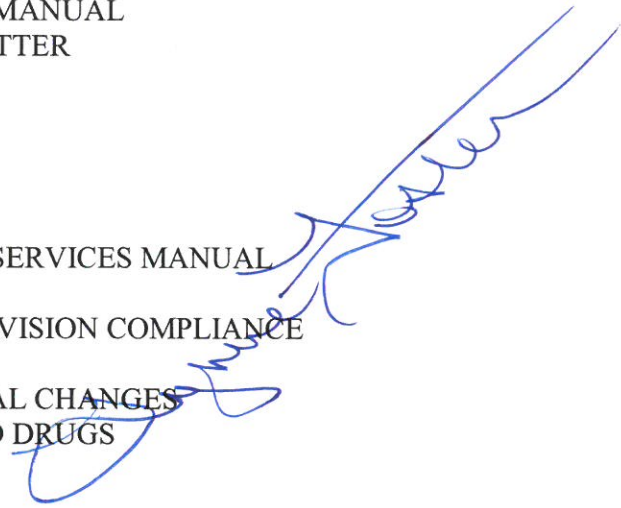


MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

December 14, 2017

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL
FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE
SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS



BACKGROUND AND EXPLANATION

The DHCFP proposes revisions to MSM Chapter 1200, Appendix A, based on recommendations approved at the August 24, 2017 Drug Use Review (DUR) Board meeting. The changes include the clinical criteria for Exondys 51® (eteplirsen) and Spinraza® (nusinersen) be added to Chapter 1200, and that Siliq® (brodalumab) be added to the list of Immunomodulators. The Board also removed the prior authorization criteria for COX-2 Inhibitors. The Board recommended the removal of the specific brand names under the therapeutic class of Antiemetics.

The following maintenance edits were made: Olysio® (simeprevir) was removed and “Previously reviewed by the DUR Board: April 28, 2016” was added to the section titled “Narcotic Withdrawal Therapy Agents.”

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 January 1, 2018.

MATERIAL TRANSMITTED

MTL NONE
Chapter 1200 – PRESCRIBED DRUGS

MATERIAL SUPERSEDED

MTL NONE
Chapter 1200 - PRESCRIBED DRUGS

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A. Section B.1-2	Cox-2 Inhibitors	Deleted section.
Appendix A. Section L	Immunomodulator Drugs	Added Siliq® (brodalumab) to the list of drugs.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A. Section BB	Narcotic Withdrawal Therapy Agents	Added, “Previously reviewed by the DUR Board: April 28, 2017.”
Appendix A. Section HH	Anti-Hepatitis Agents – Protease Inhibitor Agents	Removed “and Olysio® (simeprevir)” from the standard disclaimer related to prior authorizations and quantity limitations, (Paragraph 1). Added “and” between brand names Victrelis® (boceprevir) and Inciviek® (telaprevir). Removed comma after Victrelis® (boceprevir).
Appendix A. HH1.a.1.a.	Anti-Hepatitis Agents – Protease Inhibitor Agents	Removed the word “praluent.”
Appendix A. Section QQ	Antiemetic	Deleted brand name “Cesamet® (nabilone) and Marinol® (dronabinol)” from title and body of paragraph. Added drug class name Cannabinoid Antiemetics, to the title and the body of the paragraph.
Appendix A. Section QQ.1.a.	Antiemetic	Deleted brand name “Cesamet®.” Deleted parentheses surrounding “Nabilone.”
Appendix A. Section QQ.1.b.	Antiemetic	Deleted brand name “Marinol®.” Deleted parentheses surrounding “Dronabinol.”
Appendix A. Section MMM	Exondys 51® (eteplirsen)	Added new drug, Exondys 51® (eteplirsen) and criteria. Added Therapeutic Class, Date Reviewed by the DUR Board as August 24, 2017. Added standard disclaimer that Exondys 51® (eteplirsen) is subject to prior authorization and quantity limitations. Added Coverage and Limitations which must be met and documented. Added the recipient must have a diagnosis of Duchenne muscular dystrophy (DMD) and documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping and prescribed by or in consultation with a neurologist who has experience treating children

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and dose will not exceed 30 milligrams per kilogram of body weight once weekly.

Added Recertification Request Guidelines; authorization for continued use shall be reviewed at least every 12 months when the following criteria are met: One of the following: All of the following: patient has been on therapy for less than 12 months, and patient has experienced clinically significant benefit, and patient is tolerating therapy, and dose will not exceed 30 milligrams per kilogram of body weight once weekly, and prescribed by or in consultation with a neurologist who has experience treating children OR all of the following; patient has been on therapy for 12 months or more and patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients) and patient has experienced clinically significant benefit, and patient is tolerating therapy, and dose will not exceed 30 milligrams per kilogram of body weight once weekly, and prescribed by or in consultation with a neurologist who has experience treating children.

Added Prior Authorization Guidelines, initial request will be for six months.

**Appendix A.
Section NNN**

**Spinraza®
(nusinersen)**

Added new drug Spinraza® (nusinersen) and criteria.

Added Therapeutic Class, Date Reviewed by the DUR Board as August 24, 2017.

Added standard disclaimer that Spinraza® (nusinersen) is subject to prior authorization and quantity limitations.

Added Coverage and Limitations which must be met and documented.

Added the recipient must have a diagnosis of Spinal Muscular Atrophy (SMA) AND prescribed by or in consultation with a neurologist who has experience treating SMA.

Added Recertification Request Guidelines; authorization for continued use shall be reviewed at least every 12 months when the following criteria are met: One of the following: All of the following: patient has been on therapy for less than 12 months, and patient is

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maintaining neurological status, and patient is tolerating therapy, and prescribed by or in consultation with a neurologist who has experience in treating SMA.

Added Prior Authorization Guidelines, initial request will be for 12 months.

DIVISION OF HEALTH CARE FINANCING AND POLICY

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1200 INTRODUCTION

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

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

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

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

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

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1201 AUTHORITY

- A. The Code of Federal Regulations (CFR), Title 42, Public Health, Chapter IV, Center for Medicare and Medicaid Services (CMS), Subchapter C Medical Assistance Programs, Parts 430 through 456, states prescription drug coverage is an optional service under Title XIX.
- B. The Omnibus Budget Reconciliation Act (OBRA) of 1989 mandates additional preventive health care services for infants, children and young adults (newborn through age 20) eligible for Medicaid. These mandates provide that children and adolescents under age 21 receive follow-up services for a medically necessary condition discovered in a screening examination Early Preventative Screening and Diagnostic Testing (EPSDT), see Medicaid Services Manual (MSM) Chapter 1500; this includes prescription services.
- C. CFR Title 42 and Section 1927 of the Social Security Act, require states to provide for a Drug Utilization Review (DUR) program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary and not likely to result in adverse medical results (Social Security Administration (SSA), Title 19, (g)(1)(A)).
- D. Section 1927 of the Social Security Act allows a state to require a prior authorization on any covered outpatient drug, providing the prior authorization program complies with the requirements outlined in the act.

The Social Security Act requires the establishment of a DUR board to monitor therapeutic appropriateness, use of generic products, overutilization and underutilization of drugs and quality of care consistent with protecting the health of program beneficiaries.
- E. Chapter 422 of Nevada Revised Statute (NRS) amended by AB 384 to require the Department of Health and Human Services (DHHS) to:
 1. develop a list of preferred prescription drugs;
 2. manage prescription drug use through the use of prior authorization and step therapy; and
 3. create the Pharmacy and Therapeutics Committee.
- F. U.S. Troop Readiness, Veteran's Health Care, Katrina Recovery and Iraq Accountability Appropriations Act 2007, Section 7002(b) of the act requires Medicaid outpatient drugs (defined in Section 1927(k)(2) of the Social Security Act) will be reimbursable only if non-electronic written prescriptions are executed on a tamper-resistant prescription pad.

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- 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

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1202 RESERVED

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1203 POLICY

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

1203.1 COVERAGE AND LIMITATIONS

1. Covered drugs are subject to prior authorization and/or quantity limits and the following:
 - a. Section 1927(d)(1)(B)(i) of the Social Security Act (SSA) allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:
 1. American Hospital Formulary Service Drug Information;
 2. United States Pharmacopeia;
 3. DRUGDEX Information System; or
 4. Peer-reviewed medical literature.
 - b. Pharmaceuticals must be manufactured by companies participating in the Federal Medicaid Drug Rebate Program.
 - c. 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.
 - d. The Preferred Drug List (PDL) is a list of preferred outpatient drugs established by the Pharmacy and Therapeutics (P&T) Committee. Reference Medicaid Operations Manual (MOM) Chapter 200 for the P&T bylaws. Pharmaceuticals not on the preferred drug list, but within drug classes reviewed by the P&T Committee, require prior authorization, unless exempt under NRS or federal law or excluded through recommendations of the P&T Committee or excluded by the DHCFP.

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1. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard Preferred Drug List Exception prior authorization until or if the P&T Committee adds the drug class to the PDL and reviews the product or evidence.
2. New FDA approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the list of preferred prescription drugs and are not excluded under state plan or by NRS, are covered with an approved Standard Preferred Drug List Exception prior authorization until the P&T Committee can review the new evidence or drug.
3. Pharmaceuticals may require prior authorization due to step therapy protocols regardless of inclusion in the PDL.
4. If the P&T Committee determines that there are no significant differences between drugs within specific classes based on clinical efficacy and safety, the DHCFP or its Quality Improvement Organization (QIO)-like vendor may consider cost in determining which drugs are selected for inclusion on the PDL.
5. Due to the 76th Special Session and in accordance with Senate Bill (SB) 4, every therapeutic prescription drug that is classified as an anticonvulsant medication or antidiabetic medication that was covered by the Medicaid program on June 30, 2010 must be included on the PDL as a preferred drug. If a therapeutic prescription drug that is included on the list of preferred prescription drugs is prescribed for a clinical indication other than the indication for which it was approved as of June 30, 2010, the Committee shall review the new clinical indication for that drug in accordance with Section 1203 of this chapter.
6. Due to the 76th Special Session and in accordance with SB 4, the P&T Committee must prefer atypical and typical antipsychotic medications that are prescribed for the treatment of a mental illness, anticonvulsant medications and antidiabetic medications for a patient who is receiving services pursuant to Medicaid if the patient:
 - a. was prescribed the prescription drug on or before June 30, 2010, and takes the prescription drug continuously, as prescribed, on and after that date; and
 - b. maintains continuous eligibility for Medicaid.

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

2. 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.

a. Coverage and Limitations

1. Allergy to all preferred medications within the same class;
2. Contraindication to or drug-to-drug interaction with all preferred medications within the same class;
3. History of unacceptable/toxic side effects to all preferred medications within the same class;
4. Therapeutic failure of two preferred medications within the same class;
5. If there are not two preferred medications within the same class, therapeutic failure only needs to occur on the one preferred medication;
6. An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or a Food and Drug Administration (FDA)-approved indication;
7. 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;
8. For atypical or typical antipsychotic, anticonvulsant and antidiabetic medications the recipient demonstrated therapeutic failure on one preferred agent.

