Medicaid Services Manual
Transmittal Letter

March 26, 2024

To: Custodians of Medicaid Services Manual

From: Casey Angres
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

Background And Explanation

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on January 18, 2024, by the Drug Utilization Review (DUR) Board. The addition of Uplizna® and additional criteria regarding vaccines under Immunomodulator Drugs, removed genotypes from Anti-Hepatitis Agents, updated approval criteria for Incretin Mimetics, and added Lumryz®, FDA approved ages and Idiopathic Hypersomnia (Xywav®) to Narcolepsy Agents. New sections added including prior authorization criteria include Voxzogo™ (vosoritide) for treatment of achondroplasia, Saphnelo® (anifrolumab-fnia) for therapeutic class Systemic Lupus Erythematosus, and Tavneos™ for therapeutic class ANCA-associated vasculitis (GPA or MPA). The link for Prior Authorization forms has been updated throughout the chapter.

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

These changes are effective April 1, 2024.

Material Transmitted	Material Superseded
MTL N/A MSM Chapter 1200 – Prescribed Drugs	MTL 09/17 MSM Chapter 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section L	**Immunomodulator Drugs**	Added vaccine criteria. Added Uplizna® (inebilizumab-cdon), including prior authorization criteria.
Appendix A Section HH	**Anti-Hepatitis Agents**	Removed genotypes throughout this section.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section KK	**Incretin Mimetics**	Updated prior authorization criteria.
Appendix A Section AAA	**Narcolepsy Agents**	Moved Xyrem. Added Lumryz® and additional prior authorization criteria. Also added idiopathic hypersomnia (Xywav® only) including prior authorization criteria.
Appendix A Section TTTT	**Voxzogo™ (vosoritide)**	New drug added for treatment of achondroplasia along with prior authorization criteria.
Appendix A Section UUUU	**Saphnelo® (anifrolumab-fnia)**	New drug added for Systemic Lupus Erythematosus along with prior authorization criteria.
Appendix A Section VVVV	**Tavneos™ (avacopan)**	New drug added for ANCA-associated vasculitis (GPA or MPA) along with prior authorization criteria.

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

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

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

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

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

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

b. Make changes to the SMAC pricing file.

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

1203.1C PRIOR AUTHORIZATION PROCEDURES

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

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

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

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

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

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

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

A. Proton Pump Inhibitors (PPIs)

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

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

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

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

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

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

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

c. Prior Authorization Guidelines:

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

2. Prior Authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/documents.
~~http://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

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

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

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

1. Coverage and Limitations

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

a. General Criteria (Children and Adults)

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

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

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

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

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

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

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

2. Exception Criteria

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

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

2. The medication is prescribed by a psychiatrist; and

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

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

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

F. Transdermal Fentanyl

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

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

1. Coverage and Limitations

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

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

b. Patient requires continuous opioid administration.

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

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

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

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

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

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

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

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

2. Prior Authorization Guidelines

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

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

H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)
Last Reviewed by the DUR Board: January 19, 2023

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

1. Coverage and Limitations

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

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

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

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

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

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

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

   d. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) has adequate iron stores as demonstrated by serum ferritin greater than or equal to 100 ng/mL (mcg/L) and transferrin saturation (TSAT) greater than or equal to 20% (measured within the previous three months for renewal).

2. Non-Covered Indications

   a. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis.

   b. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) or erythroid cancers.

   c. Anemia of cancer not related to cancer treatment.

   d. Any anemia associated only with radiotherapy.

e. Prophylactic use to prevent chemotherapy-induced anemia.

f. Prophylactic use to reduce tumor hypoxia.

g. Patients with erythropoietin-type resistance due to neutralizing antibodies.

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

3. Recertification Request

a. Coverage can be renewed based upon the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria identified in section III; and

2. Previous dose was administered within the past 60 days; and

3. Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pure red cell aplasia severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in recipients with cancer, severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), etc.; and

b. Anemia Due to Myelodysplastic Syndrome (MDS):

1. Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

c. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis:

1. Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct) less than 30%.

d. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria.

e. Anemia Due to Chronic Kidney Disease (Non-Dialysis Patients):

1. Pediatric patients: Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

2. Adult patients: Hemoglobin (Hb) less than 11 g/dL and/or Hematocrit (Hct) less than 33%.

4. PA Guidelines

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

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

J. Benlysta® (belimumab)

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

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

1. Coverage and Limitations

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

a. Initial request:

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

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

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

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

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

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

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

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

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

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

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

2. PA Guidelines

a. Prior authorization approvals will be for:

1. Initial request: six months.

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

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: January 18, 2024~~October 19, 2023~~

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

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

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

   a. For all recipients:

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

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

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

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

      5. The recipient has not received live or live-attenuated vaccines within the past four weeks and will not receive live or live-attenuated vaccines during treatment with immunomodulator.

      ~~5.~~6. Each request meets the appropriate diagnosis/agent specific criteria (b-~~k~~m).

   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

m. Uplizna™ (inebilizumab-cdon).

