

<b>DRAFT</b>	<b>MTL 26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

1203 POLICY

The Division of Health Care Financing and Policy (DHCFP), Nevada Medicaid, reimburses pharmacies and practitioners for legend (prescriptions) and non-legend (over the counter) pharmaceuticals dispensed or administered to each Medicaid recipients. All prescribers must have a license as a healthcare practitioner, such as a physician, podiatrist, osteopath, dentist, Advanced Practitioner of Nursing (APN), 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, with a maximum of a 34 day supply. Maintenance medications have a maximum of 100 day supply.

~~1203.1 PHARMACEUTICALS~~

~~All legend and non-legend pharmaceuticals must be prescribed by a licensed physician, podiatrist, osteopath, dentist, Advanced Practitioner of Nursing (APN), or physician’s assistant within the scope of their practice.~~

1203.1A COVERAGE AND LIMITATIONS

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

~~The Nevada Medicaid Drug program will pay for the following prescribed pharmaceuticals with a written prescription, dispensed per the manufacturer’s guidelines, and may be subject to restrictions (such as prior authorization, quantity limitations etc):~~

- 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.
- a.b. Pharmaceuticals must be manufactured by companies participating in the Federal Medicaid Drug Rebate Program.
- b.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

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy by telephone by a prescriber. Refer to Medicaid Services Manual (MSM) Addendum for more information on tamper-resistant prescription pads.

~~e. Legend and non-legend pharmaceuticals manufactured by companies participating in the federal Medicaid Drug Rebate Program, not on the excluded list (see below).~~

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 Nevada Revised Statute (NRS) or federal law or excluded through recommendations of the P&T Committee or excluded by the ~~Division of Health Care Financing and Policy (DHCFP)~~.

1. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan ~~or by NRS~~ are ~~covered available without a Standard Preferred Drug List Exception~~ ~~under~~ prior authorization ~~guidelines~~ 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 ~~available covered with an approved Standard Preferred Drug List Exception~~ ~~under~~ prior authorization ~~guidelines~~ 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. The Drug Utilization Review (DUR) Board shall not be required to develop, review or approve prior authorization policies necessary for the operations of the PDL.~~

6.5. Due to the 76<sup>th</sup> 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

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

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.

~~7.6.~~ Due to the 76<sup>th</sup> 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.

~~e. — Pharmaceuticals prescribed for a medically accepted indication.~~

~~e. — Family planning items such as diaphragms, condoms, foams and jellies.~~

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;

	MTL 26/15
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

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 Medication – Continuity of Care.

Recipients discharged from an institution on non-preferred psychotropic 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.aspx>

3. Excluded

The Nevada Medicaid Drug Rebate program will not reimburse for the following pharmaceuticals:

a. Agents used for weight loss.

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](http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp)

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

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.
- c. 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** ~~Quantity of Medication~~ in this ~~section~~ **chapter** for more information on maintenance medications.

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.

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

- 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**~~Quantity of medication~~

~~The maximum quantity of medication per prescription payable by the Medicaid program is a 34 day supply.~~ 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 supply.

The following drug categories are considered maintenance medications:

1. Antianginals;
2. Antiarrhythmics;
3. Anticonvulsants;
4. Antidiabetics;
5. Antihypertensives;
6. Cardiac Glycosides;
7. Diuretics;
8. Thyroid preparations;
9. Estrogens;
10. Progesterone; and

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

11. Oral/Topical Contraceptives.

7. Emergency supply of medication

- a. In an emergency situation, ~~after QIO-like vendor working hours and weekends,~~ dispensing of up to a 96 hour supply ~~of those~~ 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.

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.

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 available to~~ for Medicaid eligibles age 19 years through 26 years, based on the US FDA approved indications. ~~The bivalent HPV vaccine for ages 19-26 years is also available to Medicaid eligible females only.~~ These may be accessed by following the link: <http://www.fda.gov/cber/products/gardasil.htm>. The HPV

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

vaccines are available through the ~~s~~State **Division of Public and Behavioral Health Division (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.
  - ~~3.4.~~ 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:
  - 1. The requesting pharmacist has access to the recipient's medical records.

~~1203.4B1A~~ **PROVIDER RESPONSIBILITY**

~~1. For information on In-State and Out-Of-State Provider Participation refer to MSM Chapter 100.~~

- 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 Point of Sale (POS) Systems.

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

1. Pro-DUR edits apply to POS claims and paper Uniform Claim Form (UCF) claims.
  2. Long Term Care (LTC) claims are subject to all Pro-DUR edits that apply to retail.
  3. Providers may submit override codes using the National Council for Prescription Drug Programs (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 prior authorizations 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 may be~~ 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

<b>DRAFT</b>	<b>MTL-26/15CL30445</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

1203.1BC SERVICE DELIVERY MODEL

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

1. Institutional settings
  - a. Medical/Surgical, Specialty and Psychiatric Hospitals – 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 pharmaceutical services are excluded from the daily per diem facility rate. This includes compound prescriptions and Total Parental Nutrition (TPN) solution and additives. Legend pharmaceuticals are billed directly by a licensed pharmacy through POS.  
  
