MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

August 31, 2021

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: JESSICA KEMMERER, HIPAA PRIVACY AND CIVIL RIGHTS OFFICER

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on April 22, 2021, by the Drug Use Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria for Nurtec® ODT (rimegepant) within the Anti-Migraine Medication section; addition of new prior authorization for Kesimpta®(ofatumumab) within the Multiple Sclerosis (MS) Agents section; revisions to the existing Anti-Hepatitis Agents prior authorization criteria as well as the removal of discontinued products, Daklinza® (daclatasvir), Olysio® (simeprevir), Technivie® (ombitasvir / paritaprevir / ritonavir) and Viekira® XR (dasabuvir / ombitasvir / paritaprevir / ritonavir); revisions to the existing Hereditary Angioedema Agents prior authorization criteria; formatting changes to the existing Platelet Inhibitors section; addition of new prior authorization criteria for Xywav® (calcium / magnesium / potassium / sodium oxybates) within the Narcolepsy Agents section and revisions to the existing prior authorization for Valtoco® (diazepam nasal spray) within the Anticonvulsants section. In addition, DHCFP is proposing revisions to section 1203.1E to reflect the intent Assembly Bill (AB) 178 from the 81st (2021) Nevada Legislative Session which allows DHCFP to waive the early refills requirement for a non-controlled substance prescription in areas for which an emergency or disaster has been declared.

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

Entities Financially Affected: No entities are anticipated to be financially affected.

Financial Impact on Local Government: No known financial impact on local government.

These changes are effective September 7, 2021.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL OL MSM Chapter 1200 - Prescribed Drugs	MTL 18/17 MSM Chapter 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1E	**Early Refills**	Added language to reflect the intent of AB178 from the 81st (2021) Nevada Legislative Session which allows DHCFP to waive early refills requirement for non-controlled substance prescriptions in areas for which an emergency or disaster has been declared.
Appendix A Section S	**Anti-Migraine Medications**	Updated last reviewed date. Added new prior authorization criteria for Nurtec® ODT. Updated web links throughout section.
Appendix A Section CC	**Multiple Sclerosis (MS) Agents**	Update last reviewed date. Updated general prior authorization to reflect prior authorization for Kesimpta®. Updated web links throughout section.
Appendix A Section HH	**Anti-Hepatitis Agents**	Updated last reviewed date. Removed existing prior authorization criteria for Daklinza®, Olysio®, Technivie® and Viekira XR® as these products have been discontinued. Updated existing prior authorization criteria for Viekira®.
Appendix A Section JJ	**Hereditary Angioedema Agents**	Updated last reviewed date. Updated clinical criteria for Cinryze® to include Haegarda®, Orladeyo® and Takhzyro®. Updated prior authorization criteria for Firazyr® and Ruconest® and off label use Cynryze®. Updated prior authorization criteria for Kalbitor® and Berinert®. Updated formatting and web links throughout section.
Appendix A Section NN	**Platelet Inhibitors**	Updated last reviewed date. Updated formatting and web links throughout section.
Appendix A Section AAA	**Narcolepsy Agents**	Updated last reviewed date. Added new prior authorization criteria for Xywav®. Updated web links throughout section.
Appendix A Section BBBB	**Anticonvulsants**	Updated last reviewed date. Updated current Valtoco® prior authorization criteria. Updated web links.

1203 POLICY

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

1203.1 COVERAGE AND LIMITATIONS

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

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

   a. American Hospital Formulary Service Drug Information;

   b. United States Pharmacopeia;

   c. DRUGDEX Information System; or

   d. Peer-reviewed medical literature.

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

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

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

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

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

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

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

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

B. Standard Preferred Drug List Exception Criteria

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

1. Coverage and Limitations

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

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

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

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

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

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

peer-reviewed literature or a FDA-approved indication;

g. Psychotropic, Antidepressant Medication – Continuity of Care;

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

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

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

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight loss.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

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

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

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

7. Agents used for impotence/erectile dysfunction.

D. Refills

A refill is a prescription subject to the limitations below:

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

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

E. Early Refills

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

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

~~2.~~3. In the instance that a recipient will be out of town when a refill is due, the pharmacist may enter the appropriate override code to allow an early refill. This override will be monitored by Nevada Medicaid for misuse/abuse by the recipient and/or provider.