1. Initial Requests

a. Patient is ≥ 18 years; and

b. Patient has been diagnosed with neuromyelitis optica spectrum disorder (NMOSD); and

c. Patient has positive serologic test for anti-AQP4 antibodies; and

d. Patient has a history of ≥ 1 relapse that required rescue therapy within the year prior to treatment or ≥ 2 relapses that required rescue therapy in 2 years prior to treatment (initial requests only); and

e. Patient has an Expanded Disability Status Scor (EDSS) of ≤ 8.0 (initial requests only); and

f. Medication prescribed by or on consultation with neurologist; and

g. Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; and

h. Prescriber attestation that serum immunoglobulin will be monitored at beginning, during, and after discontinuation of treatment until B-cell repletion.

2. Renewal requests:

a. Patient must continue to meet above criteria; and

b. Documentation of positive disease response as indicated by stabilization/improvement in any of the following; neurologic symptoms as evidence by a decreased in acute relapses, stability, or improvement in EDSS, reduced hospitalizations, and/or reduction in plasma exchange treatments.

c. PA guidelines for Uplizna initial authorization is six months approval and recertification is 12 months.

2. PA Guidelines:

a. PA approval will be for 12 months unless otherwise stated in criteria.

b. PA forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.

N. Psychotropic Medications for Children and Adolescents

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

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

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

1. Coverage and Limitations

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

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

1. Antipsychotics

2. Antidepressants

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

4. Sedative hypnotics

5. Antianxiety agents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Prior Authorization Guidelines

a. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

O. Lidoderm 5% Patches®

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

1. Coverage and Limitations

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

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: January 19, 2023

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

1. Coverage and Limitations

a. Xolair® (Omalizumab)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   e. One of the following:

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

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

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

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

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

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

      1. Allergist/Immunologist; or

      2. Dermatologist; or

      3. Rheumatologist; and

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

d. One of the following:

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

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

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

4. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

Table 1: Dosing for Xolair® (omalizumab)*

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

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

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

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

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

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

1. Mepolizumab: six years of age or older;

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

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

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

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

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks.

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

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

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

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

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

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

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

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

c. One of the following:

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

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

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

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

1. Both the following:

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

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

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

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

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

1. Pulmonologist; or

2. Allergist/Immunologist

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

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

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

1. Both the following:

a. ICS; and

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

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

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

1. Pulmonologist; or

2. Allergist/Immunologist

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

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

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

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

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

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

c. The recipient is currently receiving corticosteroid therapy; and

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

1. Pulmonologist; or

2. Rheumatologist; or

3. Allergist/Immunologist.

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

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

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification request will be approved 12 months.

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

e. Nucala® (mepolizumab) for treatment of Hypereosinophilic Syndrome (HES)

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

a. Recipient is greater than or equal to 12 years old; and

b. Recipient has a diagnosis of uncontrolled HES for greater than or equal to six months defined by both of the following:

1. History of greater than or equal to two flares over the past 12 months; and

2. Baseline (pre-treatment) blood eosinophil count greater than or equal to 1,000 cells/mL; and

c. No identifiable non-hematologic secondary cause of the HES; and

d. Recipient does not have FIP1L1-PDGFRa kinase-positive HES; and

e. Recipient is currently received a stable dose of background HES therapy (e.g., episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and

f. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

2. Recertification Request:

a. Documentation of positive clinical criteria response to therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroids requirements, and decreased eosinophil levels).

b. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

3. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification will be given for 12 months.

f. Nucala® (mepolizumab) for treatment of Chronic Rhinosinusitis with Nasal Polyps

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

a. Recipient is greater than or equal to 18 years old.

b. Recipient has a diagnosis of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP); and

c. Unless contraindicated, the recipient has had an inadequate response to at least two months of treatment with an intranasal corticosteroid (initial approval only); and

d. Mepolizumab will be used as add-on medication to maintenance therapy (e.g. intranasal corticosteroid, saline nasal irrigations, systemic corticosteroids, antibiotics).

2. Recertification Request:

a. Recipient continues to meet above criteria; and

b. Documentation of positive clinical response to Nucala® (mepolizumab).

3. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification approval will be given for 12 months.

e. Fasenra® (benralizumab)

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

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

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

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

d. One of the following:

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

2. Any prior intubation for an asthma exacerbation; or

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

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

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

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

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

1. Pulmonologist; or

2. Allergy/Immunology specialist.

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

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

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

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

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

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

1. Pulmonologist; or

2. Allergy/Immunology specialist.

3. Prior Authorization Guidelines:

a. Initial prior authorization will be for 12 months.

b. Recertification request will be for 12 months.

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

f. Dupixent® (dupilumab)

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

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

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

2. One of the following:

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

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

1. Elidel® (~~pimecromulus~~pimecrolimus) topical cream; or

2. Tacrolimus topical ointment; or

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

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

2. One of the following:

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

Q. Long-Acting Narcotics

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

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

1. Coverage and Limitations

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

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

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

b. All the following criteria must be met:

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

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

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

2. Prior Authorization Guidelines

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

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

R. Toradol® (ketorolac tromethamine) tablets

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

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

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

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

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

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

2. Prior Authorization Guidelines

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

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

U. Short-Acting Bronchodilators

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

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

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

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

a. Coverage and Limitations

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

1. Quantity Limits:

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

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

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

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

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

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

a. The recipient has a diagnosis of asthma; and

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

b. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

2. Xopenex®

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

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

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

b. Prior Authorization Guidelines

Prior Authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

V. Anti-Insomnia Agents (Sedative Hypnotics)

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

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

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

1. Coverage and Limitations

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

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

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

2. Prior Authorization Guidelines

   a. Prior Authorization forms are available at:
   https://nevadamedicaid.magellanrx.com/provider/forms.
   ~~https://www.medicaid.nv.gov/providers/rx/rxforms/aspx~~

W. Doxepin Topical

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

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

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

   a. The recipient has a documented diagnosis of pruritus with atopic dermatitis or lichen simplex chronicus; and

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

   c. Treatment must not exceed eight days.