Non-legend pharmaceuticals are not separately reimbursable.
    2. Intermediate Care Facilities for the Mentally Retarded (ICF/MR) – Legend and non-legend pharmaceuticals are excluded from the facility rate. Pharmaceuticals are billed directly by a licensed pharmacy through POS.
2. Outpatient Pharmaceuticals
  - a. Covered outpatient drugs that are billed separately from medical services, in accordance with Section 1927 of the Social Security Administration (SSA).
    1. Retail pharmacies (billed through POS).
    2. Home Infusion Therapy (HIT)/Free Standing Infusion Clinics, (billed through POS). Refer to the Intravenous (IV) Therapy Provider Type 37 Section of this chapter.
    3. Physician administered drugs, all pharmacy charges are billed separately. The administered drug is to be billed utilizing the appropriate National Drug Code (NDC) and NDC quantity. The administration of the drug is billed using the appropriate Current Procedural Terminology (CPT) code (billed through MMIS).
    4. Hospital based outpatient clinics, all pharmacy charges are billed separately. The administered drug is to be billed utilizing the appropriate NDC and NDC quantity. The administration of the drug is billed using the

	MTL 26/15
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 1203
MEDICAID SERVICES MANUAL	Subject: POLICY

- 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.

### 1203.1CD AUTHORIZATION PROCEDURES

Prior Authorization Requests: Physician's may request payment for exceptions to program limitations and medications requiring prior authorization by forwarding a prior authorization request to the QIO-like vendor. Prior authorization requests may be done via phone, fax or internet. Refer to the Pharmacy Manual for more information.

1. When requesting a prior authorization, providers must:
  - a. Provide all relevant diagnoses.
  - b. List all routine essential drugs being prescribed.
  - c. The requesting physician will be advised of the decision within 24 hours of receipt. A facsimile signature stamp is acceptable on faxed prior authorization requests.
  - d. Unless otherwise indicated by the QIO-like vendor, the prior authorization is for no more than one 34-day supply of prescription for each authorized drug per month.
2. Prior Authorization Protocols
  - a. Alternate media (e.g. paper/UCF claims) are subject to all prior authorization types. LTC claims, regardless of the media type, are subject to all prior authorization types. Note that the POS system does not require a "Prior Authorization Number" to be entered on a paper or electronic claim; the only requirement is that the prior authorization record is activated in the system prior to the claim submission. The approved prior authorization will be in the POS system and will be active for all pharmacies using the POS system, unless the recipient is "locked-in" to a particular pharmacy for abuse/misuse reasons.
  - b. A prior authorization will typically be required to be requested and entered prior to the dispensing of the medication, however there may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).
  - c. For clinical prior authorizations in which a Clinical Call Center Prior Authorization Unit pharmacist or pharmacy technician requests information from the prescribing physician, the prior authorization will deny if the doctor does not respond to a request for information within three working days.

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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 24, 2008~~ 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 Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

~~Agents, both stimulants and non-stimulants used for the treatment of ADD/ADHD are subject to prior authorization for pediatric, adolescent, and adult clients that meet the criteria for coverage.~~

## 1. Coverage and Limitations

Approval for medications will be given ~~at the therapeutics class level~~ 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, ~~agent at a time may be used for the treatment of ADD/ADHD (applies to the entire ADD/ADHD/Stimulant Class);~~ 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. ~~2.~~—The following ~~two~~ criteria's must be met and documented in the recipient's medical record ~~prior to treatment with ADD/ADHD agents for adult and pediatric recipients.~~
  - 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. ~~Before treatment with pharmacological methods is instituted,~~ ~~o~~Other treatable causes of ADD/ADHD have been ruled out.

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

~~In addition to the general criteria above, the following conditions apply and must be documented in the recipient's medical record.~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

1. The recipient is at least 3 years of age (short-acting stimulants) or at least 6 years of age (long-acting stimulants, long-acting alpha agonists, atomoxetine).
- ~~1. Prescriptions for ADD/ADHD medications do not require prior authorizations for children five years of age, up to eighteen years of age, if the following conditions apply:
 
  - ~~1. The medication is prescribed by a psychiatrist; and~~
  - ~~2. An ICD code for Attention Deficit Disorder with or without Hyperactivity is documented on the prescription.~~~~
- ~~2. In all other cases, prior authorization is required. The following is required for prior authorization.~~
2. An initial evaluation or regular examination has been done within the past 12 months ~~with~~ by the treating prescriber and medical notes ~~physician, pediatrician, psychiatrist or neurologist~~ documenting the developmental history, physical evaluation, medical history or a primary neurological diagnosis and all of the following:
  - a. A physical evaluation;
  - 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;
  - ~~1.d.~~ Any ~~F~~family history including: ~~psychiatric diagnoses~~ of ADD/~~and~~ ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder, ~~and other anxiety, disorders, etc.~~, past or present, family stressors, crises, ~~any~~ abuse or neglect; and an interview with parent(s) or guardian(s);-
  - e. A review of ~~D~~diagnostics~~and~~ symptoms of ADD/~~or~~ ADHD, presence or absence-child behavior checklist, development and context of symptoms and resulting impairment, (~~including~~ school, family, ~~and~~ peers), ~~diagnostic symptoms of possible alternate or comorbid psychiatric diagnosis;~~ history of ~~psychiatric, psychological pediatric or neurological treatment for ADD or ADHD;~~ and
  - a.f. School information, which should include ~~S~~standardized ~~T~~teachers ~~R~~rating ~~S~~scales, ~~testing reports such as Test of Variables of~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

~~Attention (TOVA), achievement tests, neuropsychological testing (if indicated), Conner's scale, and speech and language evaluations.;~~

