obstructive Sleep Apnea (OSA).
Appendix A Section LLL	**Qualified Infection Disease Product**	Added new prior authorization criteria for Voquenza® Dual Pak® (Vonoprazan and amoxicillin) Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin).
Appendix A Section RRR	**Antivirals**	Added new prior authorization criteria for Livtencity® (maribravir).
Appendix A Section SSS	**Anti-Parkinson's Agents**	Revised the existing clinical criteria for Xadago® (safinamide). Added Kynmobi® (apomorphine). Updated section title to Anti-Parkinson's Agents.
Appendix A Section VVV	**Copper Chelator Section**	Added new prior authorization criteria for Cuvrior® (trientine tetrahydrochloride).
Appendix A Section CCCC	**Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B)**	Added new prior authorization criteria for Amvuttra® (vutrisiran).

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section DDDD	**Oxervate**	Added new clinical criteria for Oxervate® in the newly added Ophthalmic Human Nerve Growth Factor Section.
Appendix B Section 2C	**Gender Edits**	Updated existing clinical criteria for Gender Edits Section.

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL
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PRESCRIBED DRUGS

1200 INTRODUCTION

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

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

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

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

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

1201 AUTHORITY

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

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

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

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

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

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

1. develop a list of preferred prescription drugs;

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

3. create the Pharmacy and Therapeutics Committee.

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

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

1202 RESERVED

1203 POLICY

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

1203.1 COVERAGE AND LIMITATIONS

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

1. Section 1927(d)(1)(B)(i) of the SSA allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug, which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:

   a. American Hospital Formulary Service Drug Information;

   b. United States Pharmacopeia;

   c. DRUGDEX Information System; or

   d. Peer-reviewed medical literature.

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

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

4. The Preferred Drug List (PDL) is a list of preferred outpatient drugs established by the Silver State Scripts Board (formerly known as the Pharmacy and Therapeutics (P&T) Committee). Reference Medicaid Operations Manual (MOM) Chapter 200 for the Silver State Scripts Board bylaws. Pharmaceuticals not on the PDL, but within drug classes reviewed by the Silver State Scripts Board, require prior

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

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

b. New Food and Drug Administration (FDA) approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the PDL and are not excluded under state plan or by NRS, are covered with an approved Standard Preferred Drug List Exception prior authorization until the Silver State Scripts Board can review the new evidence or drug.

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

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

B. Standard Preferred Drug List Exception Criteria

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

1. Coverage and Limitations

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

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

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

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

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

f. An indication which is unique to a non-preferred agent, and is supported by

peer-reviewed literature or a FDA-approved indication;

g. Psychotropic, Antidepressant Medication – Continuity of Care;

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

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

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

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight loss.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

5. Drug Efficacy Study Implementation (DESI) list "Less than Effective Drugs": In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is identical, related or similar to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the Medicaid Drug Rebate Program. This listing is available on the Centers for Medicare and Medicaid Services (CMS) website at: http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp

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

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

7. Agents used for impotence/erectile dysfunction.

D. Refills

A refill is a prescription subject to the limitations below:

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

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

E. Early Refills

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

2. In areas for which an emergency or disaster has been declared, Medicaid will waive the requirement for 80% of a non-controlled substance prescription to be used before paying for refills. Prescriptions for non-controlled substances will be covered up to 30 days after the declaration or until the end of the emergency or disaster, whichever is later.

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

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

F. Maintenance Medications

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

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

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

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

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

   a. Antianginals;

   b. Antiarrhythmics;

   c. Antidiabetics;

   d. Antihypertensives;

   e. Cardiac Glycosides;

   f. Diuretics;

   g. Estrogens; and

   h. Progesterone.

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

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

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

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

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

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

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

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

G. Emergency supply of medication

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

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

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

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

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

H. Nevada Check Up (NCU)

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

I. Vaccines

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

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

2. Adult vaccines: Adult vaccines such as tetanus, flu vaccine and pneumococcal vaccine are covered without prior authorization. For a list of covered adult vaccines, please reference the Physician's Fee Schedule at: http://dhcfp.nv.gov/Resources/Rates/FeeSchedules/

3. Human Papillomavirus (HPV) Vaccine: The 9-valent HPV vaccine (for both males and females) is covered for Medicaid eligible recipients ages nine years through 45 years, based on the US FDA approved indications. These may be accessed by following the link: https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil. The HPV vaccines are available through the State Division of Public and Behavioral Health (DPBH) as part of the Vaccines for Children (VFC) program for eligible females and males age nine through 18 years. Please refer to MSM Chapter 1500 for more information on the VFC program.

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

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

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

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

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

J. Pharmacist Submitted Prior Authorizations

1. The DHCFP will allow pharmacists to submit a prior authorization if:

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

K. Dispensing Practitioners:

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

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

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

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

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

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

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

1203.1A PROVIDER RESPONSIBILITY

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

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

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

2. Utilization Control

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

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

1. Pro-DUR edits apply to POS claims.

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

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

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

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

b. Retro Drug Utilization Review (DUR)

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

c. Drug Utilization Review (DUR)

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

d. Eligibility

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

e. Pharmacy Lock-In Program

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

1. Pharmacy Lock-In Criteria.

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

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

2. One of the following:

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

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

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

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

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

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

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

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

2. Duration of Lock-In Status.

   a. Initially, a recipient remains in lock-in status for period lasting 36 months. Utilizing the pharmacy lock-in criteria, the DHCFP

conducts a clinical review not less than a month prior the 36-month mark to determine whether the recipient will remain or may be removed from lock-in status.

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

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

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

3. Pharmacy Lock-In Exemption

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

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

2. The locked-in pharmacy is closed.

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

3. Generic Substitution

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

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

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

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

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

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

4. Prescriber Brand Certification

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

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

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

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

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

d. A prior authorization is required to override genetic substitution.

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

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

1203.1B SERVICE DELIVERY MODEL

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

1. Institutional settings

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

   b. Long Term Care (LTC)

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

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

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

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

2. Outpatient Pharmaceuticals

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

      1. Retail pharmacies (billed through POS).

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

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

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

3. COD(s) administered in an outpatient setting, such as a physician's office (NVPAD).

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

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

4. Hospital based outpatient clinics.

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

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

5. End Stage Renal Disease (ESRD) Facilities.

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

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

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

6. Emergency Rooms.

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

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

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

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

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

3. Disposable Medical Supplies

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

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

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

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

5. Coordination of Benefits (COB)

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

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

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

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

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

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

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

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

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

6. Pharmacy Billing Process

a. NCPDP Standard Billing Units

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

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

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

PLEASE NOTE:

Ounces must be converted to ml (1 ounce = 30ml).
Liters must be converted to ml (1L = 1000ml).
Ointments, Bulk Powders: must be billed by grams. For example, if a two ounce tube of oxiconazole nitrate is dispensed, the quantity entered will be 60.

PLEASE NOTE:

Ounces must be converted to grams (1 ounce = 30g, ½ ounce = 15g). Oral Contraceptives/Therapy packs: must be billed per "each" tablet dispensed, not the

number of packages. For example, Ortho Tri-Cyclen is a 28-day dial pack, the quantity entered will be 28.

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

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

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

PLEASE NOTE: Ounces must be converted to grams or ml.

1 ounce = 30ml
1 ounce = 30g

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

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

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

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

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

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

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

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

b. Provider Numbers

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

7. State Maximum Allowable Cost (SMAC)

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

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

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

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

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

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

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

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

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

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

   b. Make changes to the SMAC pricing file.

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

1203.1C PRIOR AUTHORIZATION PROCEDURES

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

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

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

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

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

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

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

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

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

1203.2 INTRAVENOUS (IV) THERAPY

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

A. Billing Guidelines

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

B. Long Term Care (LTC)

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

a. Non-Billable Items

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

b. Billable Items

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

1204 HEARINGS

Please reference MSM Chapter 3100 for the Medicaid Hearings process.

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

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

A. Proton Pump Inhibitors (PPIs)

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

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

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

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

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

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

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

c. Prior Authorization Guidelines

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

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

B. Pyrukynd® (mitapivat)

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

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

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

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

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

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

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

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

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

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

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

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

2. Recertification Request:

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

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

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

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

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

c. Recertification will be approved for six months.

3. Prior authorization guidelines:

a. Prior authorization will be approved for six months.

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

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

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

1. Coverage and Limitations

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

a. General Criteria (Children and Adults)

1. A diagnosis of ADD/ADHD or other FDA approved diagnosis.

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

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

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

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

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

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

2. Exception Criteria

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

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

2. The medication is prescribed by a psychiatrist; and

3. An ICD code for ADD with or without hyperactivity is documented on the prescription and transmitted on the claim.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

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

D. Growth Hormones
Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 28, 2022

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

1. Coverage and Limitations

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

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

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

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

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

The recipient must then meet one of the following:

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

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

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

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

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

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

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

   And recipient must meet one of the following:

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

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

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

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

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

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

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

structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation); and
The recipient must then meet one of the following:

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

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

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

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

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

   b. The recipient's epiphyses are open; and

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

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

   e. The recipient has not undergone a renal transplant.

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

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

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

5. Prior Authorization Guidelines

a. Initial prior authorization will be for six months.

b. Recertification approval will be for 12 months.

b. Serostim® (somatropin)

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

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

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

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

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

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

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

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

c. Zorbtive® (somatropin)

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

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

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

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

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

2. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification request will be approved for 12 months.

d. Somavert® (pegvisomant)

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

a. The recipient has a diagnosis of acromegaly; and

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

c. One of the following:

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

a. Surgery; or

b. Radiation Therapy; or

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

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

a. Surgery; and

b. Radiation Therapy; and

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

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

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

2. Recertification Criteria:

a. The recipient must meet the following:

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

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 weeks.

b. Recertification approval will be approved for 12 months.

e. Skytrofa® (Lonapegsomatropin-tcgd)

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

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

b. Recipient's weight is greater than 11.5kg; and

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

d. Recipient has short stature as defined by height that is greater than or equal to two standard deviations below the mean for chronological age; and

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

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

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

2. Recertification Criteria:

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

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

1. Improvement in height; or

2. Improvement in growth velocity.

3. Prior Authorization Guidelines:

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

E. Over-the-Counter (OTC Drugs)

Last Reviewed by the DUR Board: N/A

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

1. Coverage and Limitations

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

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

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

   d. Insulin is exempt from any prior authorization and OTC MAC limits.

2. Prior Authorization Guidelines:

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

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

F. Transdermal Fentanyl

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

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

1. Coverage and Limitations

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

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

b. Patient requires continuous opioid administration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Prior Authorization Guidelines

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

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

G. Immediate-Release Fentanyl Products

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

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

1. Coverage and Limitations

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

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

2. The recipient must meet all the following:

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

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

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

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

b. Recertification Criteria:

1. Documentation of disease improvement and/or stabilization.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for six months.

H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)
Last Reviewed by the DUR Board: October 17, 2019

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

1. Coverage and Limitations

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

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

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

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

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

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

         c. Treatment of anemia secondary to ESRD. Hb levels should not exceed 11 g/dL if on dialysis or 10 g/dL if not on dialysis.

   d. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) 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.

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

3. Prior Authorization Guidelines

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

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

I. Anti-Fungal Agents

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

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

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

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

      1. Diagnosis of onychomycosis; and

      2. At least one of the following:

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

         b. The recipient has diabetes; or

         c. The recipient has significant peripheral vascular compromise; or

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

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

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

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

2. Oral Agents (Sporanox®, Lamisil®)

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

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

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

   b. Prior Authorization Guidelines

      1. Prior authorization will be approved for 48 weeks.

3. Brexafemme® (ibrexafungerp)

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

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

2. Diagnosis of vulvovaginal candidiasis (VVC); and

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

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

5. Quantity Limit is four tablets.

b. Recertification Request:

1. Coverage is not renewable.

c. Prior Authorization Guidelines:

1. Prior Authorization will be for one day.

4. Vivjoa® (oteseconazole)

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

1. Recipient has a diagnosis of recurrent vulvoginal candidiasis with greater than or equal to three episodes of vulvovaginal candidiasis (VVC) in a 12-month period; and

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

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

4. Recipient is not pregnant; and

5. Recipient is not lactating; and

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

7. Quantity limit is 18 tablets per treatment course.

b. Recertification Request:

1. Coverage is not renewable.

c. Prior Authorization Guidelines:

1. Prior Authorization will be for 12 weeks.

J. Benlysta® (belimumab)

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

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

1. Coverage and Limitations

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

a. Initial request:

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

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

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

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

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

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

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

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

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approvals will be for:

1. Initial request: six months.

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

K. Spinal Muscular Atrophy (SMA) Agents

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

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

1. Evrysdi® (risdiplam)

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

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

      2. Both the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. One of the following:

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

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

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

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

a. One of the following HINE-2 milestones:

1. Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick; or

2. Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp; or

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

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

b. One of the following HFMSE milestones:

1. Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline; or

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

c. One of the following ULM test milestones:

1. Improvement or maintenance of a previous improvement of at least a 2-point increase in score from pretreatment baseline; or

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

d. One of the following CHOP INTEND milestones:

1. Improvement or maintenance of a previous improvement of at least a 4-point increase in score from pretreatment baseline; or

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

e. One of the following MFM-32 milestones:

1. Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline; or

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

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

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

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

5. One of the following:

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

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for 12 months.

2. Recertification request will be approved for 12 months.

2. Spinraza® (nusinersen)

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

1. Initial request:

a. The recipient has a diagnosis of SMA, and

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

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

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

b. The recipient is maintaining neurological status; and

c. The recipient is tolerating therapy; and

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

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

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

3. The recipient is maintaining neurological status; and

4. The recipient is tolerating therapy; and

3. Prior Authorization Guidelines

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

3. Zolgensma ® (onasemnogene abeparvovec-xioi)

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

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

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

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

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

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

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

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

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

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

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

b. Prior Authorization Guidelines

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

L. Immunomodulator Drugs

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

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

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

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

   a. For all recipients:

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

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

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

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

      5. Each request meets the appropriate diagnosis-specific criteria (b-j).

   b. Rheumatoid Arthritis (RA):

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

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

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

         a. The recipient has had RA for less than six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

hydroxychloroquine, leflunomide, minocycline and sulfasalazine); or

b. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has moderate disease activity and has an inadequate response to a DMARD (methotrexate, hydroxychloroquine, leflunomide, minocycline or sulfasalazine); or

c. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has high disease activity.

c. Psoriatic Arthritis:

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

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

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

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

d. Ankylosing Spondylitis:

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

2. The recipient is 18 years or older; and

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

e. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

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

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

a. Abatacept: Six years of age or older.

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

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

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

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

f. Plaque Psoriasis:

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

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

3. The agent is prescribed by a dermatologist; and

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

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

g. Crohn's Disease:

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

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

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

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

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

2. The recipient has fistulizing Crohn's Disease.

h. Ulcerative Colitis (UC):

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

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

a. Infliximab: Six years of age or older.

b. Humira: five years of age or older.