2. Prior Authorization Guidelines:

   a. Prior Authorization approval will be given for eight days.

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

X. Antiemetics

Therapeutic Class: Antiemetics, (Serotonin Receptor Antagonists (5 HT3 Antiemetics))
Last Reviewed by the DUR Board: October 28, 2010
Therapeutic Class: Antiemetic (Cannabinoid Antiemetics)
Last Reviewed by DUR Board: October 18, 2018

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

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

Serotonin Receptor Antagonists (5 HT3 Antiemetics)

1. Coverage and Limitations

   a. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses; or

   b. The recipient is receiving chemotherapy treatments more often than once a week; or

   c. The recipient has a diagnosis of Acquired Immune Deficiency Syndrome (AIDS) associated nausea and vomiting; or

   d. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.

2. Prior Authorization Guidelines

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

Cannabinoid Antiemetics

1. Coverage and Limitations

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

   a. Nabilone

      1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

2. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

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

b. Dronabinol

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

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

2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and the recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

Y. Synagis® (~~palivizumaub~~palivizumab)

Therapeutic Class: Antiviral Monoclonal Antibodies
Last Reviewed by the DUR Board: January 22, 2015

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

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

1. Coverage and Limitations

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

a. Recipients younger than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season, must meet one of the following criteria:

1. The recipient was born at 28 weeks, six days of gestation or earlier; or

2. The recipient has a diagnosis of chronic lung disease (CLD) of prematurity; or

3. The recipient has hemodynamically significant congenital heart disease; or

4. The recipient has congenital abnormalities of the airways or neuromuscular disease; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has clinical evidence of CLD and/or nutritional compromise.

b. Recipients younger than two years of age at the start of RSV season must meet one of the following criteria:

1. The recipient has a diagnosis of CLD of prematurity; and

a. The recipient has required medical therapy (e.g., bronchodilator, diuretics, oxygen, corticosteroids) within six months to the start of RSV season; or

2. The recipient has had a cardiac transplant; or

3. The recipient is severely immunocompromised (solid organ or hematopoietic stem cell transplant, chemotherapy, or other conditions) during the RSV season; or

4. The recipient has had a cardiopulmonary bypass and continues to require prophylaxis after surgery or at the conclusion of extracorporeal membrane oxygenation; or

5. The recipient has a diagnosis of cystic fibrosis; and

a. The recipient has had manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable) or weight for length less than the tenth percentile.

2. Prior Authorization Guidelines

a. Prior authorization approval will be up to five doses per RSV season for recipients meeting criteria.

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

Z. Opioids, Opioid Containing Cough Preparations, Opioids Prescribed to Under Age 18

Therapeutic Class: Opioids, Last reviewed by the DUR Board: July 26, 2018
Opioid Containing Cough Preparations Last reviewed by the DUR Board: July 26, 2018
Opioids Prescribed to Under Age 18: Last Reviewed by the DUR Board: October 18, 2018

Opioids, Opioid Containing Cough Preparations and Opioids Prescribed to Under Age 18 are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Opioids

1. Coverage and Limitations

   a. Opioids will be covered without prior authorization:

      1. For initial prescriptions of seven days or less; and

      2. For a total of 13 seven-day prescriptions in any rolling 12-month period; and

      3. For prescriptions of 60 mg morphine equivalents or less per day.

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

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

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

         a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and

         b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.); and

         c. The lowest effective dose is being requested; and

         d. A pain contract is on file.

   d. Exceptions to this policy:

      1. Recipients with cancer/malignancy related pain; or

2. Recipients who are post-surgery with an anticipated prolonged recovery (greater than three months); or

3. Recipients receiving palliative care; or

4. Recipients residing in a long-term care facility; or

5. Recipients receiving treatment for HIV/AIDS; or

6. Prescriptions written by or in consultation with a pain specialist.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

3. CDC Guidance:

a. http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

4. Opioid Containing Cough Preparations

a. The recipient must be 18 years of age or older.

b. Prior authorization approval will be for six months.

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

d. For references purposes, codeine and tramadol for children prior authorization criteria can also be found within this chapter in Section TTT.

5. Opioids Prescribed to Under Age 18

a. Short Acting Opioids will be covered without PA for:

1. Initial prescription of three days or less; and

2. A total of 13 three-day prescriptions in any rolling 12-month period; and

3. Prescriptions of 60 morphine milligram equivalents (MME) or less per day.

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

AA. Savella® (milnacipran)

Therapeutic Class: Fibromyalgia Agents: Serotonin-Norepinephrine Reuptake Inhibitor
Last Reviewed by DUR Board: July 23, 2020

Savella® (milnacipran) is subject to prior authorization.