~~b.e. Diagnosis and symptoms of ADD or ADHD, presence or absence child behavior checklist, development and context of symptoms and resulting impairment, including school, family and peers, diagnostic symptoms of possible alternate or comorbid psychiatric diagnosis, history of psychiatric, psychological pediatric or neurological treatment for ADD or ADHD; and~~

~~e.e. Family history including diagnosis of ADD and ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder and other anxiety disorders, past or present family stressors, crises, any abuse or neglect, interview with parent(s) or guardian(s).~~

d. ~~e. —Adults (18 years or older and above) In addition to the general criteria above, the following must be present and documented in the recipient's medical record:~~

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 ~~past and present~~ impairment ~~including (academic achievement, learning disorder evaluation); and~~

2. ~~One of the following~~ All of the following must be met and documented in the recipient's medical record:

a. ~~A M~~medical history, including medical or primary neurological diagnoses, any history of other psychiatric disorder(s) and the current treatment regimen; ~~identify medication(s) that could be causing symptoms (e.g. Phenobarbital, steroids), or;~~

b. ~~History of other psychiatric disorder(s) and treatment, or~~ A medication review to rule out other possible causes of symptoms (e.g. Phenobarbital, steroids);

c. Diagnostic symptoms of ADD and ADHD; ~~presence or absence,~~

~~e.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 or~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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

## 2. Exception Criteria

- a. Prescriptions for ADD/ADHD medications do not require prior authorizations for children five years of age, up to 18 years of age, if the following criteria are met and documented conditions apply:
1. The recipient is at least three years of age for short acting stimulants or at least six years of age for long-acting stimulants, long 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. ~~3.~~ Prior Authorization approval will be given for a one year time period.
- b. Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

## 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 Social Security 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:

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators

Last Reviewed by the DUR Board: November 5, 2015

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

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

## 1. 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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

modifying antirheumatic drug (DMARD) (methotrexate, 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.

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

Q. Long-Acting Narcotics

Therapeutic Class: Analgesics, Narcotic

Last Reviewed by DUR Board: ~~July 30, 2009~~ 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 Social Security 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

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.

~~Indications: Management of moderate to severe pain when continuous around the clock analgesic is needed for an extended period of time. Medications:~~

- a. ~~Oxycontin (including generic); MS Contin (including generic); Avinza; Kadian; Oramorph.~~
  1. ~~No prior authorization is required for diagnosis of terminal cancer.~~
- b. ~~Please Note: The use of Long Acting Narcotics for acute/short term treatment of pain not within the quantity limits will not be approved.~~

~~Approval will be for a three month time limit.~~

## 2. Prior Authorization Guidelines:

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

- a. The prior authorization approval will be for three months.~~must be initiated by the prescriber. The approved Payment Authorization Request (PAR) must be available if requested.~~
- b. 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 Social Security 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 Food and Drug Administration (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.

~~1. Hetlioz® (tasimelteon): A diagnosis of non-24-hour sleep-wake disorder, or~~

~~2. All other agents: A diagnosis of insomnia.~~

## 2. Prior Authorization Guidelines

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

BB. Buprenorphine/Naloxone (Suboxone®/Subutex®)

Therapeutic Class: Narcotic Withdrawal Therapy Agents

Last Reviewed by the DUR Board: ~~July 25, 2013~~ April 28, 2016

Buprenorphine/Naloxone (Brand Suboxone®) and Buprenorphine (Brand Subutex®) are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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

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

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

~~a. Buprenorphine/Naloxone (Suboxone®)~~

~~The recipient must meet all of the following:~~

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

~~b.1.~~ The recipient has a diagnosis of opioid dependence; and

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

~~2.~~ ~~The recipient is 16 years of age or older; and~~

~~d.3.~~ There is documentation ~~that~~ the recipient has honored all of their office visits; and

e. ~~4.~~ 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 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;

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

- 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).
- h. 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.

~~b. Buprenorphine (Subutex®) (for female recipients):~~

~~The recipient must meet all of the following:~~

- ~~1. There is documentation that the recipient is pregnant or there is documentation the recipient is breastfeeding an infant who is dependent on methadone or morphine; and~~
- ~~2. The recipient has a diagnosis of opioid dependence; and~~
- ~~3. The recipient is 16 years of age or older; and~~

~~There is documentation that the recipient has honored all of their office visits; and~~

- ~~5. 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.~~

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>

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

EE. Colchicine (Colcrys®)

Therapeutic Class: Antigout Agents

Last Reviewed by the DUR Board: ~~October 28, 2010~~ January 28, 2016

Colchicine (Colcrys®) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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. Colchicine Tablets

1. ~~a. —The Rrecipient has a diagnosis of acute gout (does not require prophylaxis) Familial Mediterranean Fever (FMF); or and the recipient must meet all of the following:~~

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

- b. ~~The Rrecipient has had an inadequate response, adverse reaction or contraindication to an a diagnosis of acute gout and recipient has failed therapy with NSAIDs (indomethacin, naproxen, ibuprofen, sulindac or ketoprofen); and~~

- c. ~~The recipient has had an inadequate response, adverse reaction or contraindication to or a corticosteroids (oral or intra-articular). in the last 90 days; or~~

- ~~e. —Recipient has a diagnosis of chronic gout requiring prophylaxis and recipient has failed therapy with both xanthine oxidase inhibitors within the last 180 days or recipient has a contraindication to two xanthine oxidase inhibitors.~~

## 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:

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

- b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).