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

3. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

- a. Agents used for weight loss.

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- b. Agents used to promote fertility.
- c. Agents used for cosmetic purposes or hair growth.
- d. Yohimbine.
- e. Drug Efficacy Study and Implementation (DESI) list “Less than Effective Drugs”: In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is Identical, Related or Similar to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the Medicaid Drug Rebate Program. This listing is available on the Centers for Medicare and Medicaid Services (CMS) website at:
http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp

This includes pharmaceuticals designated “ineffective” or “less than effective” (including identical, related or similar drugs) by the FDA as to substance or diagnosis for which prescribed.
- f. 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.
- g. Agents used for impotence/erectile dysfunction.

4. Refills

A refill is a prescription subject to the limitations below:

- a. Authorized refills are valid only from the pharmaceutical provider dispensing the original prescription, pursuant to Nevada Administrative Code (NAC) Chapter 639.
- b. Refill intervals must be consistent with the dosage schedule indicated on the original prescription. If a prescription is for a 34-day supply, a consistent refill would be filled in 30 days; an inconsistent refill date would be filled in 20 days from the original fill. Lost Medications. Nevada Medicaid does not pay for replacement of lost, stolen or otherwise destroyed medications even if a physician writes a new prescription for the medication. It is the responsibility of the recipient to replace these medications. Prior authorization may be granted in life-threatening situations and for maintenance medications only. See Maintenance Medications in this section for more information on maintenance medications.

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5. Early Refills

- a. 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.
- b. 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.
- c. 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.

6. Maintenance medications

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

- a. 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.)
- b. 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.
- c. The maximum quantity of medication per prescription for maintenance pharmaceuticals for chronic conditions for outpatients, payable by Medicaid, may be a 100-day (3-month) supply.

The following drug categories are considered maintenance medications:

1. Antianginals*;
2. Antiarrhythmics*;
3. Anticonvulsants;
4. Antidiabetics*;

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5. Antihypertensives*;
6. Cardiac Glycosides*;
7. Diuretics*;
8. Thyroid preparations;
9. Estrogens*;
10. Progesterone*; and
11. Oral/Topical Contraceptives*.

- a. Drug classes identified with (*) are required to be dispensed in a 3-month (up to 100 day) supply, except for initial fills which can be dispensed in quantities of less than three months (100 days).
- b. This requirement does not include skilled nursing facility pharmacies.

7. Emergency supply of medication

- a. In an emergency situation, dispensing of up to a 96-hour supply of covered outpatient drugs that require prior authorization will be allowed.
- b. Nevada Medicaid requires prior payment authorization for medications identified as requiring prior authorization.
- c. 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.
- d. 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.
- e. An approved PA (if required) will be necessary to get additional medication.

8. Nevada Check Up (NCU)

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

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9. Immunizations

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

- a. Childhood Immunizations: All childhood immunizations are covered without prior authorization under the Healthy Kids Program. Refer to MSM Chapter 1500, Healthy Kids Program, for more information on childhood immunizations.
- b. Adult Immunizations: Adult immunizations such as tetanus, flu vaccine and pneumococcal vaccine are covered without prior authorization. For a list of covered adult immunizations, please reference the Physician's Fee Schedule under "Professional Rates" at: <http://www.dhcfp.nv.gov/RatesUnit.htm>
- c. Human Papillomavirus (HPV) Vaccine: The quadrivalent HPV vaccine, the bivalent HPV vaccine and the 9-valent HPV vaccine (for both males and females) is covered for Medicaid eligibles age 19 years through 26 years, based on the US FDA approved indications. These may be accessed by following the link: <http://www.fda.gov/cber/products/gardasil.htm>. The HPV vaccines are available through the State Division of Public and Behavioral Health (DPBH) as part of the Vaccines for Children (VFC) program for eligible females and males age nine through 18 years. Please refer to MSM Chapter 1500 for more information on the VFC program.
- d. Pharmacies may administer childhood and adult vaccines/immunizations.
 1. 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.
 2. Pharmacies must receive childhood immunizations through the VFC Program. The DHCFP or Nevada Medicaid and NCU do not reimburse for vaccines included in the VFC Program.
 3. Covered immunizations not included in the VFC Program will be reimbursable per the Nevada Medicaid and NCU Pharmacy Manual.
 4. If the pharmacist administers the immunization, the dispensing fee will not be reimbursed. An administration fee is paid instead.

10. Pharmacist Submitted Prior Authorizations

- a. The DHCFP will allow pharmacists to submit a PA if:

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

11. Dispensing Practitioners:

- a. Must have a current Certificate of Registration through the Nevada State Board of Pharmacy. Refer to NRS 639.070 and NAC 639.390; and
- b. Must be enrolled with Nevada Medicaid provider enrollment as a Provider Type 28; and
- c. Dispensing practitioners' offices must be located in the State of Nevada; and
- d. All prior authorization criteria and quantity limitations apply to dispensing practitioner claims; and
- e. Only Provider Type 28 can be reimbursed for a dispensing fee; and
- f. All claims must be submitted in the National Council for Prescription Drug Programs (NCPDP) format through Medicaid's Point of Sale (POS) system; and
- g. 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.

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3. Providers may submit override codes using the (NCPDP) standard interactive DUR codes. Override codes may be submitted on the initial claim. A denied claim does not have to be on file.
4. No long term override codes are issued, codes must be entered each time errors occur. Reference the Nevada Medicaid and NCU Pharmacy Manual (Pharmacy Manual) for more information on the current Pro-DUR edits and override procedures.
5. All drugs are subject to quantity limitations. Refer to the Nevada Medicaid and NCU Pharmacy Manual for established quantity limits.

b. Retro Drug Utilization Review (DUR)

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

c. Drug Utilization Review (DUR)

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

d. Eligibility

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

e. Lock-in Program

When a recipient has shown patterns of abuse/misuse of Nevada Medicaid benefits, or the DHCFP has determined that the recipient requires close medical management, the recipient may be “locked-in” to a specific pharmacy and/or provider. This means that Medicaid will only pay for controlled substance prescriptions/medical services at a single pharmacy/provider.

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

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controlled substance prescriptions filled in 60 days.

If the recipient has filled ten or more controlled substance prescriptions in the past 60-day period (includes controlled substance pharmaceuticals given in the emergency room) then the clinical review continues with the following criteria:

- a. The recipient has utilized more than one pharmacy in the past 60-day period; or
 - b. The recipient has utilized more than three physicians in the past 60-day period; or
 - c. The recipient has utilized the emergency room(s) for receiving controlled substances; or
 - d. The recipient has been diagnosed with a drug dependency related condition; or
 - e. The dispensed quantity per prescription of controlled substances appears excessive by the clinical review team; or the recipient has other noted drug seeking behaviors(s).
2. The POS system will not allow another pharmacy to bill for controlled substance prescriptions, and a message will be given at the time of service to notify the pharmacy that the recipient is locked-in. Any non-controlled substance prescriptions can be filled at any pharmacy.
 3. Recipients (who are locked-in to one pharmacy) or their provider/prescriber can change their locked-in pharmacy at any time by contacting their Medicaid District Office.
 4. Pharmacies may call the Technical Call Center for an override to the locked-in pharmacy if:
 - a. The locked-in pharmacy is out of stock.
 - b. The locked-in pharmacy is closed.
 - c. The recipient is out of town and cannot access the locked-in pharmacy.

3. Generic Substitution

Per NRS Chapter 639, if the practitioner has not indicated that generic substitution is

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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 generic substitution.
- e. Certification is not required if a generic is not manufactured.
- f. A fax copy/verbal order may be taken by the pharmacist from the physician but the pharmacy must obtain an original printed copy and keep on file.

1203.1B SERVICE DELIVERY MODEL

For the rate and reimbursement methodology see MSM Chapter 700, Rates. For POS claims refer

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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 Social Security Act (SSA).

1. Retail pharmacies (billed through POS).

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

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

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

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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.

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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

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

- e. Even if "no other insurance" is indicated on the eligibility file, the claim will be processed as a Third Party Liability (TPL) claim if the pharmacy submits.
- f. If other insurance is indicated on the eligibility file, the claim will be processed as a TPL regardless of what TPL codes the pharmacy submits.
- g. In all cases, the Nevada Medicaid "allowed amount" will be used when calculating payment. In some cases, this may result in a "0" payment, when the insurance carrier pays more than the Medicaid "allowable amount."
- h. In order to facilitate the TPL/COB process, Nevada Medicaid will allow providers to override "days supply limits" and/or "Drug Requires PA" conditions by entering a value of "5" (exemption from prescription limits) in the PA/MC CODE field (NCPDP #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, Ophthalmic/Otic Solutions: must be billed by milliliters (mls). For example, if 560ml of guaifenesin is dispensed, the quantity entered will be 560.

PLEASE NOTE:

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

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

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

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PLEASE NOTE:

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

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

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

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

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

1 ounce = 30ml

1 ounce = 30g

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

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

Powdered Injectables (vials): must be billed by “each” vial given per dose. For example if the recipient receives Ampicillin 1g every six hours for one week, the quantity entered will be 1, as only one vial is used per dose (assuming a 1gm vial is used), and the # of doses entered will be 28 (4 per day x 7 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.

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

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

b. Provider Numbers

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

7. State Maximum Allowable Cost (SMAC)

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-

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like vendor's SMAC Coordinator for investigation and resolution.

4. If it is determined the SMAC is negatively impacting access to care for recipients, the SMAC Coordinator has the authority to:
 - a. adjust SMAC pricing for the particular claim being appealed; and
 - b. make changes to the SMAC pricing file.
5. Appeals will be responded to within three working days of the referral to the SMAC Coordinator.

1203.1C PRIOR AUTHORIZATION (PA) PROCEDURES

1. 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. PA requests must be submitted on the appropriate Prior Authorization Request form. Pharmacy PA forms can be found at the following web site:
<https://www.medicaid.nv.gov/providers/rx/rxforms.aspx>
3. LTC drug claims are subject to PA requirements.
4. The QIO-like vendor will process the PA request within 24 hours of receipt.
 - a. The requesting practitioner will be advised of the PA status (approval, denial, pending further information) within 24 hours of the receipt.
 - b. For PA requests in which the QIO-like vendor has pended the request for further information, the prior authorization will deny if the practitioner does not respond to a request for further information within three working days.
5. An approved PA will be entered in the POS system prior to the dispensing of the medication. There may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).
6. The Nevada Medicaid QIO-like vendor will send all Notice of Decision denial of service letters. Reference MSM Chapter 3100 for the information on hearings.
7. Refer to the Nevada Medicaid and Check Up Pharmacy Billing Manual for more information.