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

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

a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

4. Zeposia® (ozanimod) for diagnosis of UC

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

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

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

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

a. 6-mercaptopurine

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

c. Sulfasalzine

d. Azathioprine

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

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

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

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

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

a. Canakinumab: Four years of age or older.

b. Rilonacept: 12 years of age or older.

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

1. The recipient has a diagnosis of NOMID.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

M. Topical Immunomodulators

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

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

1. Coverage and Limitations

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

      1. Patient has a documented diagnosis of Atopic Dermatitis:

         a. Elidel® for mild to moderate, for ages greater than or equal to two years.

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

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

         d. Protopic® 0.1%; moderate to severe, for ages greater than or equal to 16 years.

      2. The agent is not for chronic use.

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

      4. Not recommended for use in immunocompromised patients.

2. Opzelura® (ruxolitinib)

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

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

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

      3. The medication will not be used chronically; and

      4. Recipient is not immunocompromised; and

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

    a. Prescription topical corticosteroids.

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

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

b. Recertification Request:

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

c. Prior Authorization Guidelines

    1. Prior authorization will be approved within 12 months.

N. Psychotropic Medications for Children and Adolescents

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

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

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

1. Coverage and Limitations

The DHCFP requires prior authorization approval for children and adolescents for the psychotropic therapeutic classes below and medication combinations considered to be polypharmacy. The DHCFP has adopted the following practice standards to strengthen treatment outcomes for our children and adolescents.

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

1. Antipsychotics

2. Antidepressants

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

4. Sedative hypnotics

5. Antianxiety agents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a prior authorization approval

and must be utilized for a medically accepted indication as established by the FDA and/or peer-reviewed literature.

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

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

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

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

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

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

3. Prior Authorization Guidelines

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

O. Lidoderm 5% Patches®

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

1. Coverage and Limitations

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

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: April 28, 2022

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

1. Coverage and Limitations

a. Xolair® (Omalizumab)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   e. One of the following:

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

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

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

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

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

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

      1. Allergist/Immunologist; or

      2. Dermatologist; or

      3. Rheumatologist; and

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

d. One of the following:

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

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

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

4. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

Table 1: Dosing for Xolair® (omalizumab)*

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

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

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

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

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

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

1. Mepolizumab: six years of age or older;

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

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

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

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

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks.

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

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

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

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

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

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

1. Baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter; or

2. Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months; and

c. One of the following:

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

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

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

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

1. Both the following:

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

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

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

e. The recipient age is greater than or equal to six years; and

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

1. Pulmonologist; or

2. Allergist/Immunologist

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

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

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

1. Both the following:

a. ICS; and

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

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

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

1. Pulmonologist; or

2. Allergist/Immunologist

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

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

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

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

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

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

c. The recipient is currently receiving corticosteroid therapy; and

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

1. Pulmonologist; or

2. Rheumatologist; or

3. Allergist/Immunologist.

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

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

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification request will be approved 12 months.

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

e. Fasenra® (benralizumab)

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

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

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

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

d. One of the following:

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

2. Any prior intubation for an asthma exacerbation; or

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

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

1. Both a high-dose ICS (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

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

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

1. Pulmonologist; or

2. Allergy/Immunology specialist.

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

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

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

1. Both an ICS (5,E) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

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

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

1. Pulmonologist; or

2. Allergy/Immunology specialist.

3. Prior Authorization Guidelines:

a. Initial prior authorization will be for 12 months.

b. Recertification request will be for 12 months.

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

f. Dupixent® (dupilumab)

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

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

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

2. One of the following:

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

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

1. Elidel® (pimecromulus) topical cream; or

2. Tacrolimus topical ointment; or

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

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

2. One of the following:

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

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

2. Any prior intubation for an asthma exacerbation.

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

b. All the following:

1. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter; and

2. The recipient has one of the following:

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

b. Any prior intubation for an asthma exacerbation.

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

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

a. Both a high-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

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

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

c. Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) and all the following:

1. Unless contraindicated, the recipient has had an inadequate response to two months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [Document drugs(s), dose, duration, and date of trial]; and

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

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

2. Recertification Request:

   a. Diagnosis of moderate to severe atopic dermatitis and all the following:

      1. Documentation of positive clinical response to Dupixent therapy
      2. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

         a. Both an ICS and additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

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

         c. Prescribed by or in consultation with a pulmonologist or Allergy/immunology specialist.

3. Prior Authorization Guidelines:

   a. Initial prior authorization will be for 12 months.

   b. Recertification request will be for 12 months.

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

Q. Long-Acting Narcotics

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by DUR Board: April 28, 2016

Long-Acting Narcotics are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

The current criteria for the use of fentanyl transdermal patches (Appendix A, (F.)) or oxycodone/acetaminophen ER tablets (Appendix A, (XX.)) is to be met.

For all other long-acting narcotics requests that exceed the quantity limit, the following criteria must be met and documented:

a. The recipient has a diagnosis of terminal cancer; or

b. All the following criteria must be met:

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

2. The requested agent will be used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment; and

3. There is documentation in the recipient's medical record that alternative agents (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain.

2. Prior Authorization Guidelines

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

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

R. Toradol® (ketorolac tromethamine) tablets

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

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

1. Ketorolac is indicated for the short-term (up to five days) management of moderately severe acute pain that requires analgesia at the opioid level. It is not indicated for minor or chronic painful conditions. The following criteria must be met:

   a. Oral treatment must be indicated only as continuation therapy to IV/IM therapy; and

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

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

2. Prior Authorization Guidelines

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

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

S. Anti-Migraine Medications

Therapeutic Class: Serotonin 5-HT1 receptor agonists (triptans)
Last Reviewed by the DUR Board: July 25, 2019

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: January 27, 2022

Therapeutic Class: Ergot Derivatives
Last Reviewed by the DUR Board: July 28, 2022

Serotonin 5-HT1 receptor agonists commonly referred to as "triptans", CGRP Receptor Inhibitor medications and Ergot Derivatives or anti-migraine medications are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Serotonin 5-HT1 Receptor Agonists (triptans)

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

      1. The recipient's current medication history documents the use of prophylactic medications for migraine headache, or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or

      2. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.

         a. Recipient's current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).

         b. Recipients whose current medication history indicates the use of propranolol will NOT be granted prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.

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

   b. Prior Authorization Guidelines:

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

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

2. Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications

a. CGRP General Criteria

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

a. The recipient must have one of the following:

1. Both the following:

a. The recipient has a diagnosis of episodic migraines; and

b. The recipient has four to 14 migraine days per month, but not more than 14 headache days per month: or (for Nurtec® requests, the recipient does not have more than 18 headache days per month); or

2. All the following:

a. The recipient has a diagnosis of chronic migraines; and

b. The recipient has greater than or equal to 15 headache days per month, of which at least eight must be migraine days for at least three months; and

c. The recipient has been considered for medication overuse headache (MOH) and potentially offending medication(s) have been discontinued; and

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

c. The recipient has a documented history of failure (after at least a two-month trial) or an intolerance/contraindication to at least one medication from two of the following categories:

1. Evail (amitriptyline) or Effexor (venlafaxine)

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

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

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

2. Recertification Request:

a. The recipient must have a documented positive response to CGRP therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The recipient has had a decrease in use of acute migraine medications (e.g., NSAIDs, triptans) since the start of CGRP therapy; and

c. For chronic migraine only: The recipient continues to be monitored for MOH.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

b. CGRPs for Acute Migraines:

1. Ubrelvy® (ubrogepant), Nurtec® ODT (rimegepant).

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

1. Recipient must have a diagnosis of acute migraine with or without aura; and

2. Recipient is 18 years of age or older; and

3. The prescribed dose will not exceed two doses per migraine and treating no more than eight migraine episodes per 30 days; and

4. The recipient has had at least one trial and failure of a triptan agent; and

5. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

b. Recertification Request:

1. The recipient must have a documented positive response to the CGRP therapy; and

2. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

2. CGRPs for Episodic Cluster Headache

a. Emgality® (galcanezumab-gnlm)

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

a. The recipient has a diagnosis of episodic cluster headache; and

b. The recipient has experienced at least two cluster periods lasting from seven days to 365 days, separated by pain-free periods lasting at least three months.

c. The recipient is 18 years of age or older.

d. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

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

2. Recertification Request:

a. The recipient has documented positive response to Emgality® therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

3. Prior Authorization Guidelines:

a. Initial request will be approved for three months.

b. Recertification request will be approved for 12 months.

3. CGRP's Antagonists for Episodic Migraines

a. Nurtec® ODT (rimegepant).

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

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

b. The recipient has a documented diagnosis of episodic migraines, having 4-18 migraine days per month but not more than 18 headache days per month; and

c. Two of the following:

1. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or has a contraindication to both Elavil® (amitriptyline) and Effexor ® (venlafaxine); or

2. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Depakote/Depakote ER (divalproex) or Topamax (topiramate); or has a contraindication to both Depakote/Depakote ER (divalproex) and Topamax (topiramate); or

3. The recipient has a history of failure (after at least a two-month trial) or intolerance to one of the following beta blockers:

a. Atenolol; or

b. Propranolol; or

c. Nadolol; or

d. Timolol; or

e. Metroprolol; and

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

2. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

4. Ergot Derivatives

a. Brand D.H.E. 45 (dihydroergotamine mesylate) injection, Generic dihydroergotamine mesylate injection, Brand Migranal nasal spray, or Generic dihydroergotamine mesylate nasal spray or Trudhesa®.

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

a. The recipient has a diagnosis of headahces with or without aura; and

b. The medication will be used for the acute treatment of migraine; and

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

d. One of the following:

1. The recipient has tried and failed or has intolerance to two triptants (e.g., eletriptan, rizatriptan, sumatriptan); or

2. The recipient has contraindication to all triptans; and

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

f. If the recipient has more than four headache days per month, they must meet at least one of the following:

1. The recipient is currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications; or

2. The recipient is currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a

contraindication or intolerance to these medications; or

3. The recipient is currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications; and

2. Recertification Request:

a. The recipient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for three months.

b. Recertication requests will be approved for 12 months.

b. Brand D.H.E. 45 injection or Generic dihydroergotamine mesylate injection

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

a. The recipient has a diagnosis of cluster headache; and

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

c. The recipient has had a trial and failure, contraindication, or intolerance to sumatriptain injection; and

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

2. Recertification Request:

   a. The recipient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and

   b. The medication is prescrived by or in consulation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification requests will be approved for three months.

T. Tobacco Cessation Products

Therapeutic Class: Tobacco Cessation Agents
Last Reviewed by the DUR Board: April 30, 2020

Smoking cessation products, including patches, gums, lozenges and inhalers (based on the recipients' route of choice), are subject to quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

U. Short-Acting Bronchodilators

Therapeutic Class: Beta Adrenergic Agents
Last Reviewed by the DUR Board: January 24, 2019

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

1. This criteria applies to, but is not limited to, the following list:

Proventil® HFA	ProAir® HFA	ProAir RespiClick®
Ventolin® HFA	Albuterol Nebulizer	Nebulizer Solution

a. Coverage and Limitations

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

1. Quantity Limits:

a. Albuterol Metered Dose Inhalers (MDI): two units per month.

b. Albuterol Nebulizer Solution: three bottles of 20ml each or 125 nebulizer units per month.

2. In order to exceed the quantity limit, a recipient must meet all of the following:

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

b. The recipient has been assessed for causes of asthma and external triggers have been removed or reduced where possible.

3. For recipients 18 years of age or younger the following criteria must be met:

a. The recipient has a diagnosis of asthma; and

b. The recipient requires an additional inhaler unit for school or equivalent program.

b. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

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

2. Xopenex®

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

1. Authorization only for recipients experiencing side effects on one other beta-adrenergic agent of any formulation.

2. Authorization for patients whose cardiovascular status is considered to be in severe deteriorating condition.

b. Prior Authorization Guidelines

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

V. Anti-Insomnia Agents (Sedative Hypnotics)

Therapeutic Class: Anxiolytics, Sedatives and Hypnotics
Last Reviewed by the DUR Board: September 3, 2015

See Section N of this Appendix for criteria for Sedatives and Hypnotics when prescribed for a psychotropic indication.

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

1. Coverage and Limitations

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

   a. An FDA approved ICD diagnosis code, such as insomnia, is documented on the prescription and transmitted on the claim; or

   b. A PA with an FDA approved diagnosis, such as insomnia, is submitted.

2. Prior Authorization Guidelines

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

W. Doxepin Topical

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

Doxepin Topical is subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for billing information.

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

   a. The recipient has a documented diagnosis of pruritus with atopic dermatitis or lichen simplex chronicus; and

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

   c. Treatment must not exceed eight days.

2. Prior Authorization Guidelines:

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

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

X. Antiemetics

Therapeutic Class: Antiemetics, (Serotonin Receptor Antagonists (5 HT3 Antiemetics))
Last Reviewed by the DUR Board: October 28, 2010
Therapeutic Class: Antiemetic (Cannabinoid Antiemetics)
Last Reviewed by DUR Board: October 18, 2018

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

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

Serotonin Receptor Antagonists (5 HT3 Antiemetics)

1. Coverage and Limitations

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

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

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

   d. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.

2. Prior Authorization Guidelines

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

Cannabinoid Antiemetics

1. Coverage and Limitations

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

   a. Nabilone

      1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

2. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

b. Dronabinol

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

c. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or

2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and the recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

a. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

Y. Synagis® (palivizumaub)

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

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

For consideration outside these guidelines, a prior authorization may also be submitted with supporting medical necessity documentation.

1. Coverage and Limitations

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

a. Recipients younger than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season, must meet one of the following criteria:

1. The recipient was born at 28 weeks, six days of gestation or earlier; or

2. The recipient has a diagnosis of chronic lung disease (CLD) of prematurity; or

3. The recipient has hemodynamically significant congenital heart disease; or

4. The recipient has congenital abnormalities of the airways or neuromuscular disease; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has clinical evidence of CLD and/or nutritional compromise.

b. Recipients younger than two years of age at the start of RSV season must meet one of the following criteria:

1. The recipient has a diagnosis of CLD of prematurity; and

a. The recipient has required medical therapy (e.g., bronchodilator, diuretics, oxygen, coritcosteroids) within six months to the start of RSV season; or

2. The recipient has had a cardiac transplant; or

3. The recipient is severely immunocompromised (solid organ or hematopoietic stem cell transplant, chemotherapy or other conditions) during the RSV season; or

4. The recipient has had a cardiopulmonary bypass and continues to require prophylaxis after surgery or at the conclusion of extracorporeal membrane oxygenation; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has had manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable) or weight for length less than the tenth percentile.