2. Prior Authorization Guidelines:

- a. ~~A prior authorization approval will be given based on diagnosis for additional medication beyond this limit will be approved for recipients with:~~
  - 1. For FMF and chronic gout: one year.
  - 2. For Acute gout: two months. ~~Chronic gout requiring prophylaxis and recipient has failed therapy with two xanthine oxidase inhibitors or has a contraindication to both xanthine oxidase inhibitors. The quantity limit for prophylaxis of chronic gout is 60 tablets/30 days.~~
  - 3. ~~Length of Approval (up to): one year~~
- b. Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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), Incivek® (telaprevir) and Olysio® (simeprevir) are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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:

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- 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.
    - ~~c. Olysio® (simeprevir)~~
- ~~1. For treatment initiation (treatment weeks one through eight), the recipient must meet 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® (telaprevir), Olysio® (simeprevir), or Victrelis®~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

~~(boceprevir) unless the drug is being switched due to an adverse event with the alternative drug; and~~

~~d. The recipient has been pre-screened and does not test positive for the 1A NS3 Q80K polymorphism.~~

~~2. For treatment continuation for treatment weeks nine through 12, the recipient must have one of the following:~~

~~a. The recipient is treatment naïve, and their HCV RNA level was <25 IU/mL at treatment week four; or~~

~~b. The recipient is a previous prior relapser and their HCV RNA level was <25 IU/mL at treatment week four; or~~

~~c. The recipient is a partial or a null responder to previous therapy of interferon and ribavirin alone (no other HCV protease inhibitors) and their HCV RNA was <25 IU/mL at treatment week four.~~

~~3. The initial prescription for Olysio, with peginterferon alfa and ribavirin must be for a two week supply. Subsequent refills can be up to 34 days.~~

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.

b. Incivek® (teleprevir) ~~and Olysio® (simeprevir)~~

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>

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

SS. Colony Stimulating Factors (Point of Sale Claims Only)

Therapeutic Class: Colony Stimulating Factors

Last Reviewed by the DUR Board: ~~July 25, 2013~~ 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 Social Security 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. 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  $\geq 20\%$ ;
    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/ $\mu$ 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.
- ~~a. Leukine® (sargramostim)~~

~~The recipient must meet one of the following:~~

- ~~1. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or~~
- ~~2. The recipient has a diagnosis of acute myeloid leukemia, and has received induction chemotherapy; or~~
- ~~3. The recipient has a diagnosis of non-Hodgkin's lymphoma, acute lymphoblastic leukemia or Hodgkin's disease and is undergoing autologous bone marrow transplantation; or~~
- ~~4. The recipient is undergoing allogeneic bone marrow transplantation from human leukocyte antigen-matched related donors; or~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

~~5. The recipient has undergone allogeneic or autologous bone marrow transplantation and is experiencing engraftment failure or delay.~~

~~b. Neulasta® (pegfilgrastim)~~

~~The recipient must meet the following criteria:~~

~~1. The recipient has a diagnosis of nonmyeloid malignancy and~~

~~a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of  $\geq 20\%$ ; or~~

~~b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age  $>65$ , absolute neutrophil count (ANC)  $<100$  cells/ $\mu\text{L}$ , or the expected duration of neutropenia is  $>10$  days); or~~

~~c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.~~

~~c. Neupogen® (filgrastim)~~

~~The recipient must meet one of the following (1 to 5):~~

~~1. The recipient has a diagnosis of nonmyeloid malignancy; and~~

~~a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of  $\geq 20\%$ ; or~~

~~b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age  $>65$ , ANC  $<100$  cells/ $\mu\text{L}$  or the expected duration of neutropenia is  $>10$  days); or~~

~~c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as a secondary prophylaxis; or~~

~~2. The recipient has a diagnosis of acute myeloid leukemia and has received induction or consolidation chemotherapy; or~~

~~3. The recipient has a diagnosis of nonmyeloid malignancy and is undergoing myeloablative chemotherapy followed by marrow transplantation; or~~

~~4. The recipient has a diagnosis of symptomatic congenital neutropenia, cyclic neutropenia or idiopathic neutropenia; or~~

~~5. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.~~

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

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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UU. Hepatitis C direct-acting antivirals Sovaldi® (sofosbuvir)

Therapeutic Class: ~~Hepatitis C direct acting antivirals~~ ~~Anti-Hepatitis Agents~~ ~~Polymerase Inhibitor Agents~~

Last Reviewed by the DUR Board: ~~January 22, 2015~~ January 28, 2016

Hepatitis C direct-acting antivirals Sovaldi® (sofosbuvir) is-are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

## 1. Coverage and Limitations:

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

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 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. ~~WW.~~ 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 (CPT 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), has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) 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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- 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 Olysio + Sovaldi), has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir), and must meet one of the following:
    - a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or
    - b. Cirrhosis (CTP class A, B, or C) will be treated with ribavirin and the requested duration is 24 weeks.
  5. 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. Cirrhosis (CTP class A, B, or C), will be treated with ribavirin and the requested duration is 24 weeks.
- c. Genotype 4, 5, 6:
1. The recipient is treatment-naïve and must meet one of the following:
    - a. The recipient is treatment-naïve and the requested duration is 12 weeks; or
    - b. The recipient is treatment-experienced (failed peginterferon + ribavirin ± an NS3 protease inhibitor) and the requested duration is 12 weeks.
- YY3. 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.
  - 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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- b. Compensated cirrhosis (CTP class A), will be treated with ribavirin 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, 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 recipient was a partial responder to peginterferon and ribavirin dual therapy and the requested duration is 12 weeks; or
  - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the recipient was a relapser after peginterferon and ribavirin dual therapy and the requested duration is 24 weeks.
- d. 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.
- GGG4. 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); and
  - b. The recipient does not have cirrhosis.
  - c. Genotype 4:
    - 1. The recipient must meet one of the following:
      - a. The recipient is treatment-naïve, will be treated with ribavirin and