~~3.~~4. Medicaid will not pay for an early prescription refill when gross negligence or failure to follow prescriber's prescription instructions has been displayed by the recipient.

S. Anti-Migraine Medications

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

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: April 22, 2021~~April 30, 2020~~

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

1. Serotonin 5-HT1 Receptor Agonists (triptans)

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

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

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

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

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

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

   b. Prior Authorization Guidelines:

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

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

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

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

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

1. CGRP General Criteria

a. The recipient must have one of the following:

1. Both the following:

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

b. The recipient has four to 14 migraine days per month, but not more than headache days per month~~;~~.: or

2. All the following:

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

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

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

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

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

d. The recipient must meet two of the following:

1. One of the following:

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

b. The recipient has a contraindication to Elavil® (amitriptyline) and Effexor® (venlafaxine); or

2. One of the following:

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

b. The recipient has a contraindication to both Depakote®/Depakote® ER (divalproex sodium) and Topamax® (topiramate); or

3. One of the following:

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

1. Atenolol; or

2. Propranolol; or

3. Nadolol; or

4. Timolol; or

5. Metoprolol; or

b. The recipient has a contraindication to all the following beta blockers:

1. Atenolol; or

2. Propranolol; or

3. Nadolol; or

4. Timolol; or

5. Metoprolol.

2. Recertification Request:

a. The recipient must have a documented positive response to Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm) or Emgality® (galcanezumab-gnlm) therapy, demonstrated by a reduction in headache frequency and/or intensity; and

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

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

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

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

3. Acute Migraines

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

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

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

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

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

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

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

2. Recertification Request:

a. The recipient must have a documented positive response to the CGRP~~Ubrelvy®~~ therapy; and

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

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

4. Episodic Cluster Headache

a. Emgality® (galcanezumab-gnlm)

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

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

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

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

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

2. Recertification Request:

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

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for three months.

b. Recertification request will be approved for 12 months.

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

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: April 22, 2021~~January 23, 2020~~

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

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

   a. The recipient has a diagnosis of MS.

~~1.~~2. Ampyr~~i~~a® (dalfampridine)

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

      1. The recipient must have a diagnosis of MS; and

      2. The medication is being used to improve the recipient's walking speed; and

      3. The medication is being prescribed by or in consultation with a neurologist; and

      4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and

      5. The recipient does not have moderate to severe renal dysfunction (CrCL less than 50 ml/min); and

      6. The recipient does not have a history of seizures; and

      7. The recipient is not currently pregnant or attempting to conceive.

   b. Prior Authorization Guidelines

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

      2. Request for continuation of therapy will be approved for one year.

3. ~~2.~~ Relapsing Forms of MS Agents:

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

      1. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses).

   b. Lemtrada® (alemtuzumab)

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

   a. The recipient must have a diagnosis of a relapsing form of MS; and one of the following:

      1. Both the following:

         a. The recipient has not been previously treated with alemtuzumab; and

         b. The recipient has had failure after a trial of at least four weeks; a contraindication, or intolerance to two of the following disease-modifying therapies for MS:

            1. Aubagio (teriflunomide)
            2. Avonex (interferon beta-1a)
            3. Betaseron (interferon beta-1b)
            4. Copaxone/Glatopa (glatiramer acetate)
            5. Extavia (interferon beta-1b)
            6. Gilenya (fingolimod)
            7. Mavenclad (cladrivine)
            8. Mayzent (siponimod)
            9. Ocrevus (ocrelizumab)
            10. Plegridy (peginterferon beta-1a)
            11. Rebif (interferon beta-1a)
            12. Tecfidera (dimethyl fumarate)
            13. Tysabri (natalizumab); or
            14. Zinbryta (daclizumab)

      c. Both the following:

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

         b. The recipient has had at least 12 months elapsed or will have elapsed since the most

recent treatment course with alemtuzumab; and

2. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

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

c. Mavenclad® (cladribine)

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

a. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and one of the following:

1. Both the following:

a. The recipient has not been previously treated with cladribine; and

b. The recipient has had failure after a trial of at least four weeks; contraindication, or intolerance to two of the following disease-modifying therapies for MS:

1. Aubagio (teriflunomide)

2. Avonex (interferon beta-1a)

3. Betaseron (interferon beta-1b)

4. Copaxone/Glatopa (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya (fingolimod)

7. Lemtrada (alemtuzumab)

8. Mayzent (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)
13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

2. Both the following:

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

b. The recipient has not already received the FDA-recommended lifetime limit of two treatment courses (or four treatment cycles total) of cladribine; and

b. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

b. Prior Authorization forms are available at:

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

d. Ocrevus® (ocrelizumab)

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

a. The recipient has a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 months.

b. Recertification approval will be for 12 months.

c. Prior Authorization forms are available at:

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

e. Zeposia® (ozanimod)

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

a. The recipient has a documented diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

a. Avonex (interferon beta-1a)

b. Betaseron (interferon beta-1b)

c. Copaxone/Glatopa (glatiramer acetate)

d. Tecfidera (dimethyl fumarate); and

c. The medication is prescribed by or in consultation with a neurologist.

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

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. The medication is prescribed by or in consultation with a neurologist.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

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

4. ~~3.~~ Primary Progressive Forms of Multiple Sclerosis (PPMS) Agents:

a. Ocrevus® (ocrelizumab)

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell target therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

3. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

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

HH. Anti-Hepatitis Agents

Therapeutic Class: Anti-Hepatitis Agents
Last Reviewed by the DUR Board: April 22, 2021~~July 26, 2018~~

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

~~1. Coverage and Limitations~~

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

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

~~1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or genotype 3 (submission of medical records e.g., chart notes, laboratory values); and~~

~~2. The medication is used in combination with Sovaldi® (sofosbuvir); and~~

~~3. One of the following:~~

~~a. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or~~

~~b. Both of the following:~~

~~1. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and~~

~~2. The medication is used in combination with Ribavirin.~~

~~4. The recipient has not failed a prior HCV NS5A-containing regimen (e.g., Daklinza); and~~

~~5. The medication must be prescribed by or in consultation with one of the following:~~

~~a. Hepatologist~~

~~b. Gastroenterologist~~

~~c. Infectious Disease Specialist~~

~~d. HIV Specialist (certified through the American Academy of HIV Medicine)~~

~~6. Prior authorization approval will be for 12 weeks.~~

~~b.~~1. Epclusa® (sofosbuvir and velpatasvir)

~~1.~~a. Approval will be given if all the following criteria are met and documented~~The following are required for all Epclusa® treatment~~:

1. The recipient is not receiving Epclusa® (sofosbuvir and velpatasvir) in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

~~2.~~b. Genotype 1, 2, 3, 4, 5 or 6, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient must not have decompensated liver disease; and

3. Epclusa® must be used alone; and

4. The request is FDA approved for recipient weight and age; and

5. Prior authorization approval will be for 12 weeks.

~~3.~~c. Genotype 1, 2, 3, 4, 5 or 6 with decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has decompensated liver disease; and

3. Epclusa® is being used in combination with Ribavirin; and

4. The request is FDA approved for recipient weight and age; and

5. Prior authorization approval will be for 24 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has decompensated liver disease; and

a. One of the following:

1. The recipient is Ribavirin intolerant or ineligible; or

2. Both of the following:

a. The recipient has had prior failure (defined as viral relapse, breakthrough while on therapy, or is a non-responder to therapy) to Sovaldi® or NS5A-based treatment; and

b. Epclusa® is used in combination with Ribavirin®.