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

   a. The recipient has a diagnosis of Fibromyalgia:

      1. If an ICD code for Myalgia and Myositis unspecified is documented on the prescription; or

      2. Completion of a prior authorization documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.

2. Prior Authorization Guidelines:

   a. Prior Authorization forms are available at:
   https://nevadamedicaid.magellanrx.com/provider/forms.
   ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

BB. Substance Abuse Agents

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: July 23, 2020

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

1. Coverage and Limitations

a. Buprenorphine/Naloxone and Buprenorphine

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

a. Prior authorization approval will be required for all prescriptions over 24 mg.

b. Requires diagnosis of opioid dependence.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

b. Lucemyra™ (lofexidine)

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

a. The recipient has a diagnosis of opioid withdrawal with symptoms due to abrupt opioid discontinuation; and

b. The requested quantity must not exceed 2.88 mg/day for up to 14 days.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 14 days.

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

c. Vivitrol® (naltrexone)

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

a. The drug is being used for an FDA approved indication; and

b. The drug must be delivered directly to the prescriber's office; and

c. The drug is only to be administered once per month; and

d. Routine urine screening and monitoring is recommended.

2. Prior Authorization Guidelines

a. Prior authorization approvals will be for six months.

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

DD. Hormones and Hormone Modifiers

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

1. Topical Androgens

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

1. Recipient is male; and

2. The medication is used for FDA-approved indication:

a. Primary (congenital or acquired); or

b. Secondary (congenital or acquired) hypogonadism; and

3. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used; and

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

5. Recipient does not have a hematocrit greater than 50%; and

6. Recipient does not have untreated severe obstructive sleep apnea; and

7. Recipient does not have uncontrolled or poorly controlled heart failure.

b. Diagnosis of Gender Dysphoria:

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

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

2. Xyosted™ (testosterone enanthate)

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

1. Diagnosis of Hypogonadism (e.g., testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

2. The recipient is male at birth; and

3. One of the following:

a. Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab; or both of the following:

1. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV, liver disorder, diabetes, obesity); and

2. One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (<0.17 nmol/L) or less than the reference range for the lab; or

b. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism or a genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome).

b. Diagnosis of Gender Dysphoria

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

a. Recipient is using the hormones to changes in their physical Characteristics; and

b. Recipient is a female-to-male transsexual

c. Prior Authorization Guidelines:

1. Prior authorization approval with a diagnosis of hypogonadism will be given for one year.

2. Prior authorization approval with a diagnosis of gender dysphoria will be given for six months for recipients new to testosterone therapy; or

a. Prior authorization approval will be given to recipients continuing testosterone therapy without a current authorization on file for 12 months.

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

3. Oral Testosterone Products

a. Hypogonadism:

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

EE. Colchicine (Colcrys®)

Therapeutic Class: Antigout Agents
Last Reviewed by the DUR Board: January 28, 2016

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

1. Coverage and Limitations

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

a. Colchicine Tablets

1. The recipient has a diagnosis of acute gout (does not require prophylaxis) and the recipient must meet all of the following:

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

b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID (indomethacin, naproxen, ibuprofen, sulindac or ketoprofen); and

c. The recipient has had an inadequate response, adverse reaction or contraindication to a corticosteroid (oral or intra-articular).

2. For prophylaxis of chronic gout:

a. The recipient is 16 years of age or older and must meet one of the following:

1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or

2. There is documentation that the recipient will be treated with colchicine monotherapy and the recipient must meet all of the following:

a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

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

3. For Familial Mediterranean Fever (FMF):

   a. The recipient is four years of age or older.

4. Requests exceeding the quantity limit may be approved for colchicine tablets if all of the following are met and documented:

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

   b. The recipient has a diagnosis of FMF; and

   c. The recipient's dose is ≤ 2.4 mg daily (120 tablets/30 days); and

   d. Medical necessity must be provided and documented in the recipient's medical record that the recipient had an inadequate response to 1.8 mg daily (90 tablets/30 days).

b. Colchicine Capsules

1. For Prophylaxis of chronic gout:

   a. The recipient is 18 years of age or older and the recipient must meet one of the following:

      1. There is documentation that the recipient will be treated with colchicine in combination with allopurinol, Uloric® (febuxostat) or probenecid; or

      2. There is documentation that the recipient will be treated with colchicine monotherapy, and the recipient must meet all of the following:

         a. The recipient has had an inadequate response to allopurinol at a dose of 600 mg/day for at least two weeks or had an adverse reaction or contraindication to allopurinol; and

         b. The recipient has had an inadequate response to Uloric® (febuxostat) at a dose of 80 mg/day for at least two weeks or has had an adverse reaction or contraindication to Uloric® (febuxostat).2. Prior Authorization Guidelines

c. Prior authorization approval will be given based on diagnosis.

1. For FMF and chronic gout: one year.

2. For acute gout: two months.

d. Prior Authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

FF. Thrombin Inhibitors

Therapeutic Class: Thrombin Inhibitors
Last Reviewed by the DUR Board: January 22, 2015

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

1. Coverage and Limitations

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

a. A diagnosis code associated with the FDA approved indication(s) is documented on the prescription and transmitted on the claim; and

b. There are no contraindications to prescribing this medication; or

c. An approved Prior Authorization documenting the recipient meeting all of the criteria above (1.) (a. and b.).