the requested duration is 12 weeks; or

- b. The recipient is treatment-naïve, provided documentation shows the recipient is unable to take ribavirin and the requested duration is 12 weeks; or
- c. The recipient is treatment-experienced (failed peginterferon and ribavirin dual therapy) will be treated with ribavirin and the requested duration is 12 weeks.

#### HH5. 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 30 mg tablet and one 60 mg tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer and the clinical rationale has been provided documenting medical necessity for continuing the moderate CYP3A inducer Daklinza therapy.
- 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 ribavirin and the requested duration is 12 weeks; or
    - b. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or
    - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi ± ribavirin and the requested duration is 12 weeks; or
    - d. Compensated cirrhosis (CTP class A), will be treated with Sovaldi + ribavirin and the requested duration is 24 weeks; or
    - e. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, 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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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, requested duration is 24 weeks and documentation is provided showing that the recipient is unable to take ribavirin.
3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor), has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) 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, documentation is provided showing the recipient is unable to take 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 12 weeks; or
    - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 24 weeks.
  2. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy), documentation has been 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 ribavirin and the

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- requested duration is 24 weeks; or
- b. No cirrhosis, will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that 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.
- 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, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; 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 and showing the recipient is unable to receive peginterferon.
  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
    - 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.
  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.
- e-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. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin; or
      - c. 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
      - d. 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.
    - 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
      - c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, and 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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- 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
  - f. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, and the requested duration is 24 weeks; or
  - g. 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.

UU.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 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 has been provided showing the recipient is unable to take ribavirin; or
    - c. No cirrhosis, genotype 1a, will be treated with Olysio and ribavirin, and the requested duration is 12 weeks; or
    - d. No cirrhosis, genotype 1a, will be treated with Olysio, the requested duration is 12 weeks, and documentation has been provided showing the recipient is unable to take ribavirin; or
    - e. No cirrhosis, genotype 1b, will be treated with Olysio, and the requested duration is 12 weeks; or
    - a.f. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin and the requested duration is 12 weeks; or
    - g. Compensated cirrhosis (CTP class A), will be treated with Daklinza

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- + ribavirin, and the requested duration is 24 weeks; or
- h. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, and documentation has been provided showing the recipient is unable to take ribavirin; or
  - i. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism; or
  - j. 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, and documentation has been provided showing the recipient is unable to take ribavirin; or
  - k. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, and the requested duration is 24 weeks; or
  - l. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, and documentation has been provided 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 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, and the requested duration is 24 weeks; or
    - d. Compesated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, and documentation is provided showing that the recipient is unable to take ribavirin; or
    - e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism; or
    - f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient 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; or

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, and the requested duration is 24 weeks; or
  - h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin.
3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor), has had no prior treatment with an NS5A polymerase inhibitor (e.g, daclatasvir, ledipasvir, ombitasvir) 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
    - b. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or
    - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks; or
    - d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or
    - e. 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:

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- a. No cirrhosis, will be treated with ribavirin and the requested duration is 16 weeks; or
  - b. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks; or
  - c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks; or
  - d. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 24 weeks; or
  - e. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks.
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
  - 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 ribavirin and peginterferon, and the requested duration is 12 weeks.
- d. Genotype 3
1. The recipient is treatment-naive 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 has been provided

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

showing that the recipient is unable to receive peginterferon;  
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 treated duration is 24 weeks and documentation has been provided the recipient is unable to receive peginterferon; or
- f. 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.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 and showing the recipient is unable to receive peginterferon.

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 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 and the requested duration is 24 weeks; or
- e. 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.

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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 and the requested duration is 24 weeks; or
  - c. Compensated cirrhosis (CTF 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 and the requested duration is 24 weeks.
- 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, and the requested duration is 12 weeks; or
    - b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or
    - c. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
    - d. Cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks.
  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 and the requested duration is 12 weeks; or
    - b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or
    - c. Cirrhosis, will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks;
    - d. Cirrhosis, will be treated with ribavirin, and the requested duration is 24 weeks.

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- 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 and the requested duration is 12 weeks; or
    - b. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.
  2. The recipient is treatment-experienced 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. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.
8. Recipients who have received previous therapy with an NS5A inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir)
- a. Genotype 1
    1. The recipient must meet one of the following:
      - a. The recipient has cirrhosis; or
      - b. Documentation includes the clinical rationale for urgent retreatment.
    2. Testing for resistance-associated variants (RAVs) have been done and results have been provided.
    3. No NS5A RAVs detected: Harvoni + ribavirin ± peginterferon x 24 weeks.
    4. NS5A RAVs detected, no NS3 RAVS detected: Olysio + Sovaldi + ribavirin ± peginterferon x 24 weeks.
9. 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 (≤ 1 log<sub>10</sub> IU/mL) on repeat testing at treatment week

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

six (or thereafter).

c. And, the recipient is compliant on all drugs in the treatment regimen.