3. Prior authorization approval will be for 24 weeks.

~~e.~~2. Harvoni® (ledipasvir/sofosbuvir)

a. Approval will be given if the following criteria are met and documented~~The following are required for all Harvoni® treatment~~:

1. The recipient is not receiving Harvoni® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is less than six million IU/mL

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. The recipient is treatment naïve; and

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

5. Prior authorization approval will be for eight weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. The recipient is treatment naïve; and

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

5. Prior authorization approval will be for 12 weeks.

d. Genotype 1, treatment naïve with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient is treatment naïve; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient does not have cirrhosis; and

3. One of the following:

a. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; or

b. Both of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) except in combination with Olysio® (simeprevir); and

2. The medication is used in combination with Ribavirin.

4. Prior authorization approval will be for 12 weeks.

f. Genotype 1, Ribavirin eligible, treatment experienced and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. Prior authorization approval will be for 12 weeks.

g. Genotype 1, Ribavirin ineligible, treatment experienced and with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

3. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

4. The recipient is Ribavirin ineligible; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. Prior authorization approval will be for 24 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); or

b. Both of the following:

1. The recipient is a liver transplant recipient; and

2. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

3. The medication is used in combination with Ribavirin; and

4. Prior authorization approval will be for 12 weeks.

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); and

3. One of the following:

a. The recipient is Ribavirin ineligible; or

b. Both of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

2. The medication is used in combination with Ribavirin; and

4. Prior authorization approval will be for 24 weeks

j. Genotype 4, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. One of the following:

1. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and is without cirrhosis; or

2. Both of the following:

a. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and has compensated cirrhosis (Child-Pugh class A); and

b. The medication is used in combination with Ribavirin; and

3. Prior authorization approval will be for 12 weeks.

k. Genotype 5 or 6, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin; and

3. Prior authorization approval will be for 12 weeks.

~~4.~~3. Mavyret® (glecaprevir/pibrentasvir)

a. Approval will be given if the following criteria are met and documented:~~The following are required for all Mavyret® treatment~~:

1. The recipient is not receiving Mavyret® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir)); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. Prior authorization approval will be for ~~eight~~ 12 weeks.

c. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is treatment naïve; and

3. The recipient has compensated cirrhosis (Child-Pugh class A); and

4. Prior authorization approval will be for ~~12~~ eight weeks.

d. Genotype 1, treatment experienced (prior failure to an NS3/4A protease inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced (prior failure to an NS5A inhibitor), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 16 weeks.

f. Genotype 3, treatment experienced (interferon or Sovaldi® based regimen), without decompensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

5. Prior authorization approval will be for 16 weeks.

g. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient is without cirrhosis; and

5. Prior authorization approval will be for eight weeks.

h. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), with compensated cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

3. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek®

(telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

4. The recipient has compensated cirrhosis (e.g., Child-Pugh class A); and

5. Prior authorization approval will be for 12 weeks.

~~e. Olysio® (simeprevir)~~

~~1. Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:~~

~~a. Both of the following:~~

~~1. Diagnosis of chronic hepatitis C genotype 1a; and~~

~~2. The recipient does not have the NS3 Q8K polymorphism; or~~

~~b. The recipient has a diagnosis of chronic hepatitis C genotype 1b; or~~

~~c. The recipient has a diagnosis of chronic hepatitis C genotype 4; and~~

~~2. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and~~

~~3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and~~

~~4. The medication is used in combination with peginterferon alfa and Ribavirin; and~~

~~5. The medication must be prescribed by or in consultation with one of the following:~~

~~a. Hepatologist~~

~~b. Gastroenterologist~~

~~c. Infectious Disease Specialist~~

~~d. HIV Specialist (certified through the American Academy of HIV Medicine)~~

~~6. Genotype 1 without cirrhosis~~

~~a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and~~

~~b. The recipient is without cirrhosis; and~~

~~c. The medication is used in combination with Sovaldi® (sofosbuvir); and~~

~~d. Prior authorization approval will be for 12 weeks.~~

~~7. Genotype 1 with cirrhosis~~

~~a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and~~

~~b. Submission of medical records (e.g., chart notes, laboratory values documenting that the recipient has cirrhosis; and~~