1203.2 INTRAVENOUS (IV) THERAPY

For specific instructions related to billing via the POS system, refer to the Nevada Medicaid Check-

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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.

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1204 HEARINGS

1204.1 Please reference MSM Chapter 3100 for the Medicaid Hearings process.

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All drugs in Appendix A may be subject to Quantity Limitations.

Check the Nevada Medicaid and Nevada Check Up Pharmacy Manual for a listing of the exact Quantity Limitation.

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

A. Proton Pump Inhibitors (PPIs)

Therapeutic Class: Proton Pump Inhibitor

Last Reviewed by the DUR Board: April 24, 2014

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

1. Coverage and Limitations

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

- a. Prior Authorization is not required for once per day treatment if the following criteria is met:
 1. The recipient is not on concomitant therapy of an H2 antagonist or sucralfate.
- b. Requests for PPIs exceeding once per day must meet one of the following:
 1. The recipient has failed an appropriate duration of once daily dosing; or
 2. The recipient has a diagnosis of a hypersecretory condition (e.g., Zollinger-Ellison Syndrome), esophagitis, Barrett's esophagitis, reflux esophagitis or treatment of an ulcer caused by H.Pylori.

2. Prior Authorization Guidelines

Prior authorization approval will be for up to one year.

Prior Authorization forms are available at:

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

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B. RESERVED

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

Therapeutic Class: ADHD/ADD Agents

Last Reviewed by the DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

a. General Criteria (Children and Adults)

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

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

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

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

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

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

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disorder, substance abuse disorder, conduct disorder, personality disorder, mood disorder and anxiety disorder, possible family stressors, any history of abuse or neglect.

2. Exception Criteria

- a. Prescriptions for ADD/ADHD medications do not require prior authorization for children five years of age, up to 18 years of age, if the following criteria are met and documented:
 1. The recipient is at least six years of age for short acting stimulants or at least six years of age for long-acting stimulants, long acting alpha agonists, atomoxetine);
 2. The medication is prescribed by a psychiatrist; and
 3. An ICD code for Attention Deficit Disorder with or without Hyperactivity is documented on the prescription and transmitted on the claim.

3. Prior Authorization Guidelines

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

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D. Growth Hormone

Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 25, 2013

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

1. Coverage and Limitations:

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

- a. Genotropin® (somatropin); Humatrope® (somatropin); Norditropin® (somatropin); Nutropin® (somatropin); Omnitrope® (somatropin); Saizen® (somatropin); Tev-Tropin® (somatropin):
 1. Children (up to age 21, with open epiphyses and with remaining growth potential) must meet all of the following:
 - a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy; and
 - b. The recipient has had an evaluation ruling out all other causes for short stature; and
 - c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones.

The recipient must then meet one of the following:

1. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender; or
2. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute), and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or
3. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and their height is at least two standard deviations below the mean or

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

4. The recipient is a newborn infant with evidence of hypoglycemia, and has low growth hormone level (<20 ng/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP) 3 (no stimulation test required for infants); or
5. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.

And recipient must meet one of the following:

- a. The recipient has failed two growth hormone stimulation tests (<10 ng/mL); or
 - b. The recipient has failed one growth hormone stimulation test (<10 ng/mL) and one IGF-1 or IGFBP-3 test; or
 - c. The recipient has failed one growth hormone stimulation test (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), adrenocorticotrophic hormone (ACTH) or antidiuretic hormone (ADH).
2. Adults (age 21 years and older, with closed epiphyses, and no remaining growth potential) must meet all of the following:
- a. The recipient is being evaluated by an endocrinologist; and
 - b. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones; and
 - c. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation); and

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The recipient must then meet one of the following:

1. The recipient has failed two growth hormone stimulation tests (<5 ng/mL); or
 2. The recipient has failed one growth hormone stimulation test (<5 ng/mL) and one IGF-1 or IGFBP-3 test; or
 3. The recipient has failed one growth hormone stimulation test (<5 ng/mL) or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH), and has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.
3. Continued authorization will be given for recipients (up to age 21, with remaining growth potential) who meet all of the following:
- a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age or Turner Syndrome; and
 - b. The recipient's epiphyses are open; and
 - c. The recipient's growth rate on treatment is at least 2.5 cm/year; and
 - d. The recipient does not have evidence of an expanding lesion or tumor formation; and
 - e. The recipient has not undergone a renal transplant.
4. Continued authorization will be given for recipients (age 21 years and older, with closed epiphyses and no remaining growth potential) who meet all of the following:
- a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease; and
 - b. There is documentation of improvement in clinical manifestations associated with growth hormone deficiency.

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b. Serostim® (somatropin)

Recipients must meet all of the following:

1. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and
2. The medication is indicated to increase lean body mass, body weight and physical endurance; and
3. The recipient is receiving and is compliant with antiretroviral therapy; and
4. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m²; and
5. The recipient has experienced an adverse event, allergy or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent; and
6. The recipient has experienced an adverse event, allergy or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone) or the recipient has a contraindication to treatment with these agents.

c. Zorbtive® (somatropin)

Recipients must meet all of the following:

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

2. Prior Authorization Guidelines:

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

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

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E. Over-the-Counter Medications

Last Reviewed by the DUR Board: N/A

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

1. Coverage and Limitations

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

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

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

Approval will be for a one month time limit.

Prior Authorization forms are available at:

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

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F. Transdermal Fentanyl

Therapeutic Class: Analgesics, Narcotic

Last Reviewed by the DUR Board: January 22, 2015

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

1. Coverage and Limitations

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

- a. Patient cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics or PRN dosing with short-acting opioid.
- b. Patient requires continuous opioid administration.
- c. Prescribers are encouraged to check the Nevada State BOPs Prescription Monitoring Program (PMP) prior to prescribing narcotic analgesics. Refer to the PMP website at <http://bop.nv.gov/links/PMP/>.
- d. If transitioning from another opioid, daily morphine equivalent doses are used to calculate the appropriate fentanyl patch dose.
 1. Morphine 60-134 mg/day PO; Initial Transdermal Fentanyl dose 25 mcg/hr.
 2. Morphine 135-224 mg/day PO; initial Transdermal Fentanyl dose 50 mcg/hr.
 3. Morphine 225-314 mg/day PO; initial Transdermal Fentanyl dose 75 mcg/hr.
 4. Morphine 315-404 mg/day PO; initial Transdermal Fentanyl dose 100 mcg/hr.
 5. Morphine 405-494 mg/day PO; initial Transdermal Fentanyl dose 125 mcg/hr.

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6. Morphine 495-584 mg/day PO; initial Transdermal Fentanyl dose 150 mcg/hr.
7. Morphine 585-674 mg/day PO; initial Transdermal Fentanyl dose 175 mcg/hr.
8. Morphine 675-764 mg/day PO; initial Transdermal Fentanyl dose 200 mcg/hr.
9. Morphine 765-854 mg/day PO; initial Transdermal Fentanyl dose 225 mcg/hr.
10. Morphine 855-944 mg/day PO; initial Transdermal Fentanyl dose 250 mcg/hr.
11. Morphine 945-1034 mg/day PO; initial Transdermal Fentanyl dose 275 mcg/hr.
12. Morphine 1035-1124 mg/day PO; initial Transdermal Fentanyl dose 300 mcg/hr.

2. Prior Authorizations

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

Prior Authorization forms are available at:

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

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G. Immediate-Release Fentanyl Products

Therapeutic Class: Analgesics, Narcotic

Last Reviewed by the DUR Board: July 25, 2013

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

1. Coverage and Limitations

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

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

The recipient must meet all of the following:

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

2. Prior Authorization Guidelines

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

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H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)

Last Reviewed by the DUR Board: January 24, 2008

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

1. Coverage and Limitations

Recipients must meet one of the following criteria for coverage:

- a. Achieve and maintain hemoglobin levels within the range of 10 to 12 gm/dl in one of the following conditions:
 - 1. Treatment of anemia secondary to myelosuppressive anticancer chemotherapy.
 - 2. Treatment of anemia related to zidovudine therapy in HIV-infected patients.
 - 3. Treatment of anemia secondary to ESRD.
- b. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) does not have this indication.

2. Non-Covered Indications

- a. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding or bone marrow fibrosis.
- b. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) or erythroid cancers.
- c. Anemia of cancer not related to cancer treatment.
- d. Any anemia associated only with radiotherapy.
- e. Prophylactic use to prevent chemotherapy-induced anemia.
- f. Prophylactic use to reduce tumor hypoxia.
- g. Patients with erythropoietin-type resistance due to neutralizing antibodies.

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

3. Prior Authorizations

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

Prior Authorization forms are available at:

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

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I. Anti-Fungal Onychomycosis

Therapeutic Class: Antifungal Agents

Last Reviewed by the DUR: September 3, 2015

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

1. Coverage and Limitations

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

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

2. Inadequate response after an appropriate length of therapy to either terbinafine tablets or itraconazole capsules or an adverse reaction or a contraindication to terbinafine tablets or itraconazole capsules or a clinical rationale why the recipient cannot use terbinafine tablets or itraconazole capsules.
 - f. Onmel (itraconazole) tablets: Clinical rationale documenting why the recipient cannot or should not use terbinafine tablets or itraconazole capsules.
2. Prior Authorization Guidelines
- a. The extent of Prior Authorization approvals will be based on the appropriate use for the individual agents.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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J. Pramlintide Injection (Symlin®)

Therapeutic Class: Antihyperglycemic, Amylin Analog-Type

Last Reviewed by the DUR Board: September 21, 2006

Pramlintide injection is subject to prior authorization and age restriction:

1. Coverage and Limitations (For recipients 15 years or older)

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

- a. Diagnosis of Type 1 or Type 2 Diabetes Mellitus;
- b. Documentation that recipient has not achieved desired HbA1c despite optimal insulin therapy;
- c. Documented HbA1c<9%;
- d. Patient is competent and has received diabetic education, able to self-administer drug and willing to perform blood glucose monitoring;
- e. Approval period of six months; and
- f. Exclusion criteria:
 1. HbA1c>9%;
 2. Confirmed diagnosis of gastroparesis;
 3. Use of drugs that alter GI motility;
 4. Presence of hypoglycemia unawareness; and
 5. Use of alpha-glucosidase inhibitors (e.g. acarbose, miglitol).