10. 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.

~~Approval for Sovaldi® (sofosbuvir) for mono infected or HCV/HIV 1 co infected recipients will be given if the following criteria are met and documented:~~

~~a. The recipient has a diagnosis of chronic hepatitis C Genotype 1 infection; and the recipient will be treated in combination with peginterferon alfa and ribavirin or, if the recipient is ineligible to receive peginterferon alfa, in combination with ribavirin; or~~

~~b. The recipient has a diagnosis of Chronic Hepatitis C Genotype 2 or 3 Infection; and the recipient will be treated in combination with ribavirin; or~~

~~c. The recipient has a diagnosis of Chronic Hepatitis C Genotype 4 Infection; and the recipient will be treated in combination with peginterferon alfa and ribavirin; or:  
 — The recipient has a diagnosis of Chronic Hepatitis C Genotype 1, 2, 3, or 4 infection; and the recipient has a diagnosis of hepatocellular carcinoma and is awaiting a liver transplant; and the recipient will be treated in combination with ribavirin.~~

~~2. The initial prescription for Sovaldi must be for a two week supply. Subsequent refills can be up to 34 days.~~

~~3. Prior Authorization Guidelines~~

~~a. Prior Authorization approval will be for 12 weeks for ALL of the following:~~

~~1. Recipients with a diagnosis of Chronic Hepatitis C Genotype 1 infection and combination therapy with peginterferon alfa and ribavirin.~~

~~2. Recipients with a diagnosis of Chronic Hepatitis C Genotype 2 infection and combination therapy with ribavirin.~~

~~b. Prior Authorization approval will be for 24 weeks for all of the following:~~

~~1. Recipients with a diagnosis of Chronic Hepatitis C Genotype 1 infection and combination therapy with ribavirin.~~

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

- ~~2. Recipient with a diagnosis of Chronic Hepatitis C Genotype 3 infection and combination therapy with ribavirin.~~
- c. ~~Prior Authorization approval will be for up to 48 weeks or until liver transplantation for recipients with a diagnosis of hepatocellular carcinoma and is awaiting a liver transplant combination therapy with ribavirin.~~
- d. ~~Prior Authorizations will be renewed in 12 week intervals based on genotype.~~
- e. ~~Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>~~

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## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

## WW. Viberzi® (eluxadoline)

Therapeutic Class:  $\mu$ -opioid receptor agonist/ $\sigma$ -opioid receptor antagonist/ $\kappa$ -receptor agonist  
 Last Reviewed by the DUR Board: April 28, 2016

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

1. Approval for Viberzi® (eluxadoline) will be given if all the following criteria are met and documented:
  - a. The recipient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
  - b. The recipient is 18 years of age or older; and
  - c. The requested agent is prescribed by or in consultation with a gastroenterologist; and
  - d. The requested dose is 75 mg twice daily or 100 mg twice daily; and
  - e. One of the following is met:
    1. The recipient has had an inadequate response or adverse reaction to one of the following: loperamide, diphenoxylate/atropine, bile acid sequestrants (cholestyramine, colestipol, colesevelam), tricyclic antidepressants (TCAs), or selective serotonin reuptake inhibitors (SSRIs); or
    2. The recipient has a contraindication to all of the alternatives noted above.
2. Prior Authorization Guidelines
  - a. Prior authorization approval will be for one year.
  - b. Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

~~WW. Harvoni® (ledipasvir/sofosbuvir)~~

~~Therapeutic Class: Anti-Hepatitis Agents-Polymerase Inhibitor Agents  
 Last Reviewed by the DUR Board: January 22, 2015~~

~~Harvoni® (ledipasvir/sofosbuvir) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

~~Approval for Harvoni® (ledipasvir/sofosbuvir) will be given if the following criteria is met and documented:~~

- ~~a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and~~
  - ~~b. The recipient is 18 years of age or older; and~~
  - ~~c. The requested dose is 90 mg/400 mg, once daily; and~~
- ~~2. The initial prescription for Harvoni® must be for a two week supply. Subsequent refills can be up to 34 days.~~
- ~~3. PA Guidelines~~
- ~~a. PA approval will be given for eight weeks of therapy if the recipient is treatment naïve, does not have cirrhosis and as a pretreatment (within the last 12 weeks) HCV RNA viral load less than 6 million IU/mL; or~~
  - ~~b. PA approval will be given for 12 weeks of therapy, if one of the following are met and documented:~~
    - ~~1. The recipient is treatment naïve, does not have cirrhosis and has a pretreatment (within the last 12 weeks) HCV RNA viral load greater than or equal to 6 million IU/mL; or~~
    - ~~2. The recipient is treatment naïve and has cirrhosis; or~~
    - ~~3. The recipient is treatment experienced (failed treatment with peginterferon alfa + ribavirin ± an HCV protease inhibitor) and does not have cirrhosis. (NOTE: recipients who have failed a previous course of therapy with Sovaldi® is also acceptable to meet this criterion); or~~
  - ~~c. Approval will be given for 24 weeks of therapy if the recipient is treatment-experienced (failed treatment with peginterferon alfa + ribavirin ± an HCV protease inhibitor) and has cirrhosis. (NOTE: recipients who have failed a previous course of therapy with Sovaldi® is also acceptable to meet this criterion).~~