~~c. The medication is used in combination with Sovaldi® (sofosbuvir); and~~

~~d. Prior authorization approval will be for 24 weeks.~~

~~f.~~4. Sovaldi® (sofosbuvir)

a. ~~1.~~ Approval will be given if the following criteria are met and documented~~The following is required for all Sovaldi® treatment~~:

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

b. ~~2.~~ Genotype 1 or 4, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or 4 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with peginterferon alfa and Ribavirin; and

3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

4. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

5. Prior authorization approval will be for 12 weeks.

c. ~~3.~~ Genotype 3, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

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

3. Both of the following:

a. The recipient has a documented diagnosis of chronic hepatitis C virus (HCV) genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is less than 12 years of age; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. Prior authorization approval will be for 24 weeks.

~~b.~~d. Genotype 2, without decompensated liver disease

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

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

3. Both of the following:

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is 12 to 17 years of age; or both of the following:

1. The recipient weighs at least 35 kg; and

2. The recipient is less than 12 years of age; and

4. The medication is used in combination with Ribavirin; and

5. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

6. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

7. Prior authorization approval will be for 12 weeks.

~~5.~~e. Genotype 1, without cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient is without cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. Prior authorization approval will be for 12 weeks.

~~6.~~f. Genotype 1, with cirrhosis

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Olysio® (simeprevir); and

3. The recipient has cirrhosis; and

4. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

5. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

6. Prior authorization approval will be for 12 weeks.

~~7.~~g. Genotype 1

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin.

5. Prior authorization approval will be for 12 weeks.

h. ~~8~~. Genotype 3

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Daklinza® (daclatasvir); and

3. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

4. One of the following:

a. The recipient is without cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has cirrhosis (compensated or decompensated) and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin.

~~1.~~5. Prior authorization approval will be for 12 weeks.

~~g. Technivie® (ombitasvir, paritaprevir and ritonavir) for genotype 4~~

~~1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and~~

~~2. One of the following:~~

~~a. The recipient is without cirrhosis; or~~

~~b. The recipient has compensated cirrhosis; and~~

~~3. The medication is used in combination with Ribavirin; and~~

~~4. The recipient is not receiving Technivie® in combination with another HCV direct acting agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and~~

~~5. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and~~

~~6. The medication must be prescribed by or in consultation with one of the following:~~

~~a. Hepatologist~~

~~b. Gastroenterologist~~

~~c. Infectious Disease Specialist~~

~~d. HIV Specialist (certified through the American Academy of HIV Medicine)~~

~~7. Prior authorization approval will be for 12 weeks.~~

5. ~~h.~~ Viekira Pak®~~, Viekira XR®~~ (ombitasvir, paritaprevir, ritonavir tablets~~,~~; dasabuvir tablets)

~~1. The following is required for all Viekira Pak®, Viekira XR® treatment:~~

~~a. The recipient has not experienced failure with a previous treatment regimen that includes HCV NS3/4A protease inhibitor (e.g.,~~

Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

b. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist
4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1a or mixed genotype 1, without cirrhosis and without liver transplant

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is without cirrhosis; and

c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 12 weeks.

3. Genotype 1a or mixed genotype 1, with cirrhosis and without liver transplant
a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 24 weeks.

~~4. Genotype 1b, without liver transplant~~

~~a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and~~

~~b. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and~~

~~c. Prior authorization approval will be for 24 weeks.~~

~~5. Genotype 1 (regardless of sub genotype), with liver transplant~~

~~a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and~~

~~b. Submission of documentation that the recipient is a liver transplant recipient; and~~

~~c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and~~

~~d. The medication is used in combination with Ribavirin; and~~

~~e. Prior authorization approval will be for 24 weeks.~~

a. Genotype 1a or Mixed Genotype 1 Infection without Cirrhosis and without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection; and

b. The recipient is without cirrhosis; and

c. The medication is used in combination with ribavirin; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hepatologist

2. Gastroenterologist

3. Infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir).

2. Prior Authorization Guidelines:

a. Prior authorization will be for 12 weeks.