2. Prior Authorization Guidelines

Prior Authorization forms are available at:

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

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K. Regranex®

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

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

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

Prior Authorization forms are available at:

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

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L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators

Last Reviewed by the DUR Board: November 5, 2015

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

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

1. Coverage and Limitations

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

a. For all recipients:

1. The recipient has had a negative tuberculin test; and
2. The recipient does not have an active infection or a history of recurring infections; and
3. The approval will not be given for the use of more than one biologic at a time (combination therapy); and
4. Each request meets the appropriate diagnosis-specific criteria (b-j).

b. Rheumatoid Arthritis (RA):

1. The recipient has a diagnosis of moderately to severely active RA; and
2. The recipient is 18 years of age or older; and
3. The recipient has had a rheumatology consultation, including the date of the visit; and one of the following:
 - a. The recipient has had RA for $\leq$ six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

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hydroxychloroquine, leflunomide, minocycline and sulfasalazine);
or

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

c. Psoriatic Arthritis:

- 1. The recipient has a diagnosis of moderate or severe psoriatic arthritis; and
- 2. The recipient is 18 years of age or older; and
- 3. The recipient has had a rheumatology consultation including the date of the visit or a dermatology consultation including the date of the visit; and
- 4. The recipient had an inadequate response to any one nonsteroidal anti-inflammatory drug (NSAID) or a contraindication to treatment with an NSAID or to any one of the following DMARDs (methotrexate, leflunomide, cyclosporine or sulfasalazine).

d. Ankylosing Spondylitis:

- 1. The recipient has a diagnosis of ankylosing spondylitis; and
- 2. The recipient is 18 years or older; and
- 3. The recipient has had an inadequate response to NSAIDs; and
- 4. The recipient has had an inadequate response to any one of the DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, leflunomide, minocycline).

e. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

- 1. The recipient has a diagnosis of moderately or severely active juvenile RA or juvenile idiopathic arthritis; and
- 2. The recipient is at an appropriate age, based on the requested agent, and:
 - a. Abatacept: Six years of age or older.

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- b. Adalimumab, canakinumab, etanercept, tocilizumab: Two years of age or older.
 - 3. And the recipient has at least five swollen joints; and
 - 4. The recipient has three or more joints with limitation of motion and pain, tenderness or both; and
 - 5. The recipient has had an inadequate response to one DMARD.
- f. Plaque Psoriasis:
 - 1. The recipient has a diagnosis of chronic, moderate to severe plaque psoriasis; and
 - 2. The recipient is 18 years of age or older; and
 - 3. The agent is prescribed by a dermatologist; and
 - 4. The recipient has failed to adequately respond to a topical agent; and
 - 5. The recipient has failed to adequately respond to at least one oral treatment.
- g. Crohn's Disease:
 - 1. The recipient has a diagnosis of moderate to severe Crohn's Disease; and
 - 2. The recipient is at an appropriate age, based on the requested agent:
 - a. Adalimumab, infliximab: Six years of age or older.
 - b. All others: 18 years of age or older.
 - 3. And the recipient has failed to adequately respond to conventional therapy (e.g. sulfasalazine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or
 - 4. The recipient has fistulizing Crohn's Disease.
- h. Ulcerative Colitis:
 - 1. The recipient has a diagnosis of moderate to severe ulcerative colitis; and
 - 2. The recipient is at an appropriate age, based on the requested agent:
 - a. Infliximab: Six years of age or older.

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- b. All others: 18 years of age or older.
 - 3. And the recipient has failed to adequately respond to one or more of the following standard therapies:
 - a. Corticosteroids;
 - b. 5-aminosalicylic acid agents;
 - c. Immunosuppressants; and/or
 - d. Thiopurines.
 - i. Cryopyrin-Associated Periodic Syndromes (CAPS): Familial Cold Autoinflammatory Syndromes (FCAS) or Muckle-Wells Syndrome (MWS):
 - 1. The recipient has a diagnosis of FCAS or MWS; and
 - 2. The recipient is at an appropriate age, based on the requested agent:
 - a. Canakinumab: Four years of age or older.
 - b. Rilonacept: 12 years of age or older.
 - j. Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID):
 - 1. The recipient has a diagnosis of NOMID.
- 2. Prior Authorization Guidelines

Prior Authorization forms are available at:

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

Prior authorization approval will be for one year.

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M. Topical Immunomodulators

Therapeutic Class: Immunomodulators, Topical
 Last Reviewed by the DUR Board: April 26, 2007

Elidel®
 Protopic®

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

1. Coverage and Limitations

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

- a. Patient must have a therapeutic failure with the use of a topical steroid.
- b. Patient has a documented diagnosis of Atopic Dermatitis:
 1. Elidel®: for mild to moderate, for ages $\geq$ two years.
 2. Protopic® 0.03%; moderate to severe, for ages $\geq$ two years.
 3. Protopic® 0.1%; moderate to severe, for ages $\geq$ 18 years.
- c. Not for chronic use.
- d. Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.
- e. Not recommended for use in immunocompromised patients.

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

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N. Psychotropic Medications for Children and Adolescents

Therapeutic Class: Psychotropic Agents

Last Reviewed by the DUR Board: September 3, 2015

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

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

1. Coverage and Limitations

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

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

1. Antipsychotics
2. Antidepressants
3. Mood Stabilizers (including lithium and anticonvulsants used for behavioral health indications.)
4. Sedative hypnotics
5. Antianxiety agents

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

1. For psychotropic medications in this age group, when possible, be prescribed by or in consultation with a child psychiatrist.
2. Psychotropic medication must be part of a comprehensive treatment plan that addresses the education, behavioral management, living home environment and psychotherapy.
3. Physician and/or prescriber monitoring is required while the recipient is utilizing any psychotropic medication.
 - a. For recipients who are in initial treatment (have not received any doses previously) or are continuing therapy but are considered

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- unstable (has had a dose change in the last three months), medical documentation must support a monthly or more frequent visit with the physician and/or prescriber. If the recipient was discharged from an institution on the medication, the follow-up visit(s) can be with their treating physician and/or prescriber.
- b. For recipients who are considered stable in their medication therapy, medical documentation must support visits with the treating physician at least every three months.
 - c. Poly-pharmacy: Each psychotropic medication prescribed must be independently treating a specific symptom and/or diagnosis.
 1. Poly-pharmacy (intra-class) is defined as more than one drug within the same therapeutic class within a 60-day time period.
 - a. Prior authorization approval is required for two or more drugs in the same therapeutic class within a 60-day period.
 2. Poly-pharmacy (inter-class) is defined as more than one drug across different therapeutic classes within a 60-day time period.
 - a. Prior authorization approval is required for four or more drugs across all psychotropic therapeutic classes listed in this policy within a 60-day time period.
 3. Approval for poly-pharmacy may be given in situations where the requested medication(s) will be used for cross tapering and situations where the recipient will be discontinuing the previously prescribed agent. A 30-day cross-taper will be allowed.
 4. Approval for poly-pharmacy may be given for a medication to augment the effect of another psychotropic medication as long as the purpose of the poly-pharmacy is clearly documented in the recipient's medical record and each agent is supported by individual authorizations.
 5. The recipient must have a trial of each individual medication alone. The reasons for an inadequate response must be documented in the medical record.
 6. For intra-class and inter-class poly-pharmacy, all psychotropic medications must be utilized for a medically accepted indication as established by the Food and Drug Administration (FDA), and/or peer reviewed literature.
 - d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a prior authorization approval

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

- e. Continuity of Care. In an effort to improve recipient safety and quality of care:
 - 1. For recipients under 18 years of age, who have been discharged from an institutional facility, they will be allowed to remain on their discharge medication regimen for up to six months to allow the recipient time to establish outpatient mental health services. The initial prior authorization after discharge must document the name of the discharge institution and the date of discharge.
 - 2. For all other recipients under the age of 18, a six month prior authorization will be granted to cover current medication(s) when it is documented that the recipient has been started and stabilized. This will allow the recipient time to establish services if necessary and to transition to medication(s) per Nevada Medicaid policy.
- 2. Exceptions to this criteria for Anticonvulsants and ADD/ADHD medications:
 - a. Treatment for seizure disorders with anticonvulsants are not subject to this policy. The ICD Codes for Epilepsy and/or Convulsions will bypass the prior authorization requirement at the pharmacy POS if the correct ICD Code is written on the prescription and transmitted on the claim. Or the prior authorization requirement will be overridden for anticonvulsant medications when the prescriber has a provider Specialty Code of 126, neurology or 135, pediatric neurology, in the POS system.
 - b. The current policy for treatment of ADD/ADHD is to be followed. Refer to this Chapter's Appendix A.

3. Prior Authorization Guidelines:

Prior Authorization forms are available at:

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

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O. Lidoderm 5% Patches®

Therapeutic Class: Topical, Local Anesthetics

Last Reviewed by the DUR Board: April 30, 2009

1. Coverage and Limitations

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

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

- a. If an ICD code for herpes zoster is documented on the prescription; or
- b. Completion of a prior authorization documenting a diagnosis of Post Herpetic Neuralgia/Neuropathy.

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P. Monoclonal Antibody Agents

Therapeutic Class: Respiratory Monoclonal Antibody Agents

Last Reviewed by the DUR Board: July 28, 2016

Xolair previously reviewed: July 24, 2014 and April 23, 2015

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

1. Coverage and Limitations

a. Xolair® (Omalizumab)

1. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies.
2. All of the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:
 - a. The recipient must be 12 years of age or older; and
 - b. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and
 - c. The prescriber must be either a pulmonologist or allergist/immunologist; and
 - d. The recipient must have had an inadequate response, adverse reaction or contraindication to inhaled, oral corticosteroids; and
 - e. The recipient must have had an inadequate response, adverse reaction or contraindication to an oral second generation antihistamine; and
 - f. The recipient must have had an inadequate response, adverse reaction or contraindication to a leukotriene receptor antagonist; and
 - g. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and
 - h. The recipient's current weight must be recorded; and
 - i. The requested dose is appropriate for the recipient's pre-treatment serum IgE and body weight (see Table 1).

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3. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU); and
 - a. The recipient is 12 years of age or older; and
 - b. The recipient must have had an inadequate response, adverse reaction or contraindication to two different oral second generation antihistamines; and
 - c. The recipient must have had an inadequate response, adverse reaction or contraindication to an oral second generation antihistamine in combination with a leukotriene receptor antagonist; and
 - d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist or a rheumatologist regarding the diagnosis and treatment recommendations; and
 - e. The requested dose is:
 1. Initial therapy: 150 mg every four weeks or 300 mg every four weeks and clinical rationale for starting therapy at 300 mg every four weeks has been provided.
 2. Continuation of therapy: 150 mg or 300 mg every four weeks.
- b. Nucala® (mepolizumab), Cinqair® (reslizumab)
 1. All the following criteria must be met and documented:
 - a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and
 - b. The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; and
 - c. The recipient must be an appropriate age:
 1. Mepolizumab: 12 years of age or older
 2. Reslizumab: 18 years of age or older

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- d. And, 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:
<http://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				

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Q. Long-Acting Narcotics

Therapeutic Class: Analgesics, Narcotic

Last Reviewed by DUR Board: April 28, 2016

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

1. Coverage and Limitations

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

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

- a. The recipient has a diagnosis of terminal cancer; or
- b. All the the following criteria must be met:
 1. The recipient is 18 years of age or older; and
 2. The requested agent will be used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
 3. There is documentation in the recipient's medical record that alternative agents (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain.