2. Prior Authorization Guidelines

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

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

Z. Opioids, Opioid Containing Cough Preparations, Opioids Prescribed to Under Age 18

Therapeutic Class: Opioids, Last reviewed by the DUR Board: July 26, 2018
Opioid Containing Cough Preparations Last reviewed by the DUR Board: July 26, 2018
Opoids Prescribed to Under Age 18: Last Reviewed by the DUR Board: October 18, 2018

Opioids, Opioid Containing Cough Preparations and Opioids Prescribed to Under Age 18 are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Opioids

1. Coverage and Limitations

   a. Opioids will be covered without prior authorization:

      1. For initial prescriptions of seven days or less; and

      2. For a total of 13 seven-day prescriptions in any rolling 12-month period; and

      3. For prescriptions of 60 mg morphine equivalents or less per day.

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

   c. Prior Authorization Criteria: To exceed the number of seven-day prescriptions, or to exceed the seven-day limit, or to exceed the 60 mg morphine equivalents or less per day:

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

         a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and

         b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.); and

         c. The lowest effective dose is being requested; and

         d. A pain contract is on file.

   d. Exceptions to this policy:

      1. Recipients with cancer/malignancy related pain; or

2. Recipients who are post-surgery with an anticipated prolonged recovery (greater than three months); or

3. Recipients receiving palliative care; or

4. Recipients residing in a long-term care facility; or

5. Recipients receiving treatment for HIV/AIDS; or

6. Prescriptions written by or in consultation with a pain specialist.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

3. CDC Guidance:

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

4. Opioid Containing Cough Preparations

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

b. Prior authorization approval will be for six months.

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

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

5. Opioids Prescribed to Under Age 18

a. Short Acting Opioids will be covered without PA for:

1. Initial prescription of three days or less; and

2. A total of 13 three-day prescriptions in any rolling 12-month period; and

3. Prescriptions of 60 morphine milligram equivalents (MME) or less per day.

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

c. To exceed the number of three-day prescriptions, or to exceed the three-day limit, or to exceed the 60 MME or less per day:

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

a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and

b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, chiropractic treatment, etc.); and

c. The lowest effective dose is being prescribed; and

d. A pain contract is on file.

d. Exceptions:

1. Recipients with cancer/malignancy related pain, recipients who are post-surgery with an anticipated prolonged recovery (greater than three months), recipients residing in a long-term care facility, recipients receiving treatment for HIV/AIDS, hospice, palliative care or end-of-life care.

2. Prescriptions written by or in consultation with a pain specialist.

e. Prior Authorization Guidelines

1. Prior authorization approval will be for three months.

f. Prescribing Guidance:

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

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

AA. Savella® (milnacipran)

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

Savella® (milnacipran) is subject to prior authorization.

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

    a. The recipient has a diagnosis of Fibromyalgia:

        1. If an ICD code for Myalgia and Myositis unspecified is documented on the prescription; or

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

2. Prior Authorization Guidelines:

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

BB. Substance Abuse Agents

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: July 23, 2020

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

1. Coverage and Limitations

a. Buprenorphine/Naloxone and Buprenorphine

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

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

b. Requires diagnosis of opioid dependence.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

b. Lucemyra™ (lofexidine)

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

a. The recipient has a diagnosis of opioid withdrawal with symptoms due to abrupt opioid discontinuation; and

b. The requested quantity must not exceed 2.88 mg/day for up to 14 days.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 14 days.

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

c. Vivitrol® (naltrexone)

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

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

b. The drug must be delivered directly to the prescriber's office; and

c. The drug is only to be administered once per month; and

d. Routine urine screening and monitoring is recommended.

2. Prior Authorization Guidelines

a. Prior authorization approvals will be for six months.

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

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: July 28, 2022

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

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

    a. The recipient has a diagnosis of MS.

2. Ampyra® (dalfampridine)

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

        1. The recipient must have a diagnosis of MS; and

        2. The medication is being used to improve the recipient's walking speed; and

        3. The medication is being prescribed by or in consultation with a neurologist; and

        4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and

        5. The recipient does not have moderate to severe renal dysfunction (CrCL less than 50 ml/min); and

        6. The recipient does not have a history of seizures; and

        7. The recipient is not currently pregnant or attempting to conceive.

    b. Prior Authorization Guidelines

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

        2. Request for continuation of therapy will be approved for one year.

3. Relapsing Forms of MS Agents:

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

        1. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses).

b. Lemtrada® (alemtuzumab)

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

a. The recipient must have a diagnosis of a relapsing form of MS; and one of the following:

1. Both the following:

a. The recipient has not been previously treated with alemtuzumab; and

b. The recipient has had failure after a trial of at least four weeks; a contraindication, or intolerance to two of the following disease-modifying therapies for MS:

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Mavenclad (cladrivine)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

c. Both the following:

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

b. The recipient has had at least 12 months elapsed or will have elapsed since the most recent treatment course with alemtuzumab; and

2. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

c. Mavenclad® (cladribine)

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

a. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and one of the following:

1. Both the following:

a. The recipient has not been previously treated with cladribine; and

b. The recipient has had failure after a trial of at least four weeks; contraindication, or intolerance to two of the following disease-modifying therapies for MS:

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone®/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Lemtrada® (alemtuzumab)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

2. Both the following:

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

b. The recipient has not already received the FDA-recommended lifetime limit of two treatment courses (or four treatment cycles total) of cladribine; and

b. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

d. Ocrevus® (ocrelizumab)

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

a. The recipient has a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 months.

b. Recertification approval will be for 12 months.

e. Zeposia® (ozanimod)

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

a. The recipient has a documented diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

a. Avonex® (interferon beta-1a)

b. Betaseron® (interferon beta-1b)

c. Copaxone®/Glatopa® (glatiramer acetate)

d. Tecfidera (dimethyl fumarate); and

c. The medication is prescribed by or in consultation with a neurologist.

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

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. The medication is prescribed by or in consultation with a neurologist.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

f. Ponvory® (ponesimod)

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

a. Recipient has a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease [RRMS]; active secondary progressive MS [SPMS]+, or clinically isolated syndrome [CIS]); and

b. Recipient will NOT be initiating therapy after previous treatment with alemtuzumab; and

c. Ponesimod will be prescribed by, or in consultation with, neurologist; and

d. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS;

a. Avonex® (interferon beta-1a); or

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

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

d. Tysabri® (natalizumab); or

e. Tefidera® (dimethyl fumarate); or

f. Aubagio® (teriflunomide); or

g. Gilenya® (fingolimod)

2. Recertification Request:

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. Ponesimod will be prescribed by, or in consultation with, neurologist.

3. Prior Authorization Guidelines:

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

4. Primary Progressive Forms of Multiple Sclerosis (PPMS) Agents:

a. Ocrevus® (ocrelizumab)

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

3. The medication must not be used in combination with another B-cell target therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

a. The medication must not be used with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

4. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

   b. Recertification approval will be for 12 months.

DD. Hormones and Hormone Modifiers

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

1. Topical Androgens

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

1. Recipient is male; and

2. The medication is used for FDA-approved indication:

a. Primary (congenital or acquired); or

b. Secondary (congenital or acquired) hypogonadism; and

3. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used; and

4. Recipient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) greater than 19; and

5. Recipient does not have a hematocrit greater than 50%; and

6. Recipient does not have untreated severe obstructive sleep apnea; and

7. Recipient does not have uncontrolled or poorly controlled heart failure.

b. Diagnosis of Gender Dysphoria:

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

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

2. Xyosted™ (testosterone enanthate)

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

1. Diagnosis of Hypogonadism (e.g., testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

2. The recipient is male at birth; and

3. One of the following:

a. Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab; or both of the following:

1. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV, liver disorder, diabetes, obesity); and

2. One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (<0.17 nmol/L) or less than the reference range for the lab; or

b. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism or a genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome).

b. Diagnosis of Gender Dysphoria

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

a. Recipient is using the hormones to changes in their physical Characteristics; and

b. Recipient is a female-to-male transsexual

c. Prior Authorization Guidelines:

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

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

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

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

3. Oral Testosterone Products

a. Hypogonadism:

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

a. The recipient is greater than 18 years of age; and

b. Recipient is male; and

c. Recipient has a diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); and

d. Recipient has history of failure, contraindication, or intolerance to both testosterone cypionate and testosterone enanthate injection; and

e. Recipient has signs/symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes); and

f. Recipient does not have "age-related hypogonadism' or another hypogonadal condition not associated with structural or genetic etiologies; and

g. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (initial approval only); and

h. Recipient is only receiving one androgen or anabolic agent; and

i. Recipient does not have current or history of breast cancer; and

j. Recipient does not have a hematocrit greater than 50%; and

k. Recipient does not have uncontrolled hypertension or heart failure; and

l. Recipient does not have uncontrolled obstructive sleep apnea; and

m. Medication is prescribed by or in consultation with an endocrinologist or urologist.

b. Diagnosis of Gender Dysphoria:

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

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

c. Recertification Request:

1. Recipient must continue to meet above criteria; and

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

d. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

EE. Colchicine (Colcrys®)

Therapeutic Class: Antigout Agents
Last Reviewed by the DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

a. Colchicine Tablets

1. The recipient has a diagnosis of acute gout (does not require prophylaxis) and the recipient must meet all of the following:

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

b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID (indomethacin, naproxen, ibuprofen, sulindac or ketoprofen); and

c. The recipient has had an inadequate response, adverse reaction or contraindication to a corticosteroid (oral or intra-articular).

2. For prophylaxis of chronic gout:

a. The recipient is 16 years of age or older and must meet one of the following:

1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or

2. There is documentation that the recipient will be treated with colchicine monotherapy and the recipient must meet all of the following:

a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).

3. For Familial Mediterranean Fever (FMF):

   a. The recipient is four years of age or older.

4. Requests exceeding the quantity limit may be approved for colchicine tablets if all of the following are met and documented:

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

   b. The recipient has a diagnosis of FMF; and

   c. The recipient's dose is ≤ 2.4 mg daily (120 tablets/30 days); and

   d. Medical necessity must be provided and documented in the recipient's medical record that the recipient had an inadequate response to 1.8 mg daily (90 tablets/30 days).

b. Colchicine Capsules

1. For Prophylaxis of chronic gout:

   a. The recipient is 18 years of age or older and the recipient must meet one of the following:

      1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or

      2. There is documentation that the recipient will be treated with colchicine monotherapy, and the recipient must meet all of the following:

         a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

         b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).2. Prior Authorization Guidelines

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

1. For FMF and chronic gout: one year.

2. For acute gout: two months.

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

FF. Thrombin Inhibitors

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

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

1. Coverage and Limitations

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

a. A diagnosis code associated with the FDA approved indication(s) is documented on the prescription and transmitted on the claim; and

b. There are no contraindications to prescribing this medication; or

c. An approved Prior Authorization documenting the recipient meeting all of the criteria above (1.) (a. and b.).

2. Prior Authorization Guidelines

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

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

GG. Antihemophilia Agents

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

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

1. Coverage and Limitations

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

a. The medication being prescribed must be for an FDA approved indication; or

b. One of the following:

1. The diagnosis is supported as a use of American Hospital Formulary Service Drug Information (AHFS DI); or

2. The diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “effective” or “evidence favors efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table); or

4. Diagnosis is supported in any other section of DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal; and

a. One of the following:

1. The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed

medical literature or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

a. AHFS Compendium;

b. Thomson Reuters (Healthcare) Micromedex/ DRUGDEX (not Drug Points) Compendium;

c. Elsevier Gold Standard's Clinical Pharmacology Compendium;

d. National Comprehensive Cancer Network Drugs and Biologics Compendium; and

c. The dispensing provider will monitor the amount of product a recipient has left to avoid over-stock; and

d. The prescriber is a specialist in treating hemophilia; and

e. A new prior authorization will be required for any dose adjustment in excess of 5% (increase or decrease).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

HH. Anti-Hepatitis Agents

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

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

1. Epclusa® (sofosbuvir and velpatasvir)

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

      1. The recipient is not receiving Epclusa® (sofosbuvir and velpatasvir) in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

         a. Hepatologist

         b. Gastroenterologist

         c. Infectious Disease Specialist

         d. HIV Specialist (certified through the American Academy of HIV Medicine)

   b. Genotype 1, 2, 3, 4, 5 or 6, without decompensated liver disease

      1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

      2. The recipient must not have decompensated liver disease; and

      3. Epclusa® must be used alone; and

      4. The request is FDA approved for recipient weight and age; and

      5. Prior authorization approval will be for 12 weeks.

   c. Genotype 1, 2, 3, 4, 5 or 6 with decompensated liver disease

      1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has decompensated liver disease; and

3. Epclusa® is being used in combination with Ribavirin; and

4. The request is FDA approved for recipient weight and age; and

5. Prior authorization approval will be for 24 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has decompensated liver disease; and

a. One of the following:

1. The recipient is Ribavirin intolerant or ineligible; or

2. Both of the following:

a. The recipient has had prior failure (defined as viral relapse, breakthrough while on therapy, or is a non-responder to therapy) to Sovaldi® or NS5A-based treatment; and

b. Epclusa® is used in combination with Ribavirin®.

3. Prior authorization approval will be for 24 weeks.

2. Harvoni® (ledipasvir/sofosbuvir)

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

1. The recipient is not receiving Harvoni® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is less than six million IU/mL

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

a. The recipient does not have cirrhosis; and

b. The recipient is treatment naïve; and

c. Medical records documenting pre-treatment HCV RNA less than six million IU/mL must be submitted; and

d. Prior authorization approval will be for eight weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. The recipient is treatment naïve; and

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

5. Prior authorization approval will be for 12 weeks.

d. Genotype 1, treatment naïve with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient is treatment naïve; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. One of the following:

a. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; or

b. Both of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) except in combination with Olysio® (simeprevir); and

2. The medication is used in combination with Ribavirin.

4. Prior authorization approval will be for 12 weeks.

f. Genotype 1, Ribavirin eligible, treatment experienced and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. Prior authorization approval will be for 12 weeks.

g. Genotype 1, Ribavirin ineligible, treatment experienced and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

4. The recipient is Ribavirin ineligible; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. Prior authorization approval will be for 24 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); or

b. Both of the following:

1. The recipient is a liver transplant recipient; and

2. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

3. The medication is used in combination with Ribavirin; and

4. Prior authorization approval will be for 12 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); and

3. One of the following:

   a. The recipient is Ribavirin ineligible; or

   b. Both of the following:

      1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

      2. The medication is used in combination with Ribavirin; and

4. Prior authorization approval will be for 24 weeks.

j. Genotype 4, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

   a. The recipient is treatment naïve; or

   b. One of the following:

      1. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and is without cirrhosis; or

      2. Both of the following:

         a. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and has compensated cirrhosis (Child-Pugh class A); and

         b. The medication is used in combination with Ribavirin.

3. Prior authorization approval will be for 12 weeks.

k. Genotype 5 or 6, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin; and

3. Prior authorization approval will be for 12 weeks.

3. Mavyret® (glecaprevir/pibrentasvir)

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

1. The recipient is not receiving Mavyret® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir)); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. Prior authorization approval will be for 12 weeks.

c. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient has compensated cirrhosis (Child-Pugh class A); and

4. Prior authorization approval will be for eight weeks.

d. Genotype 1, treatment experienced (prior failure to an NS3/4A protease inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced (prior failure to an NS5A inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 16 weeks.

f. Genotype 3, treatment experienced (interferon or Sovaldi® based regimen), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 16 weeks.

g. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without cirrhosis; and

5. Prior authorization approval will be for eight weeks.

h. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient has compensated cirrhosis (e.g., Child-Pugh class A); and

5. Prior authorization approval will be for 12 weeks.

4. Sovaldi® (sofosbuvir)

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1 or 4, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with peginterferon alfa and Ribavirin; and

3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

4. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

5. Prior authorization approval will be for 12 weeks.

c. Genotype 3, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

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

3. Both of the following:

a. The recipient has a documented diagnosis of chronic hepatitis C virus (HCV) genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is less than 12 years of age; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. Prior authorization approval will be for 24 weeks.

d. Genotype 2, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

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

3. Both of the following:

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is less than 12 years of age; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. Prior authorization approval will be for 12 weeks.

e. Genotype 1, without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. Prior authorization approval will be for 12 weeks.

f. Genotype 1, with cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient has cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. Prior authorization approval will be for 12 weeks.

g. Genotype 1

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin.