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

b. Genotype 1a or Mixed Genotype Infection with Cirrhosis and without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection; and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient has cirrhosis; and

c. The medication is being used in combination with ribavirin; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

e. The medication is prescribed by or in consultation with one of the following:

1. Hematologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g.,

Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

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

c. Genotype 1b without Liver Transplant

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's diagnosis of chronic hepatitis C genotype 1b; and

b. The recipient is without decompensated liver disease (e.g., Child-Pugh Class B or C); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist Certified through the Academy of HIV Medicine; and

d. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

e. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

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

d. Genotype 1 (Regardless of Sub genotype) – Liver Transplant Recipient

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

a. Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1; and

b. Documentation confirming the recipient is a liver transplant recipient; and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting the recipient's normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and

d. The medication is used in combination with ribavirin; and

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

1. Hepatologist

2. Gastroenterologist

3. infectious disease specialist

4. HIV specialist certified through the American Academy of HIV Medicine; and

f. The recipient has not experienced failure with a previous treatment regimen that includes a HCVNS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

g. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir).

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 weeks.

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

~~i.~~6. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

a. Approval will be given if all criteria are met and documented~~The following is required for all Vosevi® treatment~~:

1. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

2. The recipient is not receiving Vosevi® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Zepatier® (elbasvir/grazoprevir)); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

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

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

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is a previous relapse~~r~~ to an NS5A based regimen (e.g., Daklinza® (daclatasvir), Epclusa® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Technivie® (ombitasvir/ paritaprevir/ ritonavir), Viekira® (ombitasvir/ paritaprevir/ ritonavir/dasabuvir), Zepatier® (elbasvir/grazoprevir); and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and

2. Prior Authorization Guidelines:

1. ~~d.~~ Prior authorization approval will be for 12 weeks.

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

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

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

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

j. Zepatier® (elbasvir/grazoprevir)

1. Approval will be given if all criteria are met and documented~~The following is required for all Zepatier® treatment~~:

a. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and

b. The recipient is not receiving Zepatier® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

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

1. Hepatologist
2. Gastroenterologist
3. Infectious Disease Specialist
4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1a, treatment naïve, or PegIFN/RBV experienced, or PegIFN/RBV/protease inhibitor experienced, without NS5A polymorphisms

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

~~b.~~a. The recipient is treatment naïve; or

~~c.~~b. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

~~d.~~c. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir or telaprevir); and

3. Both of the following:

1. The recipient has been tested for the presence of NS5A resistance associated polymorphisms; and

2. The recipient has baseline NS5A resistance associated polymorphisms (e.g., polymorphisms at amino acid positions 28, 30, 31, or 93); and

4. The medication is used in combination with Ribavirin; and

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 16 weeks.

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

3. Genotype 1b, treatment naïve, or PegIFN/RBV experienced, or PegIFN/RBV/protease inhibitor experienced

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

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is treatment naïve; or

b. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

c. Both of the following:

1. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir or telaprevir); and

2. The medication is used in combination with Ribavirin; and

b. Prior Authorization Guidelines:

~~3.~~1. Prior authorization approval will be for 12 weeks.

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

d. Genotype 4, treatment naïve

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

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is treatment naïve; and

2. Prior Authorization Guidelines:

~~c.~~a. Prior authorization approval will be for 12 weeks.

b. Prior authorization forms are available at:

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

~~a~~c. Genotype 4, PegIFN/RBV experienced

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

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has had prior failure to peginterferon alfa plus Ribavirin; and

c. The medication is used in combination with Ribavirin; and

2. Prior Authorization Guidelines:

~~d.~~a. Prior authorization approval will be for 16 weeks.