2. Prior Authorization Guidelines

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

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

GG. Antihemophilia Agents

Therapeutic Class: Antihemophilia Agents
Last Reviewed by the DUR Board: July 26, 2018

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

1. Coverage and Limitations

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

a. The medication being prescribed must be for an FDA approved indication; or

b. One of the following:

1. The diagnosis is supported as a use of American Hospital Formulary Service Drug Information (AHFS DI); or

2. The diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “effective” or “evidence favors efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table); or

4. Diagnosis is supported in any other section of DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal; and

a. One of the following:

1. The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed

medical literature or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

a. AHFS Compendium;

b. Thomson Reuters (Healthcare) Micromedex/ DRUGDEX (not Drug Points) Compendium;

c. Elsevier Gold Standard's Clinical Pharmacology Compendium;

d. National Comprehensive Cancer Network Drugs and Biologics Compendium; and

c. The dispensing provider will monitor the amount of product a recipient has left to avoid over-stock; and

d. The prescriber is a specialist in treating hemophilia; and

e. A new prior authorization will be required for any dose adjustment in excess of 5% (increase or decrease).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

HH. Anti-Hepatitis Agents

Therapeutic Class: Anti-Hepatitis Agents
Last Reviewed by the DUR Board: January 18, 2024~~April 22, 2021~~

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

1. Epclusa® (sofosbuvir and velpatasvir)

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

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

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

         a. Hepatologist

         b. Gastroenterologist

         c. Infectious Disease Specialist

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

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

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

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

      3. Epclusa® must be used alone; and

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

      5. Prior authorization approval will be for 12 weeks.

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

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

2. The recipient has decompensated liver disease; and

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

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

5. Prior authorization approval will be for 24 weeks.

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

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

2. The recipient has decompensated liver disease; and

a. One of the following:

1. The recipient is Ribavirin intolerant or ineligible; or

2. Both of the following:

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

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

3. Prior authorization approval will be for 24 weeks.

2. Harvoni® (ledipasvir/sofosbuvir)

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

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

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

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

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

a. The recipient does not have cirrhosis; and

b. The recipient is treatment naïve; and

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

d. Prior authorization approval will be for eight weeks.

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

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

2. The recipient does not have cirrhosis; and

3. The recipient is treatment naïve; and

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

5. Prior authorization approval will be for 12 weeks.

d. Genotype 1, treatment naïve with compensated cirrhosis

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

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

3. The recipient is treatment naïve; and

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

5. Prior authorization approval will be for 12 weeks.

e. Genotype 1, treatment experienced without cirrhosis

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

2. The recipient does not have cirrhosis; and

3. One of the following:

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

b. Both of the following:

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

2. The medication is used in combination with Ribavirin.

4. Prior authorization approval will be for 12 weeks.

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

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

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

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

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

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

6. Prior authorization approval will be for 12 weeks.

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

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

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

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

4. The recipient is Ribavirin ineligible; and

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

6. Prior authorization approval will be for 24 weeks.

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

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

2. One of the following:

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

b. Both of the following:

1. The recipient is a liver transplant recipient; and

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

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

4. Prior authorization approval will be for 12 weeks.

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

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

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

3. One of the following:

   a. The recipient is Ribavirin ineligible; or

   b. Both of the following:

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

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

4. Prior authorization approval will be for 24 weeks.

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

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

2. One of the following:

   a. The recipient is treatment naïve; or

   b. One of the following:

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

      2. Both of the following:

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

         b. The medication is used in combination with Ribavirin.

3. Prior authorization approval will be for 12 weeks.

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

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

2. One of the following:

a. The recipient is treatment naïve; or

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

3. Prior authorization approval will be for 12 weeks.

3. Mavyret® (glecaprevir/pibrentasvir)

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

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

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

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

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

2. The recipient is treatment naïve; and

3. The recipient is without cirrhosis; and

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

5. Prior authorization approval will be for 12 weeks.

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

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

2. The recipient is treatment naïve; and

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

4. Prior authorization approval will be for eight weeks.

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

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

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

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

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

5. Prior authorization approval will be for 12 weeks.

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

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

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

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

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

5. Prior authorization approval will be for 16 weeks.

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

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

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

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

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

5. Prior authorization approval will be for 16 weeks.

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

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

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

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

4. The recipient is without cirrhosis; and

5. Prior authorization approval will be for eight weeks.

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

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

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

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

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

5. Prior authorization approval will be for 12 weeks.

4. Sovaldi® (sofosbuvir)

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

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

b. Genotype 1 or 4, without decompensated liver disease

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

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

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

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

5. Prior authorization approval will be for 12 weeks.

c. Genotype 3, without decompensated liver disease

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

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

3. Both of the following:

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

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

1. The recipient weighs at least 35 kg; and

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

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

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

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

7. Prior authorization approval will be for 24 weeks.

d. Genotype 2, without decompensated liver disease

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

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

3. Both of the following:

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

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

1. The recipient weighs at least 35 kg; and

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

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

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

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

7. Prior authorization approval will be for 12 weeks.

e. Genotype 1, without cirrhosis

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

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

3. The recipient is without cirrhosis; and

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

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

6. Prior authorization approval will be for 12 weeks.

f. Genotype 1, with cirrhosis

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

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

3. The recipient has cirrhosis; and

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

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

6. Prior authorization approval will be for 12 weeks.

g. Genotype 1

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

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

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

4. One of the following:

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

b. Both of the following:

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

2. The medication is used in combination with Ribavirin.

5. Prior authorization approval will be for 12 weeks.

h. Genotype 3

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

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

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

4. One of the following:

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

b. Both of the following:

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

2. The medication is used in combination with Ribavirin.

5. Prior authorization approval will be for 12 weeks.

5. Viekira Pak® (ombitasvir, paritaprevir, ritonavir tablets, dasabuvir tablets)

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

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

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

b. The recipient is without cirrhosis; and

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

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

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

1. Hepatologist

2. Gastroenterologist

3. Infectious disease specialist

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

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

2. Prior Authorization Guidelines:

a. Prior authorization will be for 12 weeks.