5. Prior authorization approval will be for 12 weeks.

h. Genotype 3

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has cirrhosis (compensated or decompensated) and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin.

5. Prior authorization approval will be for 12 weeks.

5. Viekira Pak® (ombitasvir, paritaprevir, ritonavir tablets, dasabuvir tablets)

a. Genotype 1a or Mixed Genotype 1 Infection without Cirrhosis and without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection; and

b. The recipient is without cirrhosis; and

c. The medication is used in combination with ribavirin; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hepatologist

2. Gastroenterologist

3. Infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir).

2. Prior Authorization Guidelines:

a. Prior authorization will be for 12 weeks.

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

b. Genotype 1a or Mixed Genotype Infection with Cirrhosis and without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection; and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient has cirrhosis; and

c. The medication is being used in combination with ribavirin; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hematologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

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

c. Genotype 1b without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1b; and

b. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

d. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

e. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

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

d. Genotype 1 (Regardless of Sub genotype) – Liver Transplant Recipient

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1; and

b. Documentation confirming the recipient is a liver transplant recipient; and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting the recipient's normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and

d. The medication is used in combination with ribavirin; and

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

1. Hepatologist

2. Gastroenterologist

3. infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

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

6. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

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

1. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

2. The recipient is not receiving Vosevi® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Zepatier® (elbasvir/grazoprevir)); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

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

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

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is a previous relapse to an NS5A based regimen (e.g., Daklinza® (daclatasvir), Epclusa® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Technivie® (ombitasvir/ paritaprevir/ ritonavir), Viekira® (ombitasvir/ paritaprevir/ ritonavir/dasabuvir), Zepatier® (elbasvir/grazoprevir); and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and

2. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

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

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

7. Zepatier® (elbasvir/grazoprevir)

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

1. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and

2. The recipient is not receiving Zepatier® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1a, treatment naïve, or PegIFN/RBV experienced, or PegIFN/RBV/protease inhibitor experienced, without NS5A polymorphisms

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

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

b. One of the following:

1. The recipient is treatment naïve; or

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

3. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir or telaprevir); and

c. Both of the following:

1. The recipient has been tested for the presence of NS5A resistance associated polymorphisms; and

2. The recipient has baseline NS5A resistance associated polymorphisms (e.g., polymorphisms at amino acid positions 28, 30, 31, or 93); and

d. The medication is used in combination with Ribavirin; and

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 16 weeks.

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

3. Genotype 1b, treatment naïve, or PegIFN/RBV experienced, or PegIFN/RBV/protease inhibitor experienced

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

c. Both of the following:

1. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir or telaprevir); and

2. The medication is used in combination with Ribavirin; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

4. Genotype 4, treatment naïve

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

5. Genotype 4, PegIFN/RBV experienced

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin; and

3. The medication is used in combination with Ribavirin; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 16 weeks.

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

II. Daliresp® (roflumilast)

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

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

1. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting anticholinergic agent;

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting beta (β) agonist;

c. The recipient has experienced an inadequate response, adverse event or has a contraindication to an inhaled corticosteroid;

d. The recipient has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD); and

e. The recipient has a history of COPD exacerbations.

2. Contraindication

a. Daliresp (roflumilast) may not be approved for a recipient with a diagnosis of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

3. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed by DUR Board: April 22, 2021

Hereditary Angioedema (HAE) agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Cinryze® (C1 esterase inhibitor), Haegarda® (C1 estarase inhibitor), Orladeyo® (berotralstat) or Takhzyro® (ianadelumab-flyo)

   a. Approval will be given if all the following criteria are met and documented:

      1. The recipient has a diagnosis of HAE; and

      2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

         a. C1-INh antigenic level below the lower limit of normal; or

         b. C1-INh functional level below the lower limit of normal; and

            1. The medication is being prescribed by or in consultation with an allergist or immunologist.

      3. The medication is being used as prophylaxis against attacks; and

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be approved for 12 months.

      2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Cinryze® (C1 esterase inhibitor) *, Firazyr® (icatibant), Ruconest® (C1 esterase inhibitor)

   Note: * off label use

   b. Approval will be given if all the following criteria are met and documented:

      1. The recipient has a diagnosis of HAE; and

      2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

         a. C1-INh antigenic level below the lower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

4. The medication is not used in combination with other approved treatment for acute HAE attacks; and

5. The medication is prescribed by or in consultation with an allergist or immunologist.

b. Prior Authorization Guidelines:

1. Prior authorization approval will be approved for 12 months.

2. Prior authorization forms are available https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. Kalbitor® (ecallantide)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis of HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the lower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

4. The recipient is 12 years of age or older; and

5. The medication is not used in combination with other approved treatments for acute HAE attacks; and

6. The medication is prescribed by or in consultation with an allergist or immunologist.

b. Prior Authorization Guidelines:

1. Prior authorization approval will be approved for 12 months.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

4. Berinert® (C1 esterase inhibitor)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the lower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is not used in combination with other approved treatments for acute HAE attacks; and

4. The medication is being prescribed by or in consultation with an allergist or immunologist; and

5. The medication is being used to treat acute HAEattacks and

6. One of the following:

a. The recipient has trial and failure, contraindication, or intolerance to Ruconest®; or

b. The recipient is 12 year of age or younger and there is documentation that the recipient has history of laryngeal attacks.

b. Prior Authorization Guidelines:

1. Prior authorization approval will be approved for 12 months.

2. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

KK. Incretin Mimetics

Therapeutic Class: Incretin Mimetics
Last Reviewed by the DUR Board: January 26, 2017
Previously reviewed by the DUR Board: July 26, 2012

Incretin Mimetics are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. An ICD code for Type 2 Diabetes Mellitus is documented on the prescription and transmitted on the claim; or

   b. A prior authorization documenting a diagnosis of Type 2 Diabetes Mellitus has been submitted.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

LL. Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: January 27, 2022

Cystic Fibrosis (CF) Agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given for a single agent concomitantly if the following criteria are met and documented:

   a. Kalydeco® (ivacaftor)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient is age appropriate according to the FDA-approved package labeling; and

         b. The recipient has a diagnosis of CF; and

         c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the gene mutations listed in the FDA-approved package insert; and

         d. The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a CF care center.

      2. Recertification Request (the recipient must meet all the following criteria)

         a. Documentation of a positive clinical response to Kalydeco® therapy.

      3. Prior Authorization Guidelines:

         a. Initial request will be approved for 12 months.

         b. Recertification request will be for 12 months.

         c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

   b. Orkambi® (lumacaftor/ivacaftor)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient has a diagnosis of CF; and

b. The recipient is age appropriate according to the FDA-approved package labeling; and

c. The recipient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; and

d. The requested dose is two tablets every 12 hours; or

e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

a. Prior authorization approvals will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

c. Symdeko® (tezacaftor/ivacaftor)

1. Approval will be given if the following criteria are met and documented:

a. Initial Request:

1. The recipient is age appropriate according to the FDA-approved package labeling; and

2. The recipient has a documented diagnosis of CF; and

3. The medication must be prescribed by or in consultation either a Pulmonolist or a specialist associated with a CF care center.

4. One of the following:

a. The recipient is homozygous for the F508del mutation as detected by an FDA cleared CF mutation test or Clinical Laboratory Improvement Amendments (CLIA) approved facility; or

b. The recipient has one of the FDA approved package insert listed mutations on at least one allele in the (CFTR) gene as detected by FDA cleared CF mutation test or CLIA approved facility.

b. Recertification Request (the recipient must meet the following criteria):

1. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

2. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

d. Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

1. Approval will be given if the following criteria are met and documented:

a. The recipient is age appropriate according to the FDA-approved package labeling; and

b. The recipient has a documented diagnosis of CF; and

c. The recipient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data as detected by an FDA cleared CF mutation test, or a test performed at a CLIA approved facility; and

d. The medication is prescribed by or in consultation with either a Pulmonologist or a specialist affiliated with a CF care center.

2. Recertification Request:

a. The recipient must have documentation of a positive clinical response to Trikafta® therapy (e.g. improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations)

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

MM. Gimoti® (metoclopramide)

Therapeutic Class: Gastrointestinal Prokinetic Agents
Last Reviewed by the DUR Board: October 26, 2021
Gastrointestinal Prokinetic Agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria are met and documented:

    a. The recipient has a diagnosis of acute diabetic gastroparesis; and

    b. The recipient is 18 years of age or older; and

    c. The recipient does not have any of the following:

        1. History of signs or symptoms of tardive dyskinesia (TD); or

        2. History of a dystonic reaction to metoclopramide; or

        3. Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation); or

        4. Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma; or

        5. Diagnosis of epilepsy or any other seizure disorder; or

        6. Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm); or

        7. Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute); or

        8. Moderate or severe hepatic impairment (Child-Pugh B or C); and

    d. One of the following:

        1. The recipient has had an adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., intramuscular) metoclopramide; or

        2. The recipient is NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications)

2. Recertification Request:

    a. Recipient continues to meet all initial authorization criteria; and

b. At least 2 weeks have passed (i.e., drug holiday) since completion of a previous course or metoclopramide treatment of any dosage form; and

c. Recipient demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); and

d. Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention)

3. Prior Authorization Guidelines:

a. Prior Authorization approval will be for two months

b. Recertification requests will be approved for two months

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors
Last Reviewed by the DUR Board: April 22, 2021

Platelet Inhibitors are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Authorization will be given if the following criteria are met and documented:

   a. Brilinta® (ticagrelor)

      1. The recipient has a diagnosis of Acute Coronary Syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

      2. The recipient does not have an active pathological bleed or history of intracranial hemorrhage; and

      3. The recipient will be receiving concomitant treatment with aspirin in a dose of less than 100 mg/daily; and

      4. One of the following:

         a. The recipient has been started and stabilized on the requested medication; or

         b. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

         c. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

   b. Effient® (prasugrel)

      1. The recipient has a diagnosis of ACS (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

      2. The recipient does not have an active pathological bleed or history of transient ischemic attack or cerebral vascular accident (CVA); and

      3. The recipient will be receiving concomitant treatment with aspirin in a dose of less than 100 mg/daily; and

      4. The recipient has a history of percutaneous coronary intervention; and

      5. One of the following:

a. The recipient has been started and stabilized on the requested medication; or

b. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

c. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

OO. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: October 22, 2020

Osteoporosis agents are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

a. Evenity® (romosozumab-aqqg)

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. The recipient's Bone Mineral Density (BMD) T-score is -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. The recipient has documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); or

c. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. The recipient has a documented history of low-trauma fracture of the

hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. The recipient has a documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

2. One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

a. The recipient has a major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions.

b. The recipient has a hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. The recipient has a documented trial and failure, contraindication, or intolerance to one of the following:

1. Forteo® (teriparatide)

2. Tymlos® (abaoparatide); and

d. Treatment duration of Evenity® (romosozumab-aqqg) has not exceeded a total of 12 months during the recipient's lifetime.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be given for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

b. Prolia® (denosumab)

1. For bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of nonmetastatic prostate cancer; and

2. The recipient is undergoing androgen deprivation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

3. One of the following:

a. The recipient is 70 years of age or older; or

b. Both the following:

1. The recipient is less than 70 years of age; and

a. One of the following:

1. BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

2. Documented history of one of the following resulting from minimal trauma:

a. Vertebral compression fracture

b. Fracture of the hip

c. Fracture of the distal radius

d. Fracture of the pelvis

e. Fracture of the proximal numerous; and

b. Recertification Request (the recipient must meet all criteria):

1. The recipient is undergoing androgen depravation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

2. The recipient has no evidence of metastases; and

3. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of breast cancer; and

2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]); and

3. One of the following:

a. The recipient's BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

b. Documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g. alendronate)

b. Recertification Request (recipient must meet all criteria):

1. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]); and

2. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. For Postmenopausal Osteoporosis or Osteopenia

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

2. One of the following:

a. The recipient has a BMD scan indicative of osteoporosis: T-score less than or equal to -2.5 in the

lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. Both the following:

1. The recipient has a BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following FRAX 10-year probabilities:

a. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has a documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

3. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate).

b. Recertification Request:

1. Documentation that indicates the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 24 months.

2. Recertification approval will be for 24 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. Glucocorticoid-Induced Osteoporosis

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient is initiating or continuing greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months; and

3. One of the following:

a. The recipient has a BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. One of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has a documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate).

b. Recertification Request:

1. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 24 months.

2. Recertification request will be approved for 24 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

c. Forteo® (teriparatide)

1. For Postmenopausal Osteoporosis or Osteopenia, or Men with Primary or Hypogonadal Osteoporosis or Osteopenia at High Risk for Fracture

a. Approval will be given if all criteria are met and documented:

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia, or primary or hypogonadal osteoporosis or osteopenia; and

2. One of the following:

a. Both the following:

1. The recipient has a BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following

a. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Documented trial and failure, contraindication intolerance to one osteoporosis treatment (e.g.,

alendronate, risedronate, zoledronic acid, Prolia [denosumab]); or

b. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. Recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. Recipient has a documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

2. One of the following FRAX 10-year probabilities:

a. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

3. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.

2. For Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

a. Approval will be given if all criteria are met and documented:

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient has documented history of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to three months; and

3. One of the following:

a. BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. Documented trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate); and

5. The recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceed a total of 24 months during the patient's lifetime.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

d. Tymlos® (abaloparatide)

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); or

2. Both the following:

a. Recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Recipient has a documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Both the following:

a. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during their lifetime.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

PP. Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations

Therapeutic Class: GnRH Antagonist and Combinations
Last Reviewed by DUR Board: October 22, 2020

GnRH Antagonist and Combinations are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Orilissa® (elagolix)

   a. Approval will be given if all criteria are met and documented:

      1. The recipient has a diagnosis of moderate to severe pain associated with endometriosis; and

      2. One of the following:

         a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

            1. Danazol; or

            2. Combination (estrogen/progesterone) oral contraceptive; or

            3. Progestins; or

         b. The recipient has had surgical ablation to prevent occurrence.