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

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

JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed ~~By~~ by DUR Board: April 22, 2021~~July 25, 2013~~

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

1. Cinryze® (C1 esterase inhibitor), Haegarda® (C1 estarase inhibitor), Orladeyo® (berotralstat) or Takhzyro® (ianadelumab-flyo)~~Coverage and Limitations~~

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

~~a. Cinryze® (C1 esterase inhibitor)~~

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

1. The recipient has a diagnosis of ~~hereditary angioedema~~HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the flower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

c. ~~2.~~ The medication is being prescribed by or in consultation with an allergist or immunologist~~; and~~.

d. The medication is being used as prophylaxis against ~~for hereditary angioedema~~ attacks; and

~~5. The recipient has experienced an inadequate response or adverse event with an attenuated androgen (e.g. danazol, stanozolol) or antifibrinolytic (e.g. tranexamic acid, aminocaproic acid) agent or has a contraindication to all agents in these classes; and~~

~~b.~~ Prior Authorization Guidelines:

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

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

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

Note: * off label use

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

1. The recipient has a diagnosis of HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the flower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

4. The medication is not used in combination with other approved treatment for acute HAE attacks; and

5. The medication is prescribed by or in consultation with an allergist or immunologist.

b. Prior Authorization Guidelines:

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

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

3. Kalbitor® (ecallantide)

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

1. The recipient has a diagnosis of HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the flower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is being used for the treatment of acute HAE attacks; and

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

5. The medication is not used in combination with other approved treatments for acute HAE attacks; and

6. The medication is prescribed by or in consultation with an allergist or immunologist.

b. Prior Authorization Guidelines:

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

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

~~1. The recipient routinely experiences more than one hereditary angioedema attack per month, or the recipient has a history of laryngeal attacks.~~

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

a. Approval will be given if all ~~The recipient must meet all of~~ the following criteria are met and documented:

1. The recipient has a diagnosis ~~of hereditary angioedema~~HAE; and

2. The recipient's diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:

a. C1-INh antigenic level below the flower limit of normal; or

b. C1-INh functional level below the lower limit of normal; and

3. The medication is not used in combination with other approved treatments for acute HAE attacks; and

4. ~~2.~~ The medication is being prescribed by or in consultation with an allergist or immunologist; and

5. ~~3.~~ The medication is being used to treat acute HAE~~hereditary angioedema~~ attacks~~.~~ and

6. One of the following:

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

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

b. Prior Authorization Guidelines:

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

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

~~2. Prior Authorization Guidelines~~

~~a. Initial prior authorization approval will be for six months.~~

~~b. Prior authorization requests for continuation therapy will be approved for one year.~~

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

NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors
Last Reviewed by the DUR Board: April 22, 2021~~January 23, 2014~~

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

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

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

a. Brilinta® (ticagrelor)

1. The recipient has a diagnosis of Acute Coronary Syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

2. The recipient does not have an active pathological bleed or history of intracranial hemorrhage; and

3. The recipient will be receiving concomitant treatment with aspirin in a dose of ~~<~~ less than 100 mg/daily; and

4. One of the following:

a. The recipient has been started and stabilized on the requested medication; or

b. ~~5.~~ The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

c. ~~6.~~ Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

~~b.~~c. Effient® (prasugrel)

1. The recipient has a diagnosis of ACS (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and

2. The recipient does not have an active pathological bleed or history of transient ischemic attack or cerebral vascular accident (CVA); and

3. The recipient will be receiving concomitant~~concominant~~ treatment with aspirin in a dose of less than ~~<~~100 mg/daily; and

4. The recipient has a history of percutaneous coronary intervention; and

5. One of the following:

a. The recipient has been started and stabilized on the requested medication; or

b. ~~6.~~ The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or

c. ~~7.~~ Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months~~one year~~.

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

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: April 22, 2021~~April 30, 2020~~

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

1. Coverage and Limitations

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

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

a. The recipient has a diagnosis of narcolepsy.

2. Xyrem® (sodium oxybate):

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

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

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

3. Prior Authorization Guidelines

a. Prior authorization approvals will be for 12 months.