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

6. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

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

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

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

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

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

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

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

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

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

2. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

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

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

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

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

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

2. Prior authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~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://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

7. Zepatier® (elbasvir/grazoprevir)

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

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

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

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

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

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

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

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

b. One of the following:

1. The recipient is treatment naïve; or

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

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

c. Both of the following:

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

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

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

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 16 weeks.

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

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

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

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

2. One of the following:

a. The recipient is treatment naïve; or

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

c. Both of the following:

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

b. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 weeks.

2. Prior authorization forms are available at:

https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

4. Genotype 4, treatment naïve

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

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

      2. The recipient is treatment naïve; and

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be for 12 weeks.

      2. Prior authorization forms are available at:
      https://nevadamedicaid.magellanrx.com/provider/forms.
      ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

5. Genotype 4, PegIFN/RBV experienced

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

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

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

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

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be for 16 weeks.

      2. Prior authorization forms are available at:
      https://nevadamedicaid.magellanrx.com/provider/forms.
      ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

II. Daliresp® (roflumilast)

Therapeutic Class: Phosphodiesterase-4 Inhibitors.
Last Reviewed by the DUR Board: October 17, 2019

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

1. Coverage and Limitations

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

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting anticholinergic agent;

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting beta (β) agonist;

c. The recipient has experienced an inadequate response, adverse event or has a contraindication to an inhaled corticosteroid;

d. The recipient has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD); and

e. The recipient has a history of COPD exacerbations.

2. Contraindication

a. Daliresp (roflumilast) may not be approved for a recipient with a diagnosis of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

3. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

JJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed by DUR Board: April 22, 2021

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

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

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

      1. The recipient has a diagnosis of HAE; and

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

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

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

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

      3. The medication is being used as prophylaxis against attacks; and

   b. Prior Authorization Guidelines:

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

      2. Prior authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~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 lower limit of normal; or

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

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

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

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

b. Prior Authorization Guidelines:

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

2. Prior authorization forms are available https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

3. Kalbitor® (ecallantide)

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

1. The recipient has a diagnosis of HAE; and

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

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

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

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

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

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

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

b. Prior Authorization Guidelines:

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

2. Prior authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.

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

4. Berinert® (C1 esterase inhibitor)

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

1. The recipient has a diagnosis HAE; and

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

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

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

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

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

5. The medication is being used to treat acute HAE 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~~years 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://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

KK. Incretin Mimetics

Therapeutic Class: Incretin Mimetics
Last Reviewed by the DUR Board: ~~January 26, 2017~~January 18, 2024
Previously reviewed by the DUR Board: ~~July 26, 2012~~January 26, 2017

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

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

   a. Initial Requests:

      1. Medication being prescribed for one of the following:

         a. Adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (T2DM); or

         b. Reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in patients with type 2 diabetes and established cardiovascular disease; and

      2. Documentation of A1C lab result within past 180 days; and

      3. Patient does not have history of pancreatitis; and

      4. Patient does not have type 1 diabetes mellitus; and

      5. Medication is not being prescribed for weight loss in absence of T2DM indication; and

      6. Medication prescribed at FDA-approved dose for T2DM indication; and

      7. Patient is appropriate age per FDA label.

   b. Renewal Requests:

      a. Patient continues to meet above criteria; and

      b. Documentation of positive response from therapy.

   ~~a. An ICD code for Type 2 Diabetes Mellitus is documented on the prescription and transmitted on the claim; or~~

   ~~b. A prior authorization documenting a diagnosis of Type 2 Diabetes Mellitus has been submitted.~~

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

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

LL. Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: January 27, 2022

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

1. Approval will be given for a single agent concomitantly if the following criteria are met and documented:

   a. Kalydeco® (ivacaftor)

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

         a. The recipient is age appropriate according to the FDA-approved package labeling; and

         b. The recipient has a diagnosis of CF; and

         c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the gene mutations listed in the FDA-approved package insert; and

         d. The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a CF care center.

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

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

      3. Prior Authorization Guidelines:

         a. Initial request will be approved for 12 months.

         b. Recertification request will be for 12 months.

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

   b. Orkambi® (lumacaftor/ivacaftor)

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

         a. The recipient has a diagnosis of CF; and

b. The recipient is age appropriate according to the FDA-approved package labeling; and

c. The recipient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; and

d. The requested dose is two tablets every 12 hours; or

e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

a. Prior authorization approvals will be for one year.