~~Prior Authorization forms are available at:~~

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

## YY. Diclegis® (doxylamine succinate/pyridoxine delayed release) tablets

Therapeutic Class: Antihistamine/Vitamin B6 Analog

Last Reviewed by the DUR Board: April 28, 2016

Diclegis® (doxylamine succinate/pyridoxine delayed release tablets) are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

## 1. Coverage and Limitations:

a. The initial approval will be given if all the following criteria are met and documented:

1. The recipient is female; and
2. The recipient is 18 years of age or older; and
3. The recipient has a diagnosis of excessive vomiting in pregnancy; and
4. The requested dose is four tablets/day or less.

b. Recertification for Diclegis® (doxylamine/pyridoxine delayed-release) tablets will be given if the following criterion is met and documented:

1. There is documentation provided that the recipient continues to experience excessive vomiting in pregnancy.

## 2. Prior Authorization Guidelines:

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

~~YY. Viekira Pak® (dasabuvir ombitasvir paritaprevir ritonavir)~~

~~Therapeutic Class: Anti-Hepatitis Agents Polymerase Inhibitor Agents~~

~~Last Reviewed by DUR Board: April 23, 2015~~

~~Viekira Pak® (dasabuvir ombitasvir paritaprevir ritonavir) is subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

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

- ~~a. The recipient has a diagnosis of hepatitis C virus (HCV) genotype 1; and~~
- ~~b. The recipient is 18 years of age or older; and~~
- ~~c. The recipient does not have severe hepatic impairment (Child Pugh class C); and~~
- ~~d. The recipient has not failed previous therapy that included an HCV protease inhibitor (i.e. boceprevir (Victrelis®), simeprevir (Olysio®) teleprevir (Incivek®); and~~
- ~~e. The recipient has not failed previous therapy that included sofosbuvir (Sovaldi®); and~~
- ~~f. The requested dose is 25/150/100 mg of dasabuvir paritaprevir ritonavir (two tablets) once daily in combination with dasabuvir 250 mg (one tablet) twice daily; and~~
- ~~g. The recipient will be using combination therapy with ribavirin for any of the following:~~
  - ~~1. genotype 1a infection (all);~~
  - ~~2. genotype 1b infection (cirrhosis is present);~~
  - ~~3. recipient has had a liver transplant; and~~
- ~~h. The requested duration of therapy is appropriate; and~~
- ~~i. If the recipient has had a liver transplant, they have no or mild hepatic fibrosis (Metavir fibrosis score 2 or less).~~

~~2. Prior Authorization Guidelines~~

- ~~a. Prior Authorization approvals will be given for a period of 12 weeks at a time.~~
- ~~b. Total length of therapy authorized will be based on the following:~~
  - ~~1. Genotype 1a (no cirrhosis): 12 weeks~~
  - ~~2. Genotype 1a (cirrhosis): 24 weeks~~
  - ~~3. Genotype 1b: 12 weeks~~
  - ~~4. Genotype 1a or 1b (recipient has had a liver transplant): 24 weeks.~~

~~Prior Authorization forms are available at:~~

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

## ZZ. Vivitrol® (naltrexone)

Therapeutic Class: Opioid Dependence Agents

Last Reviewed by DUR Board: ~~April 23, 2015~~ January 28, 2016

Vivitrol® (naltrexone®) is subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the Social Security 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. The drug is being used for an FDA approved indication; and
- ~~b. Recipients must be given the Naloxone Challenge Test prior to administration to assure recipient is opiate free before initiation of therapy; and~~
- ~~e.b.~~ b. The drug must be delivered directly to the prescriber's office; and
- ~~d.c.~~ c. The drug is only to be administered once per month; and
- d. Routine urine screening and monitoring is recommended.

## 2. Prior Authorization Guidelines

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

EEE. ~~Anti-lipidemic Agents – PCSK9 Inhibitors Praluent® (alirocumab)~~

Therapeutic Class: Antilepemic Agent, PCSK9 Inhibitors ~~Agent~~

Last Reviewed by the DUR Board: ~~November 5, 2015~~ January 28, 2016

~~Anti-lipidemic Agents – PCSK9 Inhibitors Praluent® (alirocumab)~~ is subject to prior authorization and quantity limitation based on the Application of Standards in Section 1927 of the Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

a. Initial Request: ~~(the recipient must meet all criteria (1-4))~~

1. The recipient has an FDA-approved diagnosis ~~of heterozygous familial hypercholesterolemia (HeFH); and~~

~~The recipient has clinical atherosclerotic cardiovascular disease and requires additional lowering of LDL-C (defined as acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin); and~~

2. The requested medication ~~agent~~ is prescribed by or in consultation with a cardiologist or lipid specialist; and

- ~~2.3.~~ The requested medication ~~agent~~ will be used as an adjunct to a low-fat diet and exercise; and

- ~~3.~~ ~~The agent is prescribed by or in consultation with a cardiologist or lipid specialist; 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.