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

b. Sunosi® (solriamfetol)

1. For treatment of Narcolepsy

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

1. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. The recipient has had trial and failure, contraindication, ~~contraindication~~ or intolerance to both of the following:

a. modafinil; and

b. armodafinil.

b. Recertification Request:

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

c. Prior Authorization Guidelines:

1. Initial request will be approved for 12 months.

2. Recertification request will be approved for 12 months.

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

2. For treatment of Obstructive Sleep Apnea (OSA)

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

1. The recipient must have a diagnosis of OSA defined by one of the following:

a. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); or

b. Both the following:

1. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. One of the following signs/symptoms are present:

a. Daytime sleepiness; or

b. Nonrestorative sleep; or

c. Fatigue; or

d. Insomnia; or

e. Waking up with breath holding, gasping, or choking; or

f. Habitual snoring noted by a bed partner or other observer; or

g. Observed apnea; and

3. Both the following:

a. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

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

4. The recipient has had a trial and failure, contraindication, ~~contraindication~~ or intolerance to both of the following:

a. Modafinil; and

b. Armodafinil.

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

1. ~~a.~~ Documentation of positive clinical response to Sunosi® therapy; and

~~1~~2. The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP)

c. Prior Authorization Guidelines

1. Initial request will be approved for six months.

2. Recertification request will be approved for for six months.

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

c. Wakix® (pitolisant)

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

a. The recipient has a documented diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

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

2. Recertification Requests:

a. The recipient must have documentation of positive clinical response to Wakix® therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

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

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

1. Narcolepsy with Cataplexy (Narcolepsy Type 1).

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

1. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. The recipient has present symptoms of cataplexy; and

3. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

4. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist.

b. Recertification Request:

1. The recipient has documentation demonstrating a reduction in the frequency of cataplexy attacks associate with therapy; or

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

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

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

2. Narcolepsy without Cataplexy (Narcolepsy Type 2)

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

1. The recipient has diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

2. The recipient symptoms of cataplexy are absent; and

3. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

4. The recipient has trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to generic modafinil or generic armodafinil and Sunosi®; and

5. One of the following:

a. The recipient has trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant; or

b. The recipient has history of or potential for substance use disorder; and

6. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist.

b. Recertification Request:

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

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

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

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: April 22, 2021~~January 28, 2021~~

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

1. Cannabinoid

   a. Epidiolex® (cannabidiol)

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

         a. The recipient has a diagnosis of Lennox-Gastaut syndrome, Dravet Syndrome or Tuberous Sclerosis Complex (TSC); and

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

         c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and

         d. The drug is prescribed by or in consultation with a neurologist; and

         e. The total dose does not exceed 20 mg/kg/day (10mg/kg twice daily); and

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

   2. Recertification Request

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

      b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.

   3. Prior Authorization Guidelines

      a. Initial prior authorization will be for three months.

      b. Recertification approval will be for 12 months.

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

4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.

2. Nayzilam® (midazolam)

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

1. The recipient has a diagnosis of acute intermittent seizures; and

2. The recipient is at least 12 years of age; and

3. The medication is prescribed by or in consultation with a Neurologist; and

4. The dose must not exceed two sprays per seizure cluster, no more than one episode every three days and treat no more than five episodes per month.

b. Recertification Request

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

c. Prior Authorization Guidelines

1. Initial prior authorization will be for six months.

2. Recertification approval will be for 12 months.

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

3. Valtoco® (diazepam)

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

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years and older; and

3. The medication is prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern; and

~~4. The prescriber documents a reason or special circumstance that precludes the use of diazepam rectal gel; and~~

4. ~~5.~~ The medication is prescribed by or in consultation with a neurologist; and

5. ~~6.~~ The quantity must not exceed five episodes per month.

b. Prior Authorization Guidelines:

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

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

4. Fintepla® (fenfluramine)

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

1. The recipient has a documented diagnosis of seizures associated with Dravet Syndrome; and

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

3. The medication is prescribed by or in consultation with a neurologist.

b. Recertification Request:

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

c. Prior Authorization Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

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