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

c. Symdeko® (tezacaftor/ivacaftor)

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

a. Initial Request:

1. The recipient is age appropriate according to the FDA-approved package labeling; and

2. The recipient has a documented diagnosis of CF; and

3. The medication must be prescribed by or in consultation with either a Pulmonologist~~Pulmonolist~~ or a specialist associated with a CF care center.

4. One of the following:

a. The recipient is homozygous for the F508del mutation as detected by an FDA cleared CF mutation test or Clinical Laboratory Improvement Amendments (CLIA) approved facility; or

b. The recipient has one of the FDA approved package insert listed mutations on at least one allele in the (CFTR) gene as detected by FDA cleared CF mutation test or CLIA approved facility.

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

1. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

2. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

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

d. Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

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

a. The recipient is age appropriate according to the FDA-approved package labeling; and

b. The recipient has a documented diagnosis of CF; and

c. The recipient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data as detected by an FDA cleared CF mutation test, or a test performed at a CLIA approved facility; and

d. The medication is prescribed by or in consultation with either a Pulmonologist or a specialist affiliated with a CF care center.

2. Recertification Request:

a. The recipient must have documentation of a positive clinical response to Trikafta® therapy (e.g. improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations)

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

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

MM. Gimoti® (metoclopramide)

Therapeutic Class: Gastrointestinal Prokinetic Agents
Last Reviewed by the DUR Board: October 26, 2021

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

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

    a. The recipient has a diagnosis of acute diabetic gastroparesis; and

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

    c. The recipient does not have any of the following:

        1. History of signs or symptoms of tardive dyskinesia (TD); or

        2. History of a dystonic reaction to metoclopramide; or

        3. Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation); or

        4. Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma; or

        5. Diagnosis of epilepsy or any other seizure disorder; or

        6. Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm); or

        7. Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute); or

        8. Moderate or severe hepatic impairment (Child-Pugh B or C); and

    d. One of the following:

        1. The recipient has had an adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., intramuscular) metoclopramide; or

        2. The recipient is NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications)

2. Recertification Request:

    a. Recipient continues to meet all initial authorization criteria; and

b. At least ~~2~~ two weeks have passed (i.e., drug holiday) since completion of a previous course or metoclopramide treatment of any dosage form; and

c. Recipient demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); and

d. Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention)

3. Prior Authorization Guidelines:

a. Prior Authorization approval will be for two months

b. Recertification requests will be approved for two months

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

NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors
Last Reviewed by the DUR Board: April 22, 2021

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

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

   a. Brilinta® (ticagrelor)

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

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

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

      4. One of the following:

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

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

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

   b. Effient® (prasugrel)

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

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

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

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

      5. One of the following:

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

OO. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: January 19, 2023

Osteoporosis agents are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

a. Evenity® (romosozumab-aqqg)

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

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. The recipient's Bone Mineral Density (BMD) T-score is -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. The recipient has documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); or

c. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. The recipient has a documented history of low-trauma fracture of the

hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. The recipient has a documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

2. One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

a. The recipient has a major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions.

b. The recipient has a hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. The recipient has a documented trial and failure, contraindication, or intolerance to one of the following:

1. Forteo® (teriparatide)

2. Tymlos® (abaloparatide~~abaoparatide~~); and

d. Treatment duration of Evenity® (romosozumab-aqqg) has not exceeded a total of 12 months during the recipient's lifetime.

2. Prior Authorization Guidelines:

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

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

b. Prolia® (denosumab)

1. Criteria for Physician Administered Drugs (PAD)

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

1. Recipient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; and

2. Recipient must not have hypocalcemia; and

3. Coverage is provided in the following conditions:

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

b. Recipient must be at a high risk for fracture; and

c. Pregnancy ruled out prior to starting therapy in women of childbearing potential; and

2. For bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.

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

1. The recipient has a diagnosis of nonmetastatic prostate cancer; and

2. The recipient is undergoing androgen deprivation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar® (triptorelin), Vantas (histrelin), and Zoladex® (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

3. One of the following:

a. The recipient is 70 years of age or older; or

b. Both the following:

1. The recipient is less than 70 years of age; and

a. One of the following:

1. BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

2. Documented history of one of the following resulting from minimal trauma:

a. Vertebral compression fracture

b. Fracture of the hip

c. Fracture of the distal radius

d. Fracture of the pelvis

e. Fracture of the proximal numerous; and

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

1. The recipient is undergoing androgen depravation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar® (triptorelin), Vantas (histrelin), and Zoladex® (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

2. The recipient has no evidence of metastases; and

3. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

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

3. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

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

1. The recipient has a diagnosis of breast cancer; and

2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]); and

3. One of the following:

a. The recipient's BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

b. Documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g. alendronate)

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

1. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]); and

2. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

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

4. For Postmenopausal Osteoporosis or Osteopenia

a. Criteria for Physician Administered Drugs (PAD)

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

a. Recipient must be a woman; and

b. Recipient has a documented diagnosis of osteoporosis indicated by one or more of the following:

1. Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to negative two and a half and/or forearm DXA at the 33% (one-third) radius site; or

2. T-score less than or equal to negative one or low bone mass and a history of fragility fracture to the hip or spine; or

3. T-score between negative one and negative two and a half with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%; and

c. Documented treatment failure or ineffective response to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; or

d. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

b. Recertification Request:

1. Documentation that indicates the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

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

5. Glucocorticoid-Induced Osteoporosis

a. Criteria for Physician Administered Drugs (PAD):

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

a. Recipient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to greater than or equal to 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least six months; and

b. Documented treatment failure or ineffective response to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; or

c. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

6. Osteoporosis treatment and prevention in prostate cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

a. Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to

negative one (or recipient meets the diagnostic criteria for osteoporosis above); and

b. Recipient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

7. Osteoporosis treatment and prevention in breast cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

a. Recipient must be receiving adjuvant aromatase inhibitor therapy for breast cancer.

b. Recertification Request:

1. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification request will be approved for 12 months.