2. Prior Authorization Guidelines:

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

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R. Toradol® (ketorolac tromethamine) tablets

Therapeutic Class: Nonsteroidal Antinflammatory Drugs, NSAIDS

Last Reviewed by the DUR Board: Not Available

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

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

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

Prior Authorization forms are available at:

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

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S. Anti-Migraine Medications

Therapeutic Class: Triptans

Last Reviewed by the DUR Board: September 21, 2006

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

1. Coverage and Limitations

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

- a. The recipient’s current medication history documents the use of prophylactic medications for migraine headache or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or
- b. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.
 1. Recipient’s current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).
 2. Recipients whose current medication history indicates the use of propranolol will NOT be granted prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.
 3. Prior authorization will NOT be given to patients with ischemic heart disease.

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

2. Prior Authorization Guidelines

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

Prior Authorization forms are available at:

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

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T. Tobacco Cessation Products

Therapeutic Class: Tobacco Cessation Agents

Last Reviewed by the DUR Board: Not Available

Smoking cessation products, including patches, gums, lozenges and inhalers (based on the recipients' route of choice), are subject to quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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U. Xopenex® (Levalbuterol)

Therapeutic Class: Beta Adrenergic Agents

Last Reviewed by the DUR Board: July 26, 2012

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

1. Coverage and Limitations

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

2. Prior Authorization Guidelines

Prior Authorization forms are available at:

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

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V. Anti-Insomnia Agents (Sedative Hypnotics)

Therapeutic Class: Anxiolytics, Sedatives and Hypnotics

Last Reviewed by the DUR Board: September 3, 2015

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

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

1. Coverage and Limitations

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

- a. A FDA approved ICD diagnosis code, such as insomnia, is documented on the prescription and transmitted on the claim; or
- b. A prior authorization with a FDA approved diagnosis, such as insomnia, is submitted.

2. Prior Authorization Guidelines

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

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W. Inhaled Anticholinergic Agents

Therapeutic Class:

Last Reviewed by the DUR Board:

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

1. General Criteria

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

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

Therapeutic Class: Antiemetics, Antivertigo Agents

Last Reviewed by the DUR Board: October 28, 2010

1. Coverage and Limitations

5-HT3 Antiemetics are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

- a. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses;
or
- b. The recipient is receiving chemotherapy treatments more often than once a week;
or
- c. The recipient has a diagnosis of AIDS associated nausea and vomiting; or
- d. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.

2. Prior Authorization Guidelines

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

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Y. Synagis® Palivizumab

Therapeutic Class: Antiviral Monoclonal Antibodies

Last Reviewed by the DUR Board: January 22, 2015

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

For consideration outside these guidelines, a prior authorization may also be submitted with supporting medical necessity documentation.

1. Coverage and Limitations

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

- a. Recipients younger than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season, must meet one of the following criteria:
 1. The recipient was born at 28 weeks, six days of gestation or earlier; or
 2. The recipient has a diagnosis of chronic lung disease (CLD) of prematurity; or
 3. The recipient has hemodynamically significant congenital heart disease; or
 4. The recipient has congenital abnormalities of the airways or neuromuscular disease; or
 5. The recipient has a diagnosis of cystic fibrosis; and
 - a. The recipient has clinical evidence of CLD and/or nutritional compromise.
- b. Recipients younger than two years of age at the start of RSV season must meet one of the following criteria:
 1. The recipient has a diagnosis of CLD of prematurity; and
 - a. The recipient has required medical therapy (e.g., bronchodilator, diuretics, oxygen, corticosteroids) within six months to the start of RSV season; or
 2. The recipient has had a cardiac transplant; or
 3. The recipient is severely immunocompromised (solid organ or

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hematopoietic stem cell transplant, chemotherapy or other conditions) during the RSV season; or

4. The recipient has had a cardiopulmonary bypass and continues to require prophylaxis after surgery or at the conclusion of extracorporeal membrane oxygenation; or
5. The recipient has a diagnosis of cystic fibrosis; and
 - a. The recipient has had manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable) or weight for length less than the tenth percentile.

2. Prior Authorization Guidelines

- a. Prior Authorization approval will be up to five doses per RSV season for recipients meeting criteria.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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Z. Opioids

Therapeutic Class: Opioids

Last Reviewed by the DUR Board: October 27, 2016

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

1. Coverage and Limitations

a. Opioids will be covered without Prior Authorization (PA):

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

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

c. Prior Authorization Criteria: To exceed the number of seven-day prescriptions, or to exceed the seven-day limit, or to exceed the 60 mg morphine equivalents or less per day:

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

- a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and
- b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.); and
- c. The lowest effective dose is being requested; and
- d. A pain contract is on file.

d. Exceptions to this policy:

1. Recipients with cancer/malignancy related pain; or
2. Recipients who are post-surgery with an anticipated prolonged recovery (greater than three months); or

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3. Recipients receiving palliative care; or
 4. Recipients residing in a long-term care facility; or
 5. Recipients receiving treatment for HIV/AIDS; or
 6. Prescriptions written by or in consultation with a pain specialist.
2. Prior Authorization Guidelines
 - a. Prior Authorization approval will be for one year.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>
3. CDC Guidance:
 - a. <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

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AA. Savella® (milnacipran)

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

Savella® (milnacipran) is subject to prior authorization.

Coverage and Limitations

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

Prior Authorization forms are available at:

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

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BB. Buprenorphine/Naloxone

Therapeutic Class: Narcotic Withdrawal Therapy Agents

Last Reviewed by the DUR Board: January 26, 2017

Previously reviewed by the DUR Board: April 28, 2016

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

1. Coverage and Limitations

a. To initiate therapy:

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

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

b. To re-initiate therapy:

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

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

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

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

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

- a. The recipient is 16 years of age or older; and
- b. The recipient has a diagnosis of opioid dependence; and
- c. Requests for a diagnosis of chronic pain will not be approved; and
- d. There is documentation the recipient has honored all of their office visits; and

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

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CC. Ampyra® (dalfampridine)

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

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

1. Coverage and Limitations

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

a. Ampyra® (dalfampridine)

The recipient must meet all of the following:

1. The recipient must have a diagnosis of Multiple Sclerosis; and
2. The medication is being used to improve the recipient's walking speed; and
3. The medication is being prescribed by or in consultation with a neurologist; and
4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and
5. The recipient does not have moderate to severe renal dysfunction (CrCL >50 ml/min); and
6. The recipient does not have a history of seizures; and
7. The recipient is not currently pregnant or attempting to conceive.

2. Prior Authorization Guidelines

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

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

Therapeutic Class: Androgenic Agents

Last Reviewed by the DUR Board: July 22, 2010

Topical Androgens are subject to prior authorization.

1. Coverage and Limitations

Recipients must meet all of the criteria for coverage:

2. Criteria for approval

a. Recipient is a male;

b. Use is for the FDA Approved Indication:

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

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

d. The patient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) > 19;

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

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

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

3. Prior Authorization Guidelines

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

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

c. Length of authorization: one year.

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EE. Colchicine (Colcrys®)

Therapeutic Class: Antigout Agents

Last Reviewed by the DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

a. Colchicine Tablets

1. The recipient has a diagnosis of acute gout (does not require prophylaxis) and the recipient must meet all of the following:
 - a. The recipient is 16 years of age or older; and
 - b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID (indomethacin, naproxen, ibuprofen, sulindac or ketoprofen); and
 - c. The recipient has had an inadequate response, adverse reaction or contraindication to a corticosteroid (oral or intra-articular).
2. For prophylaxis of chronic gout:
 - a. The recipient is 16 years of age or older and must meet one of the following:
 1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or
 2. There is documentation that the recipient will be treated with colchicine monotherapy and the recipient must meet all of the following:
 - a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

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- b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).
- 3. For Familial Mediterranean Fever (FMF):
 - a. The recipient is four years of age or older.
- 4. Requests exceeding the quantity limit may be approved for colchicine tablets if all of the following are met and documented:
 - a. The recipient is 12 years of age or older; and
 - b. The recipient has a diagnosis of FMF; and
 - c. The recipient's dose is ≤ 2.4 mg daily (120 tablets/30 days); and
 - d. Medical necessity must be provided and documented in the recipient's medical record that the recipient had an inadequate response to 1.8 mg daily (90 tablets/30 days).
- b. Colchicine Capsules
 - 1. For Prophylaxis of chronic gout:
 - a. The recipient is 18 years of age or older and the recipient must meet one of the following:
 - 1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or
 - 2. There is documentation that the recipient will be treated with colchicine monotherapy, and the recipient must meet all of the following:
 - a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and
 - b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).

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

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FF. Thrombin Inhibitors

Therapeutic Class: Thrombin Inhibitors

Last Reviewed by the DUR Board: January 22, 2015

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

1. Coverage and Limitations

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

- a. A diagnosis code associated with the FDA approved indication(s) is documented on the prescription and transmitted on the claim; and
- b. There are no contraindications to prescribing this medication; or
- c. An approved Prior Authorization documenting the recipient meeting all of the criteria above (1.) (a. and b.).

2. Prior Authorization Guidelines

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

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GG. Makena™ (Criteria for Physician Administered Drug)

Therapeutic Class: Progestational Agents

Last Reviewed by the DUR Board: April 28, 2011

Makena™ 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 all of the following criteria are met and documented:

- a. Treatment with Makena™ is ordered by or recommended by a physician specializing in Obstetrics/Gynecology, Perinatology or Maternal/Fetal Medicine; and
- b. The recipient is female, 16 years of age or older and pregnant with a singleton pregnancy; and
- c. The recipient's pregnancy is between 16 weeks, 0 days and 20 weeks, six days of gestation when therapy begins; and
- d. The recipient has a history of singleton spontaneous preterm birth (prior to 37 weeks gestation); and
- e. The recipient does not have other risk factors for preterm birth; and
- f. There is no known major fetal anomaly or fetal demise; and
- g. The recipient has not been treated with heparin therapy during the current pregnancy; and
- h. The recipient has no history of thromboembolic disease; and
- i. The recipient has no maternal/obstetrical complication (e.g. current or planned cerclage, hypertension requiring medication or seizure disorder).

2. Length of approval:

Makena™ will be approved for use until the recipient's pregnancy is 36 weeks, six days of gestation or delivery, whichever occurs first.