- 4.5. ~~And T~~the recipient must meet ~~the criteria for~~ one of the following ~~responses~~ (a, b, c, or -d):

- a. The recipient has had an inadequate response to high intensity statin

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

therapy defined ~~by~~ 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~~~~three months~~ or the recipient has a contraindication to ezetimibe therapy; and
  3. The LDL-C after therapy for at least the past three months was  $\geq$  100 mg/dL (HeFH) for  $\geq$  70 mg/dL (clinical atherosclerotic cardiovascular disease); and
  4. The statin therapy will be continued with PCSK-9 therapy.
- b. Or, the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:
1. The recipient has ~~had~~ 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~~~~three months~~ or the recipient has a contraindication to ezetimibe therapy; and
  4. The LDL-C after therapy for at least the past three months was  $\geq$  100 mg/dL (HeFH) or  $\geq$  70 mg/dL (clinical

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

atherosclerotic cardiovascular disease); and

5. Statin therapy will be continued with PCSK-9 therapy.
  - c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.
  - d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.
2. Recertification Request (The recipient must meet all criteria (a-d)).
  - a. The recipient has been adherent with PCSK-9 inhibitor therapy; and
  - b. The recipient has been adherent with statin therapy or the recipient has a labeled contraindication to statin therapy; and
  - c. The recipient is continuing a low-fat diet and exercise regimen; and
  - d. The recipient has achieved a reduction in LDL-C level.
3. Prior Authorization Guidelines:
  - a. 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>

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

## GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: 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 Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

## 1. Coverage and Limitations

Medications for recipients on hospice can be covered by Nevada Medicaid if determined to be not related to the terminal hospice diagnosis. All medications for recipients who are over the age of 20, and enrolled in the hospice program will require prior authorization approval. Approval will be given if all the following criteria are met and documented:

- a. The recipient is over the age of 20; and
- b. The prescriber has verified the recipient is enrolled in the hospice program; and
- c. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and
- d. The requested medication is not being used for palliative care but is medically necessary to treat the recipient; and
- e. The requested medication is not providing a curative or long-term prophylactic therapy.

## 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>

~~GGG. Technivie® (ombitasvir/paritaprevir/ritonavir)~~

~~Therapeutic Class: Polymerase Inhibitors/Combination Products~~

~~Last Reviewed by the DUR Board: November 5, 2015~~

~~Technivie® (ombitasvir/paritaprevir/ritonavir) is subject to prior authorization based on the Application of Standards in Section 1927 of the Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.~~

~~1. Coverage and Limitations~~

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

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- ~~a. The recipient has a diagnosis of chronic hepatitis C, genotype 4, and~~
- ~~b. The recipient is 18 years of age or older, and~~
- ~~c. The recipient does not have cirrhosis (Metavir score F4), and~~
- ~~d. The recipient does not have moderate or severe hepatic impairment (Child Pugh grade B or C), and~~
- ~~e. The requested dose is two Technivie® tablets daily, and~~
- ~~f. The total duration of therapy does not exceed 12 weeks, and~~
- ~~g. For treatment naïve recipients:
  - ~~1. Technivie® will be used in combination with ribavirin, or~~
  - ~~2. Technivie® will be used without ribavirin. There is documentation that the recipient cannot take or cannot tolerate ribavirin.~~~~
- ~~h. Or for treatment experienced recipients:
  - ~~1. Technivie® will be used in combination with ribavirin.~~~~
- ~~2. Prior Authorization Guidelines:
  - ~~a. Prior Authorization approvals will be for 12 weeks.~~
  - ~~b. Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>~~~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

## 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 Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

## 1. 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>

~~III. Daklinza® (daclatasvir)~~~~Therapeutic Class: Anti-hepatitis Agents~~~~Last Reviewed by the DUR Board: November 5, 2015~~

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

~~1. Coverage and Limitations~~

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

- ~~a. The recipient has a diagnosis of hepatitis C genotype 3, and~~
- ~~b. The recipient is 18 years of age or older, and~~
- ~~c. The recipient has not had a liver transplant, and~~
- ~~d. The requested agent will be used in combination with Sovaldi, and~~
- ~~e. The recipient is not on a strong CYP3A inducer, and~~

## DIVISION OF HEALTH CARE FINANCING AND POLICY

## MEDICAID SERVICES MANUAL

- ~~f. The recipient does not have cirrhosis (Metavir score F4), and one of the following:~~
- ~~1. The requested dose of Daklinza® is 60 mg (one tablet) daily, or~~
  - ~~2. The requested dose of Daklinza® is 30 mg (one tablet) daily and the recipient is receiving a concomitant strong CYP3A inhibitor; or~~
  - ~~3. The requested dose of Daklinza® is 90 mg (one 30 mg tablet and one 60 mg tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer. Medical necessity of continued use of the moderate CYP3A inducer during Daklinza® therapy must be provided; and~~
- ~~g. Usage is based on current clinical peer reviewed literature, and~~
- ~~h. The requested length of therapy is 12 weeks.~~
- ~~2. Prior Authorization Guidelines:~~
- ~~a. Prior Authorization approval will be for 12 weeks.~~
  - ~~b. Prior Authorization forms are available at:  
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>~~

**KKK. Neurokinin-1 Antagonists and Combinations**

Therapeutic Class: Neurokinin-1 Antagonists and Combinations

Last Reviewed by the DUR Board: April 28, 2016

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

**1. 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>

## 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 Social Security Act (SSA) and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

## 1. 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 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>

**C. Gender Edits****1. Hormones**

- ~~1.a.~~ Estrogen – payable only for female recipients.
- ~~2.b.~~ Progestins – payable only for female recipients.
- ~~3.c.~~ Estrogen and Androgen Combinations – payable only for female recipients.
- ~~4.d.~~ Estrogen and Progestin Combinations – payable only for female recipients.
- ~~5.e.~~ Contraceptive Hormones – payable only for female recipients.
- ~~6.f.~~ Transdermal Testosterone – payable only for male recipients.
- ~~7.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.