      3. For Orilissa 200 mg request only, the treatment will not exceed six months.

   b. Recertification Request (All criteria must be met and documented):

      1. The recipient has documented improvement in pain associated with endometriosis improvement in dysmenorrhea and non-menstrual pelvic pain); and

      2. Treatment duration has not exceeded a total of 24 months; and

      3. The request is for Orilissa 150 mg.

   c. Prior Authorization Guidelines:

      1. Prior authorization approval will be for six months.

      2. Recertification approval will be for six months.

      3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Oriahnn® (elagolix, estradiol, and norethindrone)

a. Approval will be given if all criteria is met and documented:

1. The recipient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and

2. One of the following:

a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

1. Danazol; or

2. Combination (estrogen/progesterone) oral contraceptive; or

3. Progestins; or

b. The recipient has had surgical ablation to prevent occurrence.

b. Recertification Request:

1. The recipient has documented improvement in menstrual bleeding; and

2. Treatment duration will not exceed a total of 24 months.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for six months.

2. Recertification approval will be for six months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

QQ. Spravato™ (esketamine)

Therapeutic Class: Miscellaneous Anti-Depressant
Last Reviewed by the DUR Board: July 25, 2019

Spravato™ (esketamine) is subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. Initial approval will be given if the following criteria are met and documented:

      1. The recipient is 18 years of age or older; and

      2. Recipient must have a diagnosis of treatment resistant depression as evidence of failure of two antidepressants; and

      3. Medication must be administered under the direct supervision of a healthcare provider with post-administration observation; and

      4. Treatment must be in conjunction with an oral antidepressant; and

      5. The medication must be prescribed by or in consultation with a psychiatrist; and

      6. The recipient must not have an aneurism or AV (arteriovenous**)** malformation.

   b. Approval will not be given for recipients who are currently pregnant or lactating and breastfeeding.

2. Recertification Request:

   a. In addition to the prior authorization criteria listed above (initial approval), the recipient must also have a positive clinical response to the medication treatment.

3. Prior Authorization Guidelines

   a. Initial prior authorization approval will be given for four weeks.

   b. Recertification authorization approval will be given for six months.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

RR. Omontys® (Peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)
Last Reviewed by DUR Board: October 25, 2012

Omontys® (Peginesatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of anemia secondary to chronic kidney disease;

   b. The recipient must be over 18 years of age;

   c. The recipient is receiving dialysis;

   d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);

   e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and

   f. The target hemoglobin level will not exceed 11 g/dL.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one month.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: 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 neuropenia risk of ≥ 20%; or

2. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age > 65 years, absolute neutrophil count (ANC) < 100 cells/μL or the expected duration of neutropenia is > 10 days); or

3. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

TT. Auvi-Q® (epinephrine injection device)

Therapeutic Class: Anaphylaxis-Self Injectable Epinephrine
Last Reviewed by the DUR Board: January 23, 2014

Auvi-Q® (Epinephrine Injection Device) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient or recipient's caregiver is unable to read or comprehend written directions.

2. Prior Authorization Guidelines

   a. Initial prior authorization approval will be for one year.

   b. Recertification approval will be for one year.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

UU. Aduhelm® (aducanumab-avwa)

Therapeutic Class: Alzheimer's Disease Agents
Last Reviewed by DUR Board: October 26, 2021

Aduhelm® is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

        1. Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one the following;

            a. Diagnosis of mild cognitive impairment due to Alzheimer's disease; or

            b. Diagnosis of probable Alzheimer's disease dementia; and

        2. All of the following:

            a. Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4; and

            b. Repeatable Battery for the Assessment of Neuropsychological (RBANS) score less than or equal to 85; and

            c. Mini-Mental State Examination score of 24-30; or

            d. Montreal Cognitive Assessment (MoCA) of 17 or above; and

    b. Documentation of beta-amyloid protein disposition, as evidenced by one of the following:

        1. Positive amyloid positron emission tomography (PET) scan; or

        2. Both of the following:

            a. Attestation that the patient does not have access to amyloid PET scanning; and

            b. Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., AB42 level, AB42:AB40 ratio); and

c. All of the following:

1. Recipient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less); and

2. Recipient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment; and

3. Recipient had no history of relevant brain hemorrhage, bleeding disorder, and cerebrovascular abnormalities in last six months; and

d. A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment to rule out other causes (e.g., stroke, small vessel disease, tumor); and

e. Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; and

f. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist, or other expert in the disease state.

2. Recertification Request:

a. Approval will be given if the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting recipientis benefitting from therapy as defined by both of the following:

a. Based on the NIA-AA criteria, one of the following:

1. Recipient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease; or

2. Recipient continues to have a diagnosis of probable disease dementia; and

b. All of the following;

1. CDR-G score of 0.5 of CDR-SB score of 0.5-4; and

2. RBANS score less than or equal to 85; and

3. Mini-Mental State Examination score of 24-30; and

2. Recipient has a follow-up brain MRI has been completed after the initiation of therapy to show one of the following:

    a. Both of the following:

        1. Less than ten new incident microhemorrhages; and

        2. Two or less focal areas of superficial siderosis; or

    b. If ten or more new incident microhemorrhages or greater than two focal areas of superficial siderosis are present then both of the following:

        1. Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances); and

        2. Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H); and

        3. The medication is prescribed by a neurologist, geriatrician, or geriatric psychiatrist.

3. Prior Authorization Guidelines

    a. Prior Authorization approval will be for six months.

    b. Recertification requests will be approved for six months.

    c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

VV. Medications for the Treatment of Acne

Therapeutic Class: Acne Agents
Last Reviewed by the DUR Board: July 24, 2014

Acne agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   No prior authorization necessary for recipients up to 21 years of age.

   Approval will be given if the following criteria are met and documented:

   a. The recipient is age 21 years of age or older; and

   b. The recipient has a diagnosis of moderate to severe acne (Grade III or higher).

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

WW. Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome Agents, Opioid-Induced Constipation Agents
Last Reviewed by the DUR Board: January 23, 2020

Functional Gastrointestinal Disorder Agents are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Chronic Idiopathic Constipation (CIC) Agents

   a. Approval will be given if all the following criteria are met and documented:

      1. The requested drug must be FDA approved for the recipient's age; and

      2. Must have a diagnosis of CIC; and

      3. Recipient has trial and failure, contraindication or intolerance to either lactulose or polyethylene glycol (Miralax); and

      4. Recipient has trial and failure, contraindication or intolerance to at least one stimulant laxative, such as sessosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada; and

      5. The maximum allowable dose for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2mg, once daily

         d. Trulance® (plecanatide): 2mg, once daily

   b. Prior Authorization Guidelines

      1. Prior authorization approval will be for one year.

      2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Irritable-Bowel Syndrome Agents

   a. Coverage and Limitations

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient is 18 years of age or older; and

b. The requested agent is being prescribed based on FDA approved guidelines; and

1. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):

a. For requests for Amitiza® (lubiprostone), the recipient must be female.

b. The requested dose is appropriate based on indication and age.

1. Linzess® (linaclotide): 290 µg daily.

2. Amitiza® (lubiprostone): 16 µg daily.

3. Trulance® (plecanatide): 3 µg daily.

2. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):

a. The medication is being prescribed by or in consultation with a gastroenterologist; and

b. The requested dose is appropriate based on indication and age.

1. Lotronex® (alosetron): 0.5 mg twice daily or 1 mg twice daily.

2. Viberzi® (eluxadoline): 75 mg twice daily or 100 mg twice daily.

3. Xifaxan® (rifaximin): 550 mg three times a day for 14 days.

b. Prior Authorization Guidelines

1. Prior authorization approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

c. Zelnorm® (tegaserod)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of IBS-C; and

b. The recipient is female; and

c. The recipient is less than 65 years of age; and

d. The recipient has had trial and failure, contraindication, or intolerance to one of the following:

1. Lactulose; or

2. Polyethylene glycol.

2. Reauthorization Request (the recipient must meet all criteria):

a. Documentation of positive clinical response to Zelnorm® therapy.

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be for six weeks.

b. Recertification approval will be 12 months.

c. Prior authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Opioid-Induced Constipation Agents

a. Approval will be given if all the following criteria are met and documented:

1. The recipient is 18 years of age or older; and

2. The requested medication is being used for an FDA approved indication; and

3. The recipient must meet the following criteria:

a. There is documentation in the recipient's medical record of an inadequate response, adverse reaction or contraindication to one agent from three of the four traditional laxative drug classes:

1. Bulk forming laxatives;

2. Osmotic laxatives;

3. Saline laxatives;

4. Stimulant laxatives.

4. And, requests for methylnaltrexone bromide that exceed the quantity limit must meet all the following criteria:

a. The recipient has opioid-induced constipation in advanced illness, is receiving palliative care, and is not enrolled in the DHCFP's hospice program; and

b. The requested dose is 0.15 mg/kg; and

c. The recipient's current weight is >114 kg.

b. Prior Authorization Guidelines

1. Prior authorization approval will be for one year.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

XX. Xartemis® XR (oxycodone and acetaminophen)

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: January 22, 2015

Xartemis® XR (oxycodone and acetaminophen) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The recipient is 18 years or older; and

b. A diagnosis code of Acute Pain is documented on the prescription and transmitted on the claim; or

c. An approved prior authorization documenting the recipient meeting the following criteria:

1. The recipient is 18 years or older; and

2. A diagnosis code of Acute Pain is documented on the Prior Authorization form.

2. Prior Authorization Guidelines

a. More than two fills of a quantity of 60 each, within six months requires an approved prior authorization documenting the reason to exceed the prescribing limit.

b. Prior authorization approval will be for six months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

YY. GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: April 26, 2018

GnRH Analogs are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. This prior authorization criteria only applies to recipients who are under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:

1. The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The medication is being prescribed by or in consultation with a pediatric endocrinologist; and

c. There is an onset of secondary sex characteristics before age eight years (females) or nine years (males); and

d. The recipient is currently less than 11 years of age (females) or 12 years of age (males).

2. The recipient has a diagnosis of gender dysphoria, formerly known as gender identity disorder; and

a. The medication is being prescribed for suppression of puberty; and

b. The provider indicates a demonstrable knowledge what gonadotropins medically can and cannot do and their social benefits and risks; and

c. One of the following:

1. A documented real-life experience (living as the other gender) for at least three months prior to the administration of gonadotropin; or

2. A period of psychotherapy for a duration specified by the mental health professional after the initial evaluation (usually a minimum of three months).

d. The member must meet the definition of gender dysphoria (see definition below):

1. Gender Disphoria:

a. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).

b. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

c. The disturbance is not concurrent with a physical intersex condition.

d. The disturbance causes clinically significant distress or impairment in social, occupational or other important areas of functioning.

e. The transsexual identity has been present persistently for at least two years.

f. The disorder is not a symptom of another mental disorder or a chromosomal abnormality.

3. The recipient has a diagnosis of endometriosis, and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID; and

c. The recipient has had an inadequate response, adverse reaction or contraindication to a hormonal contraceptive.

4. The recipient has a diagnosis of uterine leiomyomata (fibroids), and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The recipient is symptomatic; and

c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rational why surgical intervention is not required.

5. The recipient has a diagnosis of prostate cancer, and

a. The requested dose and frequency is based on FDA-approved guidelines.

2. Prior Authorization Guidelines

a. Prior authorization approval will be given for an appropriate length of therapy based on the diagnosis, unless the prescriber indicates a shorter duration of approval.

1. CPP: One year, or until the member reaches the age of 11 years (female) or 12 years (male).

2. Endometriosis: One year.

3. Uterine Leiomyomata (fibroids): One month or until the time of the documented surgery (maximum of three months).

4. Prostate Cancer: One year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

ZZ. Human Immunodeficiency Virus (HIV) Agents
Therapeutic Drug Class: HIV Agents
Last Reviewed by the DUR Board: April 28, 2022

HIV agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Cabenuva® (cabotegravir, rilpivirine) and Vocabria® (cabotegravir).

      1. All of the following:

         a. Diagnosis of HIV-1 infection; and

         b. Recipient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months; and

         c. Recipient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine; and

         d. Prescribed by or in consultation with a clinician with HIV expertise; and

         e. Will not be used concurrently with other ART medications; or

      2. The agent is used for continuation of prior therapy.

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be given in 12 months.

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: October 20, 2022

Narcolepsy Agents are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Provigil® (modafinil) and Nuvigil ® (armodafinil)

a. Approval will be given if the following criteria are met and documented:

1. The recipient has a diagnosis of narcolepsy; or

a. Obstructive Sleep Apnea (OSA); or

b. Excessive sleepiness associated with shift work disorder.

b. For treatment of OSA:

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of OSA defined by one of the following:

1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study unless the prescriber provides justification confirming that a sleep study would not be feasible; or

2. Both the following:

a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. One of the following signs/symptoms are present:

1. Daytime sleepiness; or

2. Nonrestorative sleep; or

3. Fatigue; or

4. Insomnia; or

5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

c. Recertification Request:

1. Documentation of positive clinical response to therapy.

2. For OSA: The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP).

d. Prior Authorization Guidelines:

1. Prior authorization approval will be given for 12 months.

2. Xyrem® (sodium oxybate)

a. The recipient has tried and failed on Provigil® (modafinil) or Nuvigil® (armodafinil); and/or

b. The recipient has a diagnosis of narcolepsy with cataplexy; and

c. The drug was prescribed by or in consultation with a neurologist or sleep specialist.

d. Prior Authorization Guidelines

1. Prior authorization approvals will be for 12 months.

3. Sunosi® (solriamfetol)

a. For treatment of Narcolepsy

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has had trial and failure, contraindication, or intolerance to both of the following:

1. modafinil; and

2. armodafinil.

2. Recertification Request:

a. Documentation of positive clinical response to Sunosi® therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

b. For treatment of OSA

1. Approval will be given if all the following criteria are met and documented:

a. The recipient must have a diagnosis of OSA defined by one of the following:

1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); or

2. Both the following:

a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. One of the following signs/symptoms are present:

1. Daytime sleepiness; or

2. Nonrestorative sleep; or

3. Fatigue; or

4. Insomnia; or

5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

d. The recipient has had a trial and failure, contraindication, or intolerance to both of the following:

1. Modafinil; and

2. Armodafinil.

2. Recertification Request (recipient must meet all the criteria)

a. Documentation of positive clinical response to therapy; and

b. The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP)

3. Prior Authorization Guidelines

a. Initial request will be approved for six months.

b. Recertification request will be approved for for six months.

3. Wakix® (pitolisant)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a documented diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. The recipient is 18 years of age and older.

b. Recertification Requests:

1. The recipient must have documentation of positive clinical response to Wakix® therapy.

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

4. Xywav® (calcium, magnesium, potassium, and sodium oxybates)

a. Narcolepsy with Cataplexy (Narcolepsy Type 1).

1. Approval will be given if the following criteria are met and documented:

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has present symptoms of cataplexy; and

c. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

d. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist.

2. Recertification Request:

a. The recipient has documentation demonstrating a reduction in the frequency of cataplexy attacks associate with therapy; or

b. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

b. Narcolepsy without Cataplexy (Narcolepsy Type 2)

1. Approval will be given if all the following criteria are met and documented:

a. The recipient has diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient symptoms of cataplexy are absent; and

c. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

d. The recipient has trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to generic modafinil or generic armodafinil and Sunosi®; and

e. One of the following:

1. The recipient has trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant; or

2. The recipient has history of or potential for substance use disorder; and

f. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist.