3. Prior Authorization forms are available at:

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

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HH. Anti-Hepatitis Agents – Protease Inhibitor Agents

Therapeutic Class: Anti-Hepatitis Agents-Protease Inhibitors

Last Reviewed by the DUR Board: January 22, 2015

Victrelis® (boceprevir) and Incivek® (telaprevir) 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. Victrelis® (boceprevir)

1. For treatment initiation (treatment weeks five through 28), the recipient must have all of the following:
 - a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and
 - b. The recipient will be treated with peginterferon alfa and ribavirin for four weeks prior to starting Victrelis® (boceprevir) and will continue peginterferon alfa and ribavirin for the entire duration of treatment with Victrelis® (boceprevir); and
 - c. The recipient has not received a previous course of therapy with Incivek® (telaprevir), Olysio® (simeprevir) or Victrelis® (boceprevir) unless the drug is being switched due to an adverse event with the alternative drug.
2. For treatment continuation for treatment weeks 28 through 36, the recipient must have one of the following:
 - a. The recipient is treatment-naïve and their HCV-RNA level was detectable at treatment week eight and undetectable at treatment week 24; or
 - b. The recipient is a previous partial responder or a relapser to peginterferon alfa and ribavirin and their HCV-RNA was undetectable at treatment week eight and treatment week 24.
3. For treatment continuation for treatment weeks 28 through 48, the recipient must have one of the following:

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- a. The recipient has a diagnosis of chronic hepatitis C genotype 1 with compensated cirrhosis and their HCV-RNA was detectable at treatment week 24; or
 - b. The recipient had a $<2\text{-log}_{10}$ HCV-RNA drop by treatment week 12 on prior treatment with peginterferon alfa and ribavirin and HCV-RNA on triple therapy is undetectable at treatment week 24; or
 - c. The recipient is treatment-naïve and poorly interferon responsive based on $<1\text{-log}_{10}$ decline in HCV-RNA at treatment week four following lead-in therapy with peginterferon alfa.
- b. Incivek® (telaprevir)
 - 1. For treatment initiation (weeks one through eight) the recipient must have all of the following:
 - a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and
 - b. The recipient will be treated with concomitant peginterferon alfa plus ribavirin; and
 - c. The recipient has not received a previous course of therapy with Incivek® (teaprevir), Olysio® (simeprevir) or Victrelis® (boceprevir) unless the drug is being switched due to an adverse event with the alternative drug.
 - 2. For treatment continuation for treatment weeks nine through 12:
 - a. The recipient is treatment-naïve and their HCV-RNA level was <1000 IU/mL at treatment week four.
- 2. Prior Authorization Guidelines:
 - a. Victrelis® (boceprevir)
 - 1. Initial prior authorization will be for 24 weeks (through treatment week 28).
 - 2. For recipients meeting criteria for continuation treatment for treatment weeks 28 through 36, a prior authorization may be renewed once for an additional eight weeks.
 - 3. For recipients meeting criteria for continuation treatment for treatment weeks 28 through 44, a prior authorization may be renewed once for an additional 24 weeks.

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b. Incivek® (teleprevir)

1. Initial prior authorization approval will be for eight weeks.
2. For recipients meeting criteria for continuation treatment for treatment weeks nine through 12, a prior authorization approval may be renewed once for an additional four weeks.

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

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II. Daliresp® (roflumilast)

Therapeutic Class: Phosphodiesterase-4 Inhibitors.

Last Reviewed by the DUR Board: July 26, 2012

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

1. Coverage and Limitations

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

- a. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting anticholinergic agent;
- b. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting β agonist;
- c. The recipient has experienced an inadequate response, adverse event or has a contraindication to an inhaled corticosteroid;
- d. The recipient has a diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) associated with chronic bronchitis; and
- e. The recipient has a history of COPD exacerbations.

2. Prior Authorization Guidelines:

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

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JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents

Last Reviewed By DUR Board: July 25, 2013

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

1. Coverage and Limitations

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

a. Cinryze® (C1 esterase inhibitor)

The recipient must meet all of the following:

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

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

The recipient must meet all of the following:

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

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2. Prior Authorization Guidelines:

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

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KK. Incretin Mimetics

Therapeutic Class: Incretin Mimetics

Last Reviewed by the DUR Board: January 26, 2017

Previously reviewed by the DUR Board: July 26, 2012

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

1. Coverage and Limitations

- a. An ICD code for Type 2 Diabetes Mellitus is documented on the prescription and transmitted on the claim; or
- b. A prior authorization documenting a diagnosis of Type 2 Diabetes Mellitus has been submitted.

2. Prior Authorization Guidelines:

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

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LL. Kalydeco® (ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent

Last Reviewed by the DUR Board: September 3, 2015

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

1. Coverage and Limitations

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

- a. The recipient is two years of age or older; and
- b. The recipient has a diagnosis of cystic fibrosis; and
- c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the following gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

2. Prior Authorization Guidelines

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

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MM. Natroba® (spinosad)

Therapeutic Class: Topical Antiparasitics

Last Reviewed by the DUR Board: July 26, 2012

Natroba® (spinosad) is subject to prior authorization.

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

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

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NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors

Last Reviewed by the DUR Board: January 23, 2014

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

1. Coverage and Limitations

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

a. Brilinta® (ticagrelor)

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

b. Effient® (prasugrel)

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

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4. The recipient has a history of percutaneous coronary intervention; and
 5. The recipient has been started and stabilized on the requested medication;
or
 6. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or
 7. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.
2. Prior Authorization Guidelines
 - a. Prior authorization approval will be for one year.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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OO. Prolia® (Denosumab)

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)

Last Reviewed by DUR Board: October 25, 2012

Prolia® (Denosumab) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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

a. Postmenopausal Osteoporosis

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

b. Male Osteoporosis

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

c. Non-metastatic Prostate Cancer

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

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3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
- d. Breast Cancer
1. The recipient has a history of osteoporotic fracture or has multiple risk factors for fracture;
 2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane and letrozole);
 3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
2. Prior Authorization Guidelines
- a. Prior authorization approval will be for one year.
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>.

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PP. Forteo® (Teriparatide)

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

Last Reviewed by DUR Board: October 25, 2012

Forteo® (Teriparatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

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

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QQ. **Cannabinoid Antiemetics**

Therapeutic Class: Antiemetic

Last Reviewed by DUR Board: October 25, 2012

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

1. Coverage and Limitations

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

a. Nabilone

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and
2. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and
3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and
4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

b. Dronabinol

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and
 - a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and
 - b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and
 - c. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or
2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and the recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

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- a. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

2. Prior Authorization Guidelines

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

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RR. Omontys® (Peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)

Last Reviewed by DUR Board: October 25, 2012

Omontys® (Peginesatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of anemia secondary to chronic kidney disease;
- b. The recipient must be over 18 years of age;
- c. The recipient is receiving dialysis;
- d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);
- e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and
- f. The target hemoglobin level will not exceed 11 g/dL.

2. Prior Authorization Guidelines

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

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SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors

Last Reviewed by the DUR Board: April 28, 2016

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

1. Coverage and Limitations

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

- a. The requested agent is being used for an FDA-approved indication.
- b. The requests for a diagnosis of nonmyeloid malignancy must meet one of the following criteria:
 1. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of $\geq 20\%$; or
 2. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age > 65 years, absolute neutrophil count (ANC) < 100 cells/ μ L or the expected duration of neutropenia is > 10 days); or
 3. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.

2. Prior Authorization Guidelines

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

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TT. Auvi-Q (epinephrine injection device)

Therapeutic Class: Anaphylaxis-Self Injectable Epinephrine

Last Reviewed by the DUR Board: January 23, 2014

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

1. Coverage and Limitations

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

- a. The recipient or recipient's caregiver is unable to read or comprehend written directions.

2. Prior Authorization Guidelines:

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

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UU. Hepatitis C direct-acting antivirals

Therapeutic Class: Hepatitis C direct acting antivirals

Last Reviewed by the DUR Board: July 28, 2016

Previously reviewed by the DUR Board: January 28, 2016

Hepatitis C direct-acting antivirals 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.
- b. Recipients must meet all of the following criteria:
 1. The recipient has a diagnosis of chronic Hepatitis C Virus (HCV) infection; and
 2. The recipient is 18 years of age or older; and
 3. All of the following must be included with the PA request:
 - a. Medical records and results of laboratory and diagnostic tests which support all of the following:
 1. The HCV genotype (and subtype, if applicable); and
 2. The baseline HCV RNA viral load and date drawn; and
 3. The hepatic fibrosis stage, including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4). (Results of diagnostic tests or imaging studies that are inconclusive may require additional testing); and
 - b. A complete treatment regimen; and
 - c. The duration of treatment; and
 - d. Any previous treatment experience and length of treatment, if any, including outcome (e.g. discontinued due to side effects, relapsed, non-responder, null-responder); and
 4. The prescriber must certify that the treatment will be discontinued if the viral load is detectable at week four of treatment and has increased by greater than 10-fold ($>1 \log_{10}$ IU/mL) on repeat testing at week six (or

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thereafter); and

5. Requests for recipients with decompensated cirrhosis (Child Turcotte Pugh (CTP) class B or C) and requests for recipients who have chronic hepatitis C infection status-post liver transplant will be evaluated on a case by case basis.
2. Harvoni® (ledipasvir/sofosbuvir) Initial Requests
 - a. The requested dose is one 90 mg/400 mg tablet once daily.
 - b. Genotype 1:
 1. The recipient is treatment naïve and must meet one of the following:
 - a. No cirrhosis, pre-treatment HCV RNA < six million and the requested duration is eight weeks; or
 - b. No cirrhosis, pre-treatment HCV RNA $\geq$ six million and the requested duration is 12 weeks; or
 - c. Compensated Cirrhosis (CTP class A), requested duration is 12 weeks.
 2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.
 3. The recipient is treatment-experienced (failed peginterferon + ribavirin + an NS3 protease inhibitor) and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks; or

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- c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.
 - 4. The recipient is treatment-experienced (failed Sovaldi + ribavirin ± peginterferon) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 24 weeks.
- c. Genotype 4:
 - 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
 - 2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), documentation is provided the recipient is unable to take ribavirin and the requested duration is 24 weeks.
- d. Genotype 5 and 6:
 - 1. The recipient is treatment-naïve and the requested duration is 12 weeks; or
 - 2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and the requested duration is 12 weeks.
- 3. Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir) (Initial Requests)
 - a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg) and one dasabuvir 250 mg tablet twice daily.

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b. Genotype 1a:

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, recipient will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

c. Genotype 1b:

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

4. Technivie® (ombitasvir/paritaprevir/ritonavir) (Initial Requests)

- a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg).

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b. Genotype 4:

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
2. The recipient is treatment-experienced (failed peginterferon and ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks.