2. Recertification Request:

a. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

BBB. Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine)

Therapeutic Class: Nonsteroidal Anti-inflammatory Drug/Anti-ulcer Agent Combinations
Last Reviewed by the DUR Board: April 23, 2015

Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine) are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The drug is being used for an FDA approved indication; and

b. The recipient's medical records documents one of the following risk factors for developing a NSAID-related ulcer:

1. Previous history of a major gastrointestinal bleed, perforation or obstruction; or

2. Previous history of a peptic ulcer, hemorrhagic gastritis, hemorrhagic gastropathy or erosive esophagitis; or

3. Concomitant therapy for an anticoagulant or antiplatelet agent (including aspirin) or chronic oral corticosteroids; or

4. The recipient has had gastric bypass surgery (Roux-en-Y gastric bypass); and

c. The recipient is intolerant to a COX-2 inhibitor or has had a gastric or duodenal ulcer while taking a COX-2 inhibitor; and

d. The recipient has experienced an NSAID-associated ulcer in the past while taking a single-entity proton pump inhibitor (PPI) or prostaglandin agent concomitantly with an NSAID or the recipient is intolerant to both PPIs and prostaglandin agents; and

e. The recipient's medical records document an inadequate response or adverse reaction with concurrent therapy of an equivalent dose of the individual components.

2. Prior Authorization Guidelines

a. Prior authorization approvals will be for one year.

b. Prior Authorization forms available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

CCC. Rayos® (prednisone delayed-release)

Therapeutic Class: Corticosteroid, Systemic
Last Reviewed by the DUR Board: April 23, 2015

Rayos® (prednisone delayed-release) is subject to prior authorizations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

   Approval will be given if all of the following criteria are met and documented:

   a. The requested drug is being used for a FDA approved indication; and

   b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate–release tablets.

2. Prior Authorization Guidelines

   a. Prior authorization approvals will be:

      1. Initial therapy: three months.

      2. Recertification: one year.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

DDD. Corlanor® (ivabradine)

Therapeutic Class: Cardiovascular Agent
Last Reviewed by the DUR Board: September 3, 2015

Corlanor® (ivabradine) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. A diagnosis of chronic heart failure; and

b. A left ventricular ejection fraction (LVEF) $\leq$ 35%; and

c. A resting heart rate $\geq$ 70 bpm; and

d. The recipient is $\geq$ 18 years of age; and

e. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted regarding the diagnosis and treatment recommendations; and

f. The recipient is in a normal sinus rhythm; and

g. The recipient is on a maximally tolerated dose of a beta-blocker or the recipient has a contraindication to beta-blocker use.

2. Prior Authorization Guidelines

a. The extent of prior authorization approvals will be based on the appropriate use for the individual agents.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: AntilipemicAgent, PCSK9 Inhibitors
Last Reviewed by the DUR Board: July 23, 2020

Anti-lipidemic Agents – PCSK9 Inhibitors are subject to prior authorization and quantity limitation based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria are met and document:

   a. Initial Request:

      1. The recipient has an FDA-approved diagnosis; and

      2. The requested medication was prescribed by or in consultation with a cardiologist or lipid specialist; and

      3. The requested medication will be used as an adjunct to a low-fat diet and exercise; and

      4. For the treatment of homozygous familial hypercholesterolemia:

         a. With alirocumab (Praluent®)

            1. The recipient is 18 years of age or older; or

         b. With evolocumab (Repatha®)

            1. The recipient is 13 years of age or older.

      5. And the recipient must meet one of the following (a, b, c, or d):

         a. The recipient has had an inadequate response to high intensity statin therapy defined as all of the following:

            1. The recipient has received therapy with atorvastatin $\geq$ 40 mg or rosuvastatin $\geq$ 20 mg for at least the past three months; and

            2. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

            3. The LDL-C after therapy for at least the past three months was $\geq$ 100 mg/dL (HeFH) for $\geq$ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

4. The statin therapy will be continued with PCSK-9 therapy.

b. Or, the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:

1. The recipient has an intolerance or contraindication to high intensity statin therapy; and

2. The recipient has received therapy with:

a. atorvastatin 10 to 20 mg; or

b. rosuvastatin 5 to 10 mg; or

c. simvastatin > 20 mg; or

d. pravastatin >40 mg; or

e. lovastatin 40 mg; or

f. fluvastatin XL 80 mg; or

g. fluvastatin 40 mg twice daily; or

h. pitavastatin > 2 mg

for at least the past three months; and

3. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

4. The LDL-C after therapy for at least the past three months was $\geq$ 100 mg/dL (HeFH) or $\geq$ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

5. Statin therapy will be continued with PCSK-9 therapy.

c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.

d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.

2. Recertification Request (The recipient must meet all criteria (a-d))

a. The recipient has been adherent with PCSK-9 inhibitor therapy; and

b. The recipient has been adherent with statin therapy, or the recipient has a labeled contraindication to statin therapy; and

c. The recipient is continuing a low-fat diet and exercise regimen; and

d. The recipient has achieved a reduction in LDL-C level.

3. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification approval will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

FFF. Antipsychotic Drugs: Atypical

Therapeutic Class: Second Generation (Atypical) Antipsychotic
Last Reviewed by the DUR Board: July 28, 2022

Atypical Antipsychotic Drugs

1. Invega Trinza® (paliperidone palmitate)

   a. Approval will be given if the following criteria are met and documented.

      1. The recipient has a diagnosis of schizophrenia; and

      2. The recipient has been stabilized on once-monthly paliperidone palmitrate injection (Invega Sustenna®) for at least four months with the two most recent doses of the once-monthly injection being the same strength; and

      3. The recipient is 18 years of age or older; and

      4. The requested dose is one injection every three months.

   b. Prior Authorization Guidelines

      1. Prior authorization approvals will be for one year.

2. Invega Hafyera® (paliperidone palmitate)

   a. Approval will be given if the following criteria are met and documented.

      1. The recipient has a diagnosis of schizophrenia; and

      2. The recipient has been stabilized on once-monthly palperidone palmitrate extended-release (PP1M) injectable suspension (Invega Sustenna®) for at least four months, the two most recent doses of the once-monthly injection being the same strength or one dose of three-month IM paliperidone (Inevga Trinza®); and

      3. Patient is 18 years of age or older; and

      4. The requested dose is one injection every six months.

   b. Recertification Requests:

      1. Recipient must have a positive response from therapy.

   c. Prior Authorization Guidelines:

      1. Prior authorization approvals will be for one year.

GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: January 27, 2017
Previously reviewed: January 28, 2016

Medications for recipients on hospice are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   a. For recipients 21 years of age or older:

      1. The prescriber has verified the recipient is enrolled in the hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care; and

      4. The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient; and

      5. The requested medication is not providing a curative or long-term prophylactic therapy.

   b. For recipients 20 years of age or younger:

      1. The prescriber has verified the recipient is enrolled in a hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care.

      4. Medically necessary curative medications for this age group are covered by the DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for three months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

HHH. Ileal Bile Acid Transporter (IBAT) Inhibitor (D7F))

Therapeutic Drug Class: Ileal bile acid transporter (IBAT) inhibitor (D7F)
Last Reviewed by the DUR Board: July 28, 2022

Ileal bile acid transporter (IBAT) inhibitor (D7F) drugs are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Bylvay® (odevixibat)

   a. Approval will be given if the following criteria are met and documented:

      1. Recipient is three months of age or older; and

      2. Recipient is diagnosed with progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; and

      3. Recipient has elevated serum bile acid concentration; and

      4. Recipient experiences persistent moderate to severe pruritus; and

      5. Recipient does not have any of the following:

         a. Positive test for the ABCB11 gene variant that predicts complete absence of the bile salt export pump (BSEP) protein; and

         b. Prior heaptic decompensation event; and

         c. Another concomitant liver disease; and

         d. An international normalized ratio (INR) greater than 1.4; and

         e. Significant portal hypertension; and

         f. An alanine aminotransferase (ALT) or total bilirubin (TB) level more than 10 times the upper limit of normal (ULN); and

         g. Medical history or ongoing chronic diarrhea; and

         h. Decompensated cirrhosis; and

         i. Significant portal hypertension; and

      6. Bylvay® is prescribed by or in consultation with a specialist (e.g. gastroenterologist, hepatologist, dermatologist).

b. Recertification Request:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite vitamin A,D,E,K supplementation; elevated liver function tests [alanine aminotransferase (ALT), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension

c. Prior Authorization Guidelines:

1. Prior authorization approval will be given for 12 months

2. Livmarli® (maralixibat)

a. Approval will be given if all the following criteria are met and documented:

1. Recipient is one year of age or older; and

2. Recipient is diagnosed with Alagille syndrome; and

3. Recipient experiences persistent moderate to severe pruritus; and

4. Recipient does not have any of the following:

a. Chronic diarrhea requiring ongoing intravenous fluid or nutritional intervention; and

b. Prior hepatic decompensation event; and

c. Significant portal hypertension; and

d. Decompensated cirrhosis; and

e. Another concomitant liver disease; and

5. Maralixibat is prescribed by or in consultation with a specialist (e.g.,gastroenterologist, hepatologist, dermatologist); and

6. Patient has failed an adequate trial, or is intolerant to, or has a contraindication to at least one pruritus treatment (e.g., ursodeoxycholic acid [ursodiol], cholestyramine, rifampin, naloxone, naltrexone, antihistamine).

b. Recertification Request:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet the above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite Vitamin A, D, E, K supplementation; elevated liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension.

c. Prior Authorization Guidelines:

1. Prior Authorization approval will be given for six months.

2. Recertification will be given for 12 months.

III. Hetlioz® (tasimelteon)

Therapeutic Class: Sedative Hypnotic
Last Reviewed by the DUR Board: April 28, 2022

Hetlioz® (tasimelteon) is subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

2. Coverage and Limitations

a. For treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

1. Approval will be given if all following criteria are met and documented:

a. The recipient has a diagnosis of Non-24 disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome); and

b. The medication is being prescribed by or in consultation with a sleep specialist; and

c. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least three months of therapy) to a therapeutic dose of melatonin.

2. Recertification Request:

a. Documentation of positive clinical response to therapy.

3. Prior Authorization Guidelines:

a. Initial prior authorization will be approved for six months.

b. Recertification will be approved for 12 months.

b. For the treatment for nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

1. Approval will be given if all criteria are met and documented:

a. The recipient has a diagnosis of SMS; and

b. The recipient is at least 16 years of age and older (3 through 15 years of age for LQ suspension); and

c. The recipient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking); and

d. Prescribed by a neurologist or a specialist in sleep disorder; and

e. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least three months of therapy) to a therapeutic dose of melatonin.

2. Recertification Request:

a. Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality).

3. Prior Authorization Guidelines:

a. Initial Prior Authorization will be approved after six months.

b. Recertification will be approved after 12 months.

JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker
Last Reviewed by the DUR Board: October 26, 2021

Entresto® (sacubitril/valsartan) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of chronic heart failure NYHA Class II to IV; and

   b. The recipient has reduced left ventricular ejection fraction (LVEF); and

   c. The recipient is one year of age or older; and

   d. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted; and

   e. The recipient has had a trial of an angiotensin converting enzyme (ACE) or an angiotensin receptor blocker (ARB) for at least four weeks prior to the initiation of therapy; and

   f. The recipient will not concurrently receive an ACE inhibitor; and

   g. The recipient is on an individualized dose of a beta blocker, or the recipient has a contraindication to beta blocker use; and

   h. Entresto® will be given twice daily with a maximum dose of 97/103 mg.

2. Prior Authorization Guidelines:

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at:
   https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

KKK. Neurokinin-1 Antagonists and Combinations

Therapeutic Class: Neurokinin-1 Antagonists and Combinations
Last Reviewed by the DUR Board: April 28, 2016

Neurokinin-1 antagonists and combinations are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

For requests to exceed the quantity limits approval will be given if all the following criteria are met and documented:

a. The requested medication is being used for an FDA-approved indication; and

b. The requested medication is being prescribed by an oncologist or in consultation with an oncologist; and

c. The recipient must meet one of the following criteria:

1. The recipient is 18 years of age or older; or

2. The recipient is 12 years of age or older, the requested medication is aprepitant (Emend®) and the recipient is diagnosed with nausea and vomiting caused by chemotherapy; and

d. It is medical necessity for the recipient to exceed the quantity limit (e.g., duration of chemotherapy cycle).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

LLL. Voquenza® Dual Pak® (Vonoprazan and amoxicillin), Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin)

Therapeutic Drug Class: Qualified Infection Disease Product
Last Reviewed by DUR Board: October 20, 2022

Voquenza® Dual Pak® (Vonoprazan and amoxicillin), Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin) are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. Recipient is 18 years or age or older; and

   b. Recipient has a confirmed diagnosis of Helicobacter pylori (H. pylori) infection; and

   c. Recipient must not have hypersensitivity or cross-hypersensitivity to any component or drug class of the product (e.g., penicillins, cephalosporings, macrolides); and

   d. Treatment will not be used concurrently with rilpivrine-containing products; and

   e. For vonoprazan/amoxicillin/clarithromycin requests (Voquenza® Triple Pak®), the patient does not have a history or hepatic dysfunction or cholestatic jaundice associated with prior use of clarithromycin; and

   f. For vonoprazan/amoxicillin/clarithromycin (Voquenza® Triple Pak®), the patient does not have ventricular cardiac arrythmia, prolongation of the QT interval, or proarrhythmic condition (e.g., uncorrected hypokalemia or hypomagnesemia); and

   g. Recipient must have an adequate trial and failure of, or relevant medical reason for not using, proton pump inhibitor-based H.pylori treatment regimen; and

   h. Baseline renal and hepatic function laboratory tests have been obtained; and

   i. Quantity limit of 14-day supply.

2. Recertification Request:

   a. Coverage is not renewable.

3. Prior Authorization Guidelines:

   a. Prior Authorization will be given for 14 days.

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: January 27, 2022

DMD agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Exondys 51® (eteplirsen)

   a. Approval will be given if all the following criteria are met and documented:

      1. Initial request:

         a. The recipient has a diagnosis of Duchenne muscular dystrophy (DMD); and

         b. There is documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping; and

         c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

         d. The prescribed dose does not exceed 30 milligrams per kilogram of body weight once weekly.