5. Daklinza® (daclatasvir) (Initial Requests)

a. The requested dose is one of the following:

1. 60 mg (one tablet) daily; or
2. 30 mg (one tablet) and the recipient is receiving a strong CYP3A inhibitor; or
3. 90 mg (one tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer.

b. Genotype 1

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi + ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, documentation has been provided showing the recipient is unable to take ribavirin and

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documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing that the recipient is unable to take ribavirin.

c. Genotype 2

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 16 weeks and documentation is provided showing the recipient is unable to take ribavirin.
2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing the recipient is unable to take

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ribavirin and must meet one of the following:

- a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 16 to 24 weeks.
3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy), documentation has been provided showing the recipient is unable to take peginterferon and must meet one of the following:
- a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - b. No cirrhosis, will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin.

d. Genotype 3

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.
2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing that the recipient is unable to receive peginterferon and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

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- b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.
 - 3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy), documentation is provided that the recipient is unable to receive peginterferon and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.
- 6. Olysio® (simeprevir) (Initial Request)
 - a. The requested dose is 150 mg (one capsule) daily.
 - b. Genotype 1a
 - 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
 - 2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and the recipient is negative for the Q80K polymorphism; or

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- c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation has been provided showing that the recipient is unable to take ribavirin.
 - c. Genotype 1b
 - 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.
 - 2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.
- 7. Sovaldi® (sofosbuvir) (Initial Requests)
 - a. The requested dose is 400 mg daily.
 - b. Genotype 1
 - 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - b. No cirrhosis, will be treated with Olysio and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-

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recommended regimen; or

- d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, documentation is provided showing the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, documentation has been provided that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
- a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - b. No cirrhosis, will be treated with Olysio and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, documentation is provided showing

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that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

- e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen; or
 - f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:
 - a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 24 weeks; or
 - c. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.
- c. Genotype 2
 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

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- b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 16 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.
- 2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or
 - b. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation is provided showing the recipient is unable to take ribavirin.
 - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 16 weeks to 24 weeks, and documentation is provided showing the recipient is unable to take ribavirin; or
 - e. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
- 3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to receive peginterferon; or
 - b. No cirrhosis, will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and documentation has been provided showing that the recipient is unable to receive peginterferon; or

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- c. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; or
 - e. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon and ribavirin.
 - f. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.
- d. Genotype 3
 - 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - c. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
 - e. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - f. Compensated cirrhosis (CTP class A) will be treated with Daklinza and ribavirin, the requested duration is 24 weeks; or
 - g. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.
 - 2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with peginterferon and ribavirin and the

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- requested duration is 12 weeks; or
- b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
 - c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.
3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
 - b. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon; or
 - c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
 - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.
- e. Genotype 4
 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
 2. The recipient is treatment-experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to

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why the recipient cannot use a guideline-recommended regimen; or

- b. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks, documentation is provided as to why the recipient cannot take peginterferon and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

f. Genotype 5, 6

- 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
- 2. The recipient is treatment-experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

8. Zepatier® (elbasvir and grazoprevir)

- a. The requested dose is one tablet (50/100 mg) daily.
- b. Genotype 1a

- 1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

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- c. Compensated cirrhosis (CTP class A), requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
- 2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
 - c. Compensated cirrhosis (CTP class A), requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.
- 3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected; or
 - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

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c. Genotype 1b

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:
 - a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and baseline NS5A RAVs for elbasvir have been detected; or
 - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

d. Genotype 4

1. The recipient is treatment-naïve and must meet one of the following:
 - a. No cirrhosis and the requested duration is 12 weeks; or
 - b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual

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therapy) and must meet one of the following:

- a. No cirrhosis, the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or
 - b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy; or
 - c. Compensated cirrhosis (CTP class A), the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or
 - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy.
9. Recipients who have received previous therapy with an NS5A inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) or combination therapy with sofosbuvir + simeprevir.
- a. The recipient must meet one of the following:
 1. The recipient has cirrhosis; or
 2. Documentation includes the clinical rationale for urgent retreatment.
 - b. Testing for resistance-associated variants (RAVs) have been done and results have been provided.
 - c. The requested regimen does not include agents in which RAVs have developed.
 - d. The requested regimen includes ribavirin or documentation has been provided that ribavirin is contraindicated.
10. Epclusa® (sofosbuvir/velpatasvir)
- a. The requested dose is one tab daily; and
 1. The recipient is treatment-naïve, with or without cirrhosis and the requested duration is 12 weeks; or
 2. The recipient is treatment-experienced, with or without cirrhosis, the requested duration is 12 weeks and must meet one of the following:

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- a. Genotype 1a, peginterferon + ribavirin treatment experienced; or
 - b. Genotype 1b, peginterferon + ribavirin treatment experienced; or
 - c. Genotype 1, HCV nonstructural protein 3 (NS3) protease inhibitor (telaprevir, boceprevir, or simeprevir) plus peginterferon + ribavirin treatment experienced; or
 - d. Genotype 2, peginterferon + ribavirin treatment experienced; or
 - e. Genotype 2, sofosbuvir + ribavirin treatment experienced; or
 - f. Genotype 3, peginterferon + ribavirin treatment experienced; or
 - g. Genotype 3, sofosbuvir + ribavirin treatment experienced; or
 - h. Genotype 4, peginterferon + ribavirin treatment experienced; or
 - i. Genotype 5 or 6, peginterferon + ribavirin treatment experienced.
11. For requests for recertification (for treatment beyond 12 weeks), the recipient must meet all of the following:
- a. Laboratory results for HCV RNA viral load at week four and week six (if applicable) have been submitted with the PA request; and
 - b. The recipient's HCV viral load must meet one of the following:
 - 1. Undetectable HCV RNA viral load week four; or
 - 2. Detectable HCV RNA viral load at treatment week four and HCV RNA increased by ≤ 10 -fold ($\leq 1 \log_{10}$ IU/mL) on repeat testing at treatment week six (or thereafter).
 - 3. And, the recipient is compliant on all drugs in the treatment regimen.
12. Prior Authorization Guidelines:
- a. Prior authorization approval will be for a maximum of 12 weeks (unless the requested regimen is less than 12 weeks long or the remaining duration of therapy is less than 12 weeks).
 - b. The initial prescription will be limited to a 14-day supply; subsequent refills can be up to 34 days.
 - c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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VV. Medications for the Treatment of Acne

Therapeutic Class: Acne Agents

Last Reviewed by the DUR Board: July 24, 2014

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

1. Coverage and Limitations

No prior authorization necessary for recipients up to 21 years of age.

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

- a. The recipient is age 21 years of age or older; and
- b. The recipient has a diagnosis of moderate to severe acne (Grade III or higher).

2. Prior Authorization Guidelines

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

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WW. Irritable-Bowel Syndrome Agents

Therapeutic Class: Irritable-Bowel Syndrome Agents

Last Reviewed by the DUR Board: July 28, 2016

Viberzi® last reviewed April 28, 2016

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

1. Coverage and Limitations

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

1. The recipient is 18 years of age or older; and
2. The requested agent is being prescribed based on FDA approved guidelines; and
 - a. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):
 1. For requests for lubiprostone, the recipient must be female.
 2. The requested dose is appropriate based on indication and age.
 - a. Linaclotide: 290 µg daily.
 - b. Lubiprostone: 16 µg daily.
 - b. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):
 1. The medication is being prescribed by or in consultation with a gastroenterologist; and
 2. The requested dose is appropriate based on indication and age.
 - a. Alosetron: 0.5 mg twice daily or 1 mg twice daily.
 - b. Eluxadoline: 75 mg twice daily or 100 mg twice daily.
 - c. Rifaximin: 550 mg three times a day for 14 days.

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2. Prior Authorization Guidelines

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

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XX. Xartemis® XR (oxycodone and acetaminophen)

Therapeutic Class: Opioid Analgesic

Last Reviewed by the DUR Board: January 22, 2015

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

1. Coverage and Limitations

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

- a. The recipient is 18 years or older; and
- b. A diagnosis code of Acute Pain is documented on the prescription and transmitted on the claim; or
- c. An approved Prior Authorization documenting the recipient meeting the following criteria:
 1. The recipient is 18 years or older; and
 2. A diagnosis code of Acute Pain is documented on the Prior Authorization form.

2. PA Guidelines

- a. More than two fills of a quantity of 60 each, within six months requires an approved Prior Authorization documenting the reason to exceed the prescribing limit.
- b. Prior Authorization approval will be for six months.
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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YY. GnRH Analogs

Therapeutic Class: GnRH Analogs

Last Reviewed by the DUR Board: July 28, 2016

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 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.
3. The recipient has a diagnosis of uterine leiomyomata (fibroids), and
 - a. The requested dose and frequency is based on FDA-approved guidelines; and
 - b. The recipient is symptomatic; and

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- c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rationale why surgical intervention is not required.
 - 4. 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:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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ZZ. Vivitrol® (naltrexone)

Therapeutic Class: Opioid Dependence Agents

Last Reviewed by DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

- a. The drug is being used for an FDA approved indication; and
- b. The drug must be delivered directly to the prescriber's office; and
- c. The drug is only to be administered once per month; and
- d. Routine urine screening and monitoring is recommended.

2. Prior Authorization Guidelines

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

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

Therapeutic Class: Narcolepsy Agents (non-stimulants)

Last Reviewed by DUR Board: April 23, 2015

Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil) are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

a. Provigil® (modafinil), and Nuvigil® (armodafinil):

1. The recipient has a diagnosis of narcolepsy.

b. Xyrem® (sodium oxybate):

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

2. Prior Authorization Guidelines

a. Prior Authorization approvals will be for one year.

b. Prior Authorization forms are available at:

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

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

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

Last Reviewed by DUR Board: April 23, 2015

Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine) are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

- a. The drug is being used for an FDA approved indication; and
- b. The recipient's medical records documents one of the following risk factors for developing a NSAID-related ulcer:
 1. Previous history of a major gastrointestinal bleed, perforation or obstruction; or
 2. Previous history of a peptic ulcer, hemorrhagic gastritis, hemorrhagic gastropathy or erosive esophagitis; or
 3. Concomitant therapy for an anticoagulant or antiplatelet agent (including aspirin) or chronic oral corticosteroids; or
 4. The recipient has had gastric bypass surgery (Roux-en-Y gastric bypass); and
- c. The recipient is intolerant to a COX-2 inhibitor or has had a gastric or duodenal ulcer while taking a COX-2 inhibitor; and
- d. The recipient has experienced an NSAID-associated ulcer in the past while taking a single-entity proton pump inhibitor (PPI) or prostaglandin agent concomitantly with an NSAID or the recipient is intolerant to both PPIs and prostaglandin agents; and
- e. The recipient's medical records document an inadequate response or adverse reaction with concurrent therapy of an equivalent dose of the individual components.

2. Prior Authorization Guidelines

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

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CCC. Rayos® (prednisone delayed-release)

Therapeutic Class: Corticosteroid, Systemic

Last Reviewed by DUR Board: April 23, 2015

Rayos® (prednisone delayed-release) is subject to prior authorizations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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

- a. The requested drug is being used for a FDA approved indication; and
- b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate-release tablets.

2. Prior Authorization Guidelines

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

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DDD. Corlanor® (ivabradine)

Therapeutic Class: Cardiovascular Agent

Last Reviewed by the DUR Board: September 3, 2015

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

1. Coverage and Limitations:

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

- a. A diagnosis of chronic heart failure; and
- b. A left ventricular ejection fraction (LVEF) $\leq$ 35%; and
- c. A resting heart rate $\geq$ 70 bpm; and
- d. The recipient is $\geq$ 18 years of age; and
- e. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted regarding the diagnosis and treatment recommendations; and
- f. The recipient is in a normal sinus rhythm; and
- g. The recipient is on a maximally tolerated dose of a beta-blocker or the recipient has a contraindication to beta-blocker use.

2. Prior Authorization Guidelines:

- a. The extent of prior authorization approvals will be based on the appropriate use for the individual agents.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: Antilepemic Agent, PCSK9 Inhibitors

Last Reviewed by the DUR Board: January 28, 2016

Anti-lipidemic Agents – PCSK9 Inhibitors are subject to prior authorization and quantity limitation based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

a. Initial Request:

1. The recipient has an FDA-approved diagnosis; and
2. The requested medication was prescribed by or in consultation with a cardiologist or lipid specialist; and
3. The requested medication will be used as an adjunct to a low-fat diet and exercise; and
4. For the treatment of homozygous familial hypercholesterolemia:

a. With alirocumab (Praluent®)

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

b. With evolocumab (Repatha®)

1. The recipient is 13 years of age or older.

5. And the recipient must meet one of the following (a, b, c or d):

a. The recipient has had an inadequate response to high intensity statin therapy defined as all of the following:

1. The recipient has received therapy with atorvastatin $\geq$ 40 mg or rosuvastatin $\geq$ 20 mg for at least the past three months; and
2. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

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3. The LDL-C after therapy for at least the past three months was ≥ 100 mg/dL (HeFH) for ≥ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and
4. The statin therapy will be continued with PCSK-9 therapy.
- b. Or, the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:
 1. The recipient has an intolerance or contraindication to high intensity statin therapy; and
 2. The recipient has received therapy with:
 - a. atorvastatin 10 to 20 mg; or
 - b. rosuvastatin 5 to 10 mg; or
 - c. simvastatin > 20 mg; or
 - d. pravastatin > 40 mg; or
 - e. lovastatin 40 mg; or
 - f. fluvastatin XL 80 mg; or
 - g. fluvastatin 40 mg twice daily; or
 - h. pitavastatin > 2 mg
 for at least the past three months; and
 3. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and
 4. The LDL-C after therapy for at least the past three months was ≥ 100 mg/dL (HeFH) or ≥ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and
 5. Statin therapy will be continued with PCSK-9 therapy.
- c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.
- d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.

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2. Recertification Request (The recipient must meet all criteria (a-d)).
 - a. The recipient has been adherent with PCSK-9 inhibitor therapy; and
 - b. The recipient has been adherent with statin therapy or the recipient has a labeled contraindication to statin therapy; and
 - c. The recipient is continuing a low-fat diet and exercise regimen; and
 - d. The recipient has achieved a reduction in LDL-C level.
3. Prior Authorization Guidelines:
 - a. Prior Authorizaiton approvals will be for:
 1. Initial request: six months
 2. Recertification request: one year
 - b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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FFF. Invega Trinza® (paliperidone palmitate)

Therapeutic Class: Second Generation (Atypical) Antipsychotic

Last Reviewed by the DUR Board: November 5, 2015

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

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of schizophrenia; and
- b. The recipient has been stabilized on once-monthly paliperidone palmitate injection (Invega Sustenna®) for at least four months with the two most recent doses of the once-monthly injection being the same strength; and
- c. The recipient is 18 years of age or older; and
- d. The requested dose is one injection every three months.

2. Prior Authorization Guidelines:

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

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GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: January 27, 2017

Previously reviewed: January 28, 2016

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

1. Coverage and Limitations

a. For recipients 21 years of age or older:

1. The prescriber has verified the recipient is enrolled in the hospice program; and
2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and
3. The requested medication is not being used for palliative care; and
4. The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient; and
5. The requested medication is not providing a curative or long-term prophylactic therapy.

b. For recipients 20 years of age or younger:

1. The prescriber has verified the recipient is enrolled in a hospice program; and
2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and
3. The requested medication is not being used for palliative care.
4. Medically necessary curative medications for this age group are covered by the DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for three months.

b. Prior Authorization forms are available at:

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

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HHH. Orkambi® (lumacaftor/ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent

Last Reviewed by the DUR Board: January 26, 2017

Previously reviewed November 5, 2015

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

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of cystic fibrosis; and
- b. The recipient is six years of age or older; and
- c. The recipient is homozygous for the F508del mutation in the CFTR gene; and
- d. The requested dose is two tablets every 12 hours; or
- e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

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

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III. Hetlioz® (tasimelteon)

Therapeutic Class: Sedative Hypnotic

Last Reviewed by the DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

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

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JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker

Last Reviewed by the DUR Board: November 5, 2015

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

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of chronic heart failure NYHA Class II to IV; and
- b. The recipient has reduced left ventricular ejection fraction (LVEF); and
- c. The recipient is 18 years of age or older; and
- d. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted; and
- e. The recipient has had a trial of an ACE or an ARB for at least four weeks prior to the initiation of therapy; and
- f. The recipient will not concurrently receive an ACE inhibitor; and
- g. The recipient is on an individualized dose of a beta blocker or the recipient has a contraindication to beta blocker use; and
- h. Entresto® will be given twice daily with a maximum dose of 97/103 mg.

2. Prior Authorization Guidelines:

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

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KKK. Neurokinin-1 Antagonists and Combinations

Therapeutic Class: Neurokinin-1 Antagonists and Combinations

Last Reviewed by the DUR Board: April 28, 2016

Neurokinin-1 antagonists and combinations are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

For requests to exceed the quantity limits approval will be given if all the following criteria are met and documented:

- a. The requested medication is being used for an FDA-approved indication; and
- b. The requested medication is being prescribed by an oncologist or in consultation with an oncologist; and
- c. The recipient must meet one of the following criteria:
 1. The recipient is 18 years of age or older; or
 2. The recipient is 12 years of age or older, the requested medication is aprepitant (Emend®) and the recipient is diagnosed with nausea and vomiting caused by chemotherapy.
- d. And, it is medical necessity for the recipient to exceed the quantity limit (e.g., duration of chemotherapy cycle).

2. Prior Authorization Guidelines

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

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LLL. Opioid-Induced Constipation Agents

Therapeutic Class: Opioid-Induced Constipation Agents

Last Reviewed by the DUR Board: April 28, 2016

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

1. Coverage and Limitations:

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

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

2. Prior Authorization Guidelines

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

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MMM.Exondys 51® (eteplirsén)

Therapeutic Class: Exondys 51® (eteplirsén)

Last Reviewed by the DUR Board: August 24, 2017

Exondys 51® (eteplirsén) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

a. Initial request:

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

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

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

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- d. The recipient is tolerating therapy; and
- e. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and
- f. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

2. Prior Authorization Guidelines:

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

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NNN. Spinraza® (nusinersen)

Therapeutic Class: Spinraza® (nusinersen)

Last Reviewed by the DUR Board: August 24, 2017

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

1. Coverage and Limitations

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

a. Initial request:

1. The recipient has a diagnosis of Spinal Muscular Atrophy (SMA), and
2. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA.

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

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

2. Prior Authorization Guidelines:

a. Prior Authorization approvals will be for:

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

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- 2. MEDICATIONS WITH GENDER/AGE EDITS
 - A. Prenatal Vitamins
 - 1. Payable only for female recipients.

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- B. Oral/Topical Contraceptives
 - 1. Payable only for female recipients.

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C. Gender Edits

1. Hormones

- a. Estrogen – payable only for female recipients.
- b. Progestins – payable only for female recipients.
- c. Estrogen and Androgen Combinations – payable only for female recipients.
- d. Estrogen and Progestin Combinations – payable only for female recipients.
- e. Contraceptive Hormones – payable only for female recipients.
- f. Transdermal Testosterone – payable only for male recipients.
- g. Androgen Hormone Inhibitor – payable only for male recipients.

2. Exception to the above gender edits:

A diagnosis of Gender Identity Disorder will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

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D. Vitamins with Fluoride

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

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3. ANTIRETROVIRALS

Antiretrovirals for the treatment of HIV/AIDS are a covered benefit for Nevada Medicaid recipients. FDA approved antiretrovirals whose manufacturers participate in the federal Drug Rebate Program and are not DESI drugs, are covered.

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4. BLOOD GLUCOSE TESTING

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

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

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

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

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

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

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MEDICAID SERVICES MANUAL

CATAMARAN AD HOC REPORTING SYSTEM
STANDARD THERAPEUTIC CLASSES

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

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41	NON-NARCOTIC ANALGESICS
42	ANTIARTHRITICS
43	ANESTHETICS GEN INHALANT
44	ANESTHETICS GEN INJECT
45	ANESTHETIC LOCAL TOPICAL
46	SEDATIVE BARBITURATE
47	SEDATIVE NON-BARBITURATE
48	ANTICONVULSANTS
49	ANTINAUSEANTS
50	CORTICOTROPINS
51	GLUCOCORTICOIDS
52	MINERALOCORTICOIDS
53	ALDOSTERONE ANTAGONISTS
54	ANTIDOTES
55	THYROID PREPS
56	ANTITHYROID PREPS
57	IODINE THERAPY
58	DIABETIC THERAPY
59	ANABOLICS
60	ANDROGENS
61	ESTROGENS
62	PROGESTERONE
63	SYSTEMIC CONTRACEPTIVES
64	OTHER HORMONES
65	LIPOTROPICS
66	CHOLESTEROL REDUCERS
67	DIGESTANTS
68	PROTEIN LYSATES
69	ENZYMES
70	RAUWOLFIA
71	OTHER HYPOTENSIVES
72	VASODILATORS CORONARY
73	VASODILATORS PERIPHERAL
74	DIGITALIS PREPARATIONS
75	XANTHINE DERIVATIVES
76	OTHER CARDIOVASCULAR PREPS
77	ANTICOAGULANTS
78	HEMOSTATICS
79	DIURETICS
80	FAT SOLUBLE VITAMINS
81	WATER SOLUBLE VITAMINS
82	MULTIVITAMINS
83	FOLIC ACID PREPARATIONS
84	B COMPLEX WITH VITAMIN C
85	VITAMIN K

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86	INFANT FORMULAS
87	ELECTROLYTES & MISCELLANEOUS N
88	HEMATINICS & BLOOD CELL STIMUL
89	ALLERGENS
90	BIOLOGICALS
91	ANTIPRURITICS
92	COAL TAR
93	EMOLLIENTS PROTECTIVES
94	FUNGICIDES
95	ALL OTHER DERMATOLOGICALS
96	HEMORRHOIDAL PREPARATIONS
97	OXYTOCICS
98	PARASYMPATHETIC AGENTS
99	MISCELLANEOUS