      2. Recertification Request (the recipient must meet all the following criteria).

         a. The recipient has been on therapy for less than 12 months; and

         b. The recipient has experienced clinically significant benefit; and

         c. The recipient is tolerating therapy; and

         d. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

         e. The medication is prescribed by or in consultation with a neurologist who has experience treating children, or all the following:

            1. The recipient has been on therapy for 12 months or more; and

            2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

            3. The recipient has experienced clinically significant benefit; and

4. The recipient is tolerating therapy; and

5. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

6. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

b. Prior Authorization Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Emflaza® (deflazacort)

a. Approval will be given if all the following criteria are met and documented:

1. Initial request:

a. The recipient must have a diagnosis of (DMD); and

b. The recipient must be five years of age or older; and

c. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:

1. Documentation of a confirmed mutation of the dystrophin gene; or

2. Muscle biopsy confirming an absence of dystrophin protein; and

d. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and

e. The recipient has had at least a three-month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and

The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

b. Recertification request (the recipient must meet all the following criteria):

1. Documentation of positive clinical response to Emflaza® therapy (e.g., improvement or preservation of muscle strength); and

2. The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

c. Prior Authorization Guidelines:

1. Initial prior authorization approval will be approved for 12 months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. Vyondys 53® (golodirsen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g. chart notes, laboratory values) documenting the following:

a. The recipient has a diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

3. The dose will not exceed 30 milligrams per kilogram of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. One of the following:

a. All the following:

1. The recipient has been on therapy for less than 12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a neurologist who has experience treating children; or

b. All the following:

1. The recipient has been on therapy for 12 months or more; and

2. Recipient experienced a benefit from therapy (e.g. disease amelioration compared to untreated patients); and

3. Recipient is tolerating therapy; and

4. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a neurologist who has experience in treating children.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. Viltepso ® (viltolarsen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. The recipient has a diagnosis of DMD; and

b. The recipient has documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. One of the following:

a. All of the following:

1. The recipient has been on therapy for less than 12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; or

b. All of the following:

1. The recipient has been on therapy for 12 months or more; and

2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

3. The recipient is tolerating therapy; and

4. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a Neurologist who has experience treating children.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. Amondys 45® (casimersen)

a. Approval will be given if all the following criteria are met and documented:

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. Diagnosis of Dystrophy (DMD); and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 to exon 45 skipping; and

2. Prescribed by or in consultation with a neurologist who has experience treating children; and

3. Dose will not exceed 30 milligrams per kilograms of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. Recipient is tolerating therapy; and

2. Dose will not exceed 30 milligrams per kilogram of body weight infused weekly; and

3. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

NNN. Qutenza® (capsaicin)

Therapeutic Class: Topical Neuropathic Pain Agents
Last Reviewed by the DUR Board: January 27, 2022

Qutenza® (capsaicin) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if all the following criteria is met and documented:

   a. The recipient has a diagnosis of neuropathic pain associated with postherpetic neuralgia; or

   b. The recipient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet; and

   c. The recipient has history of failure or intolerance to over-the-counter capsaicin.

2. Recertification Request (recipient must meet all criteria):

   a. At least three months have transpired since the last Qutenza® application/administration; and

   b. The recipient experienced pain relief with a prior course of therapy; and

   c. The recipient is experiencing a return of neuropathic pain.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification request will be approved for three months.

   c. The Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

OOO. Movement Disorder Agents

Therapeutic Class: Movement Disorder Agents
Last Reviewed by the DUR Board: April 28, 2022

Movement Disorder Agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Austedo® (deutetrabenazine)

   a. For treatment of Chorea Associated with Huntington's Disease.

      1. Approval will be given if all the following criteria are met and documented:

         a. The recipient must have a diagnosis of chorea associated with Huntington's disease; and

         b. The recipient must be 18 years of age or older; and

         c. The medication is prescribed by or in consultation with a neurologist; and

      2. Recertification criteria:

         a. Documentation of positive clinical response to therapy.

      3. Prior Authorization Guidelines

         a. Initial prior authorization approval will be for 12 months.

         b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

   b. For the treatment of Tardive Dyskinesia (TD).

      1. Approval will be given if all the following criteria are met and documented:

         a. The recipient must have a confirmed diagnosis of TD; and

         b. The recipient must be 18 years of age or older; and

         c. The medication is prescribed by or in consultation with a neurologist or psychiatrist; and

         d. One of the following:

            1. Persistent symptoms of TD despite a trial dose reduction, tapering or discontinuation of the offending medication; or

2. The recipient is not a candidate for trial dose reduction, tapering or discontinuation of the offending medication.

2. Recertification request:

a. Documentation of positive clinical response to therapy

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be for three months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Ingrezza® (valbenazine)

a. Approval will be given if the following criteria are met and documented:

2. Initial request:

a. The recipient must have a diagnosis of severe tardive dyskinesia (TD);

b. The recipient must be 18 years of age or older; and

c. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and

d. One of the following:

1. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or

2. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.

b. Recertification Request:

1. Documentation of positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for three months.

2. Recertification will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

PPP. Brineura® (cerliponase alfa)

Therapeutic Class: Brineura® (cerliponase alfa)
Last Reviewed by the DUR Board: October 19, 2017

Brineura® (cerliponase alfa) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial request:

1. The recipient must have a diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis Type 2 (CLN2) also known as tripeptidyl peptidase 1 (TPP1) deficiency; and

2. The diagnosis must be confirmed by TPP1 enzyme detected by a dried blood spot test and CLN2 genotype analysis; and

3. The recipient must be three years of age or older; and

4. The drug must be prescribed by or in consultation with a neurologist with expertise in the diagnosis of CLN2; and

5. The drug must be administered by, or under the direction of, a physician knowledgeable in intraventricular administration; and

6. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

7. The recipient must not have a ventriculoperitoneal shunt.

b. Recertification request (the recipient must meet all of the following criteria):

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

b. The recipient must not have a ventriculoperitoneal shunt; and

c. Documentation of positive clinical response to Brineura®, (e.g., improvement in walking or crawling, or no evidence of disease progression).

c. Prior Authorization Guidelines

1. Initial prior authorization approval will be for four months.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

QQQ. Vuity® (pilocarpine) 1.25% Ophthalmic Solution

Therapeutic Class: Ophthalmic Agents, Intraocular Pressure (IOP)-Modifying

Last Reviewed by the DUR Board: April 28, 2022

Vuity® (pilocarpine) 1.25% Ophthalmic Solution is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of presbyopia; and

   b. The medication prescribed by or in consultation with an ophthalmologist or optometrist; and

   c. The recipient is unable to use corrective lenses (e.g., eyeglasses or contact lenses) confirmed by medical records (e.g., chart notes); and

   d. Vuity will not be prescribed concurrently with any ophthalmic pilocarpine formulations.

2. Recertification Request:

   a. Documentation or positive clinical response to therapy (e.g., improvement in near vision in low light conditions without loss of distance vision); and

   b. Prescribed by or in consultation with an ophthalmologist or optometrist.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for one month.

   b. Recertification will be approved for six months.

   c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

RRR. Livtencity® (maribravir)

Therapeutic Drug Class: Antivirals
Last Reviewed by DUR Board: October 20, 2022

Livencity® (maribravir) are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. Recipient is greater than or equal to 12 years of age; and

    b. Recipient must weigh greater than 35 kilograms (kg); and

    c. Recipient of a hematopoietic stem cell or solid organ transplant; and

    d. Recipient has documented cytomegalovirus (CMV) infection in whole blood or plasma (screening value greater than or equal to 2,730 IU/mL in whole blood or greater than or equal to 910 IU/mL in plasma) in two consecutive assessments separated by greater than or equal to one day; and

    e. Recipient has current CMV infection that is refractory (documented failure to achieve greater than 1 log10 decrease in CMV deoxyribonucleic acid [DNA] level in whole blood or plasma after greater than or equal to 14 days treatment) to anti-CMV treatment agents (ganciclovir, valganciclovir, cidofovir, or foscarnet), even with documented genetic mutations associated with resistance; and

    f. Maribravir will not be coadministered with ganciclovir or valganciclovir; and

    g. Recipient will be monitored for clinically important drug interactions that could results in decreased therapeutic effect of maribravir.

2. Recertification Request:

    a. Recipient must continue to meet the above criteria; and

    b. Recipient must have disease improvement and/or stabilization or improvement in the slope of decline (greater than 1 log10 decrease in CMV DNA level in whole blood or plasma after 14 days or longer treatment); and

    c. Recipient has not experienced any treatment-restricting adverse effects (e.g., dysgeusia, diarrhea, nausea, and recurrence of underlying disease); and

    d. Recipient is not a non-responder (resistant) to maribravir.

3. Prior Authorization Guidelines:

    a. Prior authorization will be approved for six months

SSS. Anti-Parkinson's Agents

Therapeutic Class: Anti-Parkinson's Agents
Last Reviewed by the DUR Board: October 20, 2022

Anti-Parkinson's Agents is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Xadago ® (safinamide)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient must have a diagnosis of Parkinson's disease: and

2. The recipient must be five years of age or older; and

3. Documented continued Levodopa and/or other dopaminergic treatments; and

4. Recipient reports greater than 1.5 hours per day "off" episodes ("off" episodes refer to "end-of-dose wearing off" and unpredictable "on/off" episodes); and

5. Recipient must not also be taking any of the following drugs: other MAOIs or other drugs that are potent inhibitors of MAOI (e.g., linezolid), opioid drugs (e.g., tramadol, meperidine and related derivatives), selective norepinephrine reuptake inhibitors (SNRIs), tri- or tetra-cyclic or triazolopyridine antidepressants (TCAs), cyclobenzaprine, methylphenidate, amphetamine and their derivatives, St. John's wort or dextromethorphan; and

6. The recipient must not have severe hepatic impairment (e.g., Child-Pugh C).

b. Recertification Request:

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. Documentation of positive clinical response to Xadago® therapy; and

b. Documented continued Levodopa and/or other dopaminergic treatments.

c. Prior Authorization Guidelines:

1. Initial prior authorization approval will be for three months.

2. Kynmobi® (apomorphine)

a. Approval will be given if the following criteria are met and documented:

1. Recipient is 18 years of age or older; and

2. Recipient has a documented diagnosis of Parkinson's disease (PD); and

3. Recipient is experiencing "off" episodes of PD at least two hours per day on average; and

4. Recipient is on a stable levodopa-based therapy; and

5. Recipients will not be on a concomitant 5HT3 antagonists (e.g., ondansetron, granisetron, dolansetron, palonosetron, alosetron); and

6. Recipient will be prescribed a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide) for initial therapy; and

7. Recipient does not have a major psychotic disorder.

b. Recertification Request:

1. Recipient must continue to meet the initial criteria above; and

2. Recipient has demonstrated a beneficial response to therapy (e.g., decrease in frequency and duration from baseline in motor fluctuations ["off episodes]); and

3. Recipient is absent of unacceptable toxicity from the drug (e.g., nausea or vomiting, oral mucosal irritation or stomatitis, decreased impulse control, syncope or hypotension, hallucinations or psychotic-like behavior, QTc prolongation, fibrotic complications, priapism, retinal atrophy or degeneration, excessive daytime sleepiness including falling asleep during activities that require active participation).

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for 12 months.

TTT. Codeine and Tramadol for Children

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: October 19, 2017

Codeine, codeine with acetaminophen and tramadol, tramadol with acetaminophen are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Codeine, codeine with acetaminophen

1. All of the following criteria must be met:

a. The recipient must be 12 years of age or older; and

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI > 30 kg/m^2), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy.

b. Tramadol, tramadol with acetaminophen

1. All of the following criteria must be met:

a. The recipient must be 12 years of age or older; and

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI > 30 kg/m^2), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy; and

e. The prescribed dose does not exceed 200mg/day and does not exceed a five-day supply.

2. Tramadol Extended Release (ER) will not be approved for children under 18 years of age and will reject at point of sale.

c. Prior Authorization Guidelines

1. Codeine, codeine with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

1. Prior authorization will be given for a one-month time period.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Tramadol, tramadol with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

b. Prior authorization will be given for a one-month time period.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

UUU. High Dollar Claim

Last Reviewed by the DUR Board: April 26, 2018

A High Dollar Claim is defined as a single point-of-sale claim that exceeds $10,000. A High Dollar Claim is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits. If other prior authorization criteria exists, it will supersede this criteria.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. One of the following:

1. The medication is being prescribed for a Food and Drug Administration (FDA) approved indication; or

2. One of the following:

a. Diagnosis is supported as a use of American Society of Health-System Pharmacists Drug Information (AHFS DI); or

b. Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “Effective” or “Evidence Favors Efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table); or

4. Diagnosis is supported in any other section in DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

b. And one of the following:

1. The dosage/quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

a. American Hospital Formulary Service (AHFS) Compendium.

b. Thomson Reuters (Healthcare) Micromedex/DRUGDEX (not Drug Points) Compendium.

c. Elsevier Gold Standard Clinical Pharmacology Compendium.

d. National Comprehensive Cancer Network Drugs and Biologics Compendium.

c. Excluded:

1. Hemostatic coagulation factors used for the treatment of hemophilia are excluded from this criteria.

d. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

VVV. Cuvrior® (trientine tetrahydrochloride)

Therapeutic Drug Class: Copper Chelator
Last Reviewed by DUR Board: October 20, 2022

Cuvrior® (trientine tetrahydrochloride) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given once the following criteria are met and documented:

   a. Recipient is 18 years of age or older; and

   b. Recipient has Wilson's disease (defined by a prior or current Leipzig score of greater than or equal to four); and

   c. Recipient is being treated with penicillamine for greater than or equal to one year at a stable dose and regimen for greater than or equal to four months, and recipient is tolerating penicillamine and adequately controlled (e.g., serum non-ceruloplasmin copper [NCC] level between greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour urinary copper excretion [UCE] of between levels greater than or equal to 100 and less than or equal to 900 mcg/24 hours); and

   d. Penicillamine will be discontinued before initiating Cuvrior; and

   e. Recipient will not concurrently use another formulation of trientine (e.g., Syprine, generics); and

   f. Prescribed by or in consultation with a hepatologist or neurologist; and

   g. Quantity limit is 300 tablets/30 days (max daily dose 3,000mg).

2. Recertification Request:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient has evidence of effectiveness of therapy (e.g., as assessed by serum NCC level between greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour UCE levels greater than or equal to 100 and less than or equal to 900 mcg/24 hours); and

   c. Recipient does not exhibit clinical manifestations of advancement of Wilson's disease from baseline (e.g., jaundice, edema, ascites, esophageal varices, liver failure, central nervous system symptoms); and

   d. Recipient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity reactions, copper deficiency, iron deficiency).

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

WWW. Botulinum Toxin

Therapeutic Class: Neurotoxic Protein
Last reviewed by the DUR Board: July 26, 2018

Botulinum toxins are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Policy

   Botulinum toxin injections are a Nevada Medicaid covered benefit for certain spastic conditions including, but not limited to cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis. The injections may reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and ambulation, to allow improved range of motion, to permit better physical therapy and provide adequate perineal hygiene.

2. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. It is expected that physicians be familiar with and experienced in the use of botulinum toxin products and utilize FDA-approved product labeling, compendia and peer-reviewed scientific literature to select the appropriate drug and dose regimen for each recipient condition. A complete list of covered indications can be found within the "Provider Type 20, 24 and 77 Billing Guide" applicable to botulinum toxins.

   b. Documentation must be provided that the recipient has been unresponsive to conventional methods of treatment (e.g., medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions); and

   c. If maximum dose is reached and positive clinical response is not established, treatment must be discontinued; and

   d. Documentation of medical necessity is required for treatment more frequent than every 90 days; and

   e. Coverage will be approved for one injection per site. A site is defined as including muscles of a single contiguous body part, such as a single limb, eyelid, face or neck.

   f. Coverage will not be provided for injections given for cosmetic or for investigational purposes.

3. Recertification Request (the recipient must meet all the following criteria):

   a. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

1. Documentation of a positive clinical response to Botulinum Toxin therapy.

4. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

XXX. Compounded Medications

Last Reviewed by the DUR Board: January 24, 2019

Compounded medications are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and

b. The therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery; and

c. If any prescription ingredients require prior authorization and/or step therapy, all drug specific criteria must also be met; and

d. The compounded medication must not be used for cosmetic purpose; and

e. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (drugs withdrawn from the market due to safety or effectiveness); and

f. The recipient has tried and failed therapy or had an intolerance to at least two FDA-approved, commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

1. The recipient has a contraindication to commercially available products; or

2. One or no other therapeutic alternatives are commercially available; or

3. Compound medication is prepared in a different dosage form for a recipient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does not meet this criteria); or

4. The recipient has an allergy or sensitivity to inactive ingredients (e.g., dyes, preservatives, sugars, etc.) that are found in commercially available products.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for six months unless the provider requests for a shorter length of therapy.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

YYY. Antibiotics

Last Reviewed by the DUR Board: July 26, 2018

Antibiotic medications are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

The outpatient antibiotic class criteria apply to the following:

Third Generation Cephalosporins	**Fluoroquinolones**	**Oxazolidinones**
cefixime	ciprofloxacin	tedizolid
cefdinir	levofloxacin	linezolid
cefpodoxime	delafloxacin	
ceftibuten	moxifloxacin	
cefdotoren	ofloxacin	

If applicable, reference current Infectious Disease Society of America (IDSA) (or equivalent organization) guidelines to support the use of the following:

1. Coverage and Limitations for Third Generation Cephalosporins and Fluoroquinolones

   Approval will be given if the following criteria are met and documented:

   a. Culture and sensitivity-proven susceptibilities and resistance to other agents suggest the requested drug is necessary.

2. Coverage and Limitations for Oxazolidinones

   a. Sivextro® (tedizolid)

      Approval will be given if the following criteria are met and documented:

      1. Recipient has diagnosis of Acute Bacterial Skin and Skin Structure Infection; and

      2. Infection is caused by methicillin-resistant *Staphylococcus aureus* (MRSA); and

      3. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to:

trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, vancomycin, daptomycin, telavancin, clindamycin); or

4. Recipient started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy.

b. Zyvox® (linezolid)

Approval will be given if the following criteria are met and documented:

1. Recipient has a diagnosis of vancomycin-resistant *enterococcus* (VRE) *faecium* infection or diagnosis of MRSA infection; and

2. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, tetracycline, clindamycin); or

3. Recipient started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy.

3. Exception Criteria (applies to antibiotic medications)

a. Prescribed by an infectious disease specialist or by an emergency department provider; or

b. Ceftriaxone prescribed as first line treatment for gonorrhea, pelvic inflammatory disease, epididymo-orchitis and as an alternative to benzylpenicillin to treat meningitis for those with a severe penicillin allergy; or

c. If cefixime is prescribed for gonococcal infection where ceftriaxone is unavailable; or

d. The recipient resides in one of the following:

1. Acute Care

2. Long-term Acute Care (LTAC)

3. Skilled Nursing Facility (SNF)

4. Prior Authorization Guidelines

a. Prior authorization approval will be for a single course.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. References

a. CDC Antibiotic Prescribing and Use in Doctor's Offices: https://www.cdc.gov/antibiotic-use/community/for-hcp/outpatient-hcp/index.html

b. CDC Improving Prescribing: https://www.cdc.gov/antibiotic-use/community/improving-prescribing/index.html

c. IDSA Guidelines: https://www.idsociety.org/practice-guidelines/#/score/DESC/0/+/

ZZZ. Oral Oncology Agents

Therapeutic Class: Oral Oncology Agents
Last Reviewed by the DUR Board: January 24, 2019

Oral oncology agents are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations (this criteria only applies if other product-specific criteria is not available in MSM Chapter 1200 – Prescribed Drugs)

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis that is indicated in the FDA approved package insert or listed in nationally recognized compendia, for the determination of medically accepted indications; and

   b. If the oral oncology medication is not indicated as a first line agent, either in the FDA approved package insert or nationally recognized compendia, then documentation of previous therapies tried and failed is required; and

   c. The medication is prescribed by or in consultation with an oncologist or hematologist; and

   d. The recipient does not have any contraindications to the requested oral oncology medication; and

   e. The requested quantity and dosing regimen falls within the manufacturer's published dosing guidelines or nationally recognized compendia and is appropriate for the recipient's age; and

   f. The medication must be used in combination with other chemotherapeutic or adjuvant agents according to the FDA approved prescribing information; and

   g. One of the following:

      1. If an FDA-approved companion diagnostic test for the requested agent exists, then documentation that the test was performed to confirm the diagnosis is required; or

      2. If a test with adequate ability to confirm a disease mutation exists, then documentation that the test was performed to confirm the diagnosis is required.

2. Recertification Request

   a. Documentation of a positive clinical response to the oral oncology treatment.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

AAAA. Pulmonary Arterial Hypertension Agents

Therapeutic Class: Pulmonary Arterial Hypertension Agents
Reviewed by the DUR Board: January 24, 2019

Pulmonary arterial hypertension (PAH) agents are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Approval will be given if the following criteria are met and documented:

a. The recipient has a documented diagnosis of pulmonary arterial hypertension; or

b. The recipient has one of the following ICD-10 diagnosis codes submitted on the pharmacy claim:

ICD-10	Description
127.20	Pulmonary Hypertension, Unspecified
127.21	Secondary Pulmonary Arterial Hypertension
127.22	Pulmonary Hypertension Due to Left Heart Disease
127.23	Pulmonary Hypertension Due to Lung Diseases and Hypoxia
127.9	Pulmonary Heart Disease, Unspecified

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: April 22, 2021

Anticonvulsants are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Cannabinoid

   a. Epidiolex® (cannabidiol)

      1. Approval will be given if the following criteria are met and documented:

         a. The recipient has a diagnosis of Lennox-Gastaut syndrome, Dravet Syndrome or Tuberous Sclerosis Complex (TSC); and

         b. The recipient is one years of age or older; and

         c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and

         d. The drug is prescribed by or in consultation with a neurologist; and

         e. The total dose does not exceed 20 mg/kg/day (10mg/kg twice daily); and

         f. The medication will be used as adjunctive therapy (the recipient has been taking one or more antiepileptic drugs and has chart notes confirming the presence of at least four convulsive seizures per month).

      2. Recertification Request

         a. Documentation of a positive clinical response to Epidiolex® therapy; and

         b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.

      3. Prior Authorization Guidelines

         a. Initial prior authorization will be for three months.

         b. Recertification approval will be for 12 months.

         c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.

2. Nayzilam® (midazolam)

a. Approval will be given if the following criteria are met and documented:

1. The recipient has a diagnosis of acute intermittent seizures; and

2. The recipient is at least 12 years of age; and

3. The medication is prescribed by or in consultation with a Neurologist; and

4. The dose must not exceed two sprays per seizure cluster, no more than one episode every three days and treat no more than five episodes per month.

b. Recertification Request

1. Documentation of positive clinical response to Nayzilam® therapy.

c. Prior Authorization Guidelines

1. Initial prior authorization will be for six months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Valtoco® (diazepam)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years and older; and

3. The medication is prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern; and

4. The medication is prescribed by or in consultation with a neurologist; and

5. The quantity must not exceed five episodes per month.

b. Prior Authorization Guidelines:

1. Documentation of positive clinical response to Valtoco® therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. Fintepla® (fenfluramine)

a. Approval will be given if all the following criteria are met and documented:

1. The recipient has a documented diagnosis of seizures associated with Dravet Syndrome; and

2. The recipient is two years of age or older; and

3. The medication is prescribed by or in consultation with a neurologist.

b. Recertification Request:

1. The recipient has documentation of positive clinical response to Fintepla® therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

CCCC. Amvuttra® (Vutrisiran)

Therapeutic Drug Class: Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B)
Last Reviewed by DUR Board: October 20, 2022

Amvuttra® (Vutrisiran) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity.

1. Approval will be given if the following criteria are met and documented:

    a. Recipient is greater than or equal to 18 years of age; and

    b. Recipient will receive supplementation with vitamin A as the recommended daily allowance during vutrisiran therapy; and

    c. Vutrisiran must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen [Tegsedi®], tafamidis [Vyndamax®, Vyndaqel®], patisiran [Onpattro®]); and

    d. Recipient has a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis/FAP (familial amyloidotic polyneuropathy) as documented by amyloid deposition on tissue biopsy and identification of a pathogenic TTR variant using molecular genetic testing; and

    e. Polyneuropathy is demonstrated by greater than or equal to two of the following criteria:

        1. Subjective patient symptoms are suggestive of neuropathy; or

        2. Abnormal nerve conduction studies are consistent with polyneuropathy; or

        3. Abnormal neurological examination is suggestive of neuropathy; and

    f. Recipient’s peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; and

    g. Baseline strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council [MRC] muscle strength); and

    h. Recipient has not had an orthotopic liver transplant (OLT); and

    i. Quantity limit is one syringe every three months.

2. Recertification Request:

    a. Recipient continues to meet the above criteria; and

b. Recipient is absent of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ocular symptoms related to hypovitaminosis A, etc.; and

c. Recipient has experienced disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in greater than or equal to one of the following:

1. Signs and symptoms of neuropathy; or

2. MRC muscle strength.

d. Recertification will be approved for six months.

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

DDDD. Oxervate® (cenegermin-bkbj)

Therpeutic Drug Class: Ophthalmic Human Nerve Growth Factor (Q25)
Last Reviewed by DUR Board: October 20, 2022

Oxervate® (Cenegermin-bkbj) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity.

1. Approval will be given if the following criteria are met and documented:

    a. Recipient must be greater than or equal to two years of age; and

    b. Recipient must have a diagnosis of moderate to severe (stage two or stage three) neurotrophic keratitis (NK); and

    c. Prescribed by or in consultation with an ophthalmologist; and

    d. Prescriber attestation that patient or caregiver has been counseled on proper administration technique; and

    e. Quantity Limit of eight kits per affected eye per lifetime.

2. Renewal Criteria:

    a. Coverage not renewable.

3. Prior Authorization Guidelines:

    a. Prior authorization will be approved for eight weeks.

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

2. MEDICATIONS WITH GENDER/AGE EDITS

A. Prenatal Vitamins

1. Payable only for female recipients.

B. Oral/Topical Contraceptives

1. Payable only for female recipients.

C. Gender Edits

1. Hormones

a. Estrogen – payable only for female recipients.

b. Progestins – payable only for female recipients.

c. Estrogen and Androgen Combinations – payable only for female recipients.

d. Estrogen and Progestin Combinations – payable only for female recipients.

e. Contraceptive Hormones – payable only for female recipients.

f. Testosterone – payable only for male recipients.

g. Androgen Hormone Inhibitor – payable only for male recipients.

2. Exception to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

D. Vitamins with Fluoride

1. Payable only for recipients up to age 21 years.

3. ANTIRETROVIRALS

Antiretrovirals for the treatment of HIV/AIDS are a covered benefit for Nevada Medicaid recipients. FDA approved antiretrovirals whose manufacturers participate in the federal Drug Rebate Program and are not DESI drugs, are covered.

4. DIABETIC SUPPLY PROGRAM

Diabetic Supplies are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Prior authorization is required for preferred and non-preferred diabetic products (including insulin delivery system and Continuous Glucose Monitor [CGM] receivers and readers).

Preferred diabetic product information is found at:
https://www.medicaid.nv.gov/providers/rx/diabeticsupplies.aspx

Preferred (including sensors and transmitters) and nonpreferred (including tubing, reservoirs for pumps and transmitters and sensors for CGM's) diabetic supplies do not require a prior authorization. These items require a documented diagnosis of diabetes mellitus type I (DM1) or gestational diabetes and recipients must meet all age restrictions stated on the manufacturer's label.

Pharmacy benefit allows a 100-day supply for insulin system and CGM supplies.

A. Preferred Insulin Delivery System

1. Approval will be given if the following criteria are met and documented:

a. Recipient must have a documented diagnosis of Diabetes Mellitus Type I or Gestational Diabetes; and

b. The product must be prescribed by or in consultation with an endocrinologist; and

c. The recipient must meet all age restrictions stated in the manufacturer's label; and

d. The recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple day injections of insulin (requiring at least three injections per day); and

e. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL, or

3. Prior use of an insulin pump with documented frequency of glucose self-testing of at least four times per day in the month immediately prior to the request.

2. Prior Authorization Guidelines

a. Initial prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

3. Recertification Request

a. Recertification of prior authorization approval will be given if the recipient has documented positive clinical response to the product (including current HbA1C).

b. Recertification prior authorization approval will be for one year.

B. Non-Preferred Insulin Delivery System

1. Approval will be given if the following criteria are met and documented:

a. In addition to meeting the "Preferred Insulin Delivery System" criteria, the recipient must also meet the following:

1. The recipient must have been trained to use the non-preferred product; and

2. The recipient must have benefited from use of the non-preferred product; and

3. The recipient must have one of the following reasons/special circumstances:

4. Recipient has had an allergic reaction to a preferred product or related supply; or

5. Recipient has a visual impairment which requires the use of a non-preferred product; or

6. Recipient has medical necessity justification (e.g. mental or physical limitation) which requires them to stay on their current product.

C. Preferred Continuous Glucose Monitors (CGMs)

1. Approval will be given if the following criteria are met and documented:

a. Recipient must have a documented diagnosis of Diabetes Mellitus Type I or Gestational Diabetes; and

b. Recipient must meet all age restrictions stated in the manufacturer's label; and

c. Recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple daily injections of insulin (requiring at least three injections per day); and

d. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; or

3. Recipient is currently using insulin pump therapy while continuing to need frequent dosage adjustments or experiencing recurring episodes of severe hypoglycemia (50 mg/dL).

2. Prior Authorization Guidelines

a. Initial prior authorization approval will be for one year.

b. Prior Authorization forms are available at: https/www.medicaid.nv.gov/providers/rx/rxforms.aspx

D. Non-Preferred Continuous Glucose Monitor (CGM)

1. Approval will be given if the following criteria are met and documented:

a. In addition to meeting the Preferred CGM criteria, the recipient must also meet the following:

1. Recipient has had an allergic reaction to a preferred product or related supply; or

2. Recipient has a visual impairment which requires the use of a non-preferred product; or

3. Recipient has medical necessity justification (e.g. mental or physical limitation) which requires them to stay on their current product; or

4. The recipient must have been trained to use the non-preferred product; and

5. The recipient must have benefited from use of the non-preferred product.

E. Test Strips and Lancets

1. Pharmacy Services billing information including Billing Manual and Quantity Limits is available at: https://www.medicaid.nv.gov/providers/rx/billinginfo.aspx

*Blood Glucose monitors with special features (e.g. voice synthesizers) require a prior authorization. For special blood glucose monitors, a diagnosis and a statement from the physician documenting the impairment is required with a prior authorization.