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

c. Forteo® (teriparatide)

1. For Postmenopausal Osteoporosis or Osteopenia, or Men with Primary or Hypogonadal Osteoporosis or Osteopenia at High Risk for Fracture

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

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia, or primary or hypogonadal osteoporosis or osteopenia; and

2. One of the following:

a. Both the following:

1. The recipient has a BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following

   a. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

   b. Documented trial and failure, contraindication intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); or

b. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

   a. Recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

   b. Both the following:

      1. Recipient has a documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

      2. One of the following FRAX 10-year probabilities:

         a. Major osteoporotic fracture at 20% or more in the U.S., or

the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

3. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.

2. For Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

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

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient has documented history of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to three months; and

3. One of the following:

a. BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. Documented trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate); and

5. The recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

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

d. Tymlos® (abaloparatide)

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

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); or

2. Both the following:

a. Recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Recipient has a documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Both the following:

a. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia® [denosumab]); and

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos® [abaloparatide]) has not exceeded a total of 24 months during their lifetime.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

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

QQ. Spravato™ (esketamine)

Therapeutic Class: Miscellaneous Anti-Depressant
Last Reviewed by the DUR Board: July 25, 2019

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

1. Coverage and Limitations

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

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

      2. Recipient must have a diagnosis of treatment resistant depression as evidence of failure of two antidepressants; and

      3. Medication must be administered under the direct supervision of a healthcare provider with post-administration observation; and

      4. Treatment must be in conjunction with an oral antidepressant; and

      5. The medication must be prescribed by or in consultation with a psychiatrist; and

      6. The recipient must not have an aneurism or AV (arteriovenous**)** malformation.

   b. Approval will not be given for recipients who are currently pregnant or lactating and breastfeeding.

2. Recertification Request:

   a. In addition to the prior authorization criteria listed above (initial approval), the recipient must also have a positive clinical response to the medication treatment.

3. Prior Authorization Guidelines

   a. Initial prior authorization approval will be given for four weeks.

   b. Recertification authorization approval will be given for six months.

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

RR. Omontys® (Peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)
Last Reviewed by DUR Board: October 25, 2012

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

1. Coverage and Limitations

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

   a. The recipient has a diagnosis of anemia secondary to chronic kidney disease;

   b. The recipient must be over 18 years of age;

   c. The recipient is receiving dialysis;

   d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);

   e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and

   f. The target hemoglobin level will not exceed 11 g/dL.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one month.

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

SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: January 19, 2023

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

1. Coverage and Limitations

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

a. The requested agent is being used for an FDA-approved indication.

b. The requests for a diagnosis of nonmyeloid malignancy must meet one of the following criteria:

1. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile ~~neuropenia~~neutropenia risk of ≥ 20%; or

2. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age > 65 years, absolute neutrophil count (ANC) < 100 cells/µL or the expected duration of neutropenia is > 10 days); or

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

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

TT. Auvi-Q® (epinephrine injection device)

Therapeutic Class: Anaphylaxis-Self Injectable Epinephrine
Last Reviewed by the DUR Board: January 23, 2014

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

1. Coverage and Limitations

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

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

2. Prior Authorization Guidelines

   a. Initial prior authorization approval will be for one year.

   b. Recertification approval will be for one year.

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

VV. Medications for the Treatment of Acne

Therapeutic Class: Acne Agents
Last Reviewed by the DUR Board: July 24, 2014

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

1. Coverage and Limitations

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

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

a. The recipient is age 21 years of age or older; and

b. The recipient has a diagnosis of moderate to severe acne (Grade III or higher).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

WW. Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome Agents, Opioid-Induced Constipation Agents
Last Reviewed by the DUR Board: January 23, 2020

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

1. Chronic Idiopathic Constipation (CIC) Agents

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

      1. The requested drug must be FDA approved for the recipient's age; and

      2. Must have a diagnosis of CIC; and

      3. Recipient has trial and failure, contraindication or intolerance to either lactulose or polyethylene glycol (Miralax); and

      4. Recipient has trial and failure, contraindication or intolerance to at least one stimulant laxative, such as ~~sessosidessennosides~~ (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada; and

      5. The maximum allowable dose for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2mg, once daily

         d. Trulance® (plecanatide): 2mg, once daily

   b. Prior Authorization Guidelines

      1. Prior authorization approval will be for one year.

      2. Prior Authorization forms are available at:
      https://nevadamedicaid.magellanrx.com/provider/forms.
      ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

2. Irritable-Bowel Syndrome Agents

   a. Coverage and Limitations

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

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

b. The requested agent is being prescribed based on FDA approved guidelines; and

1. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):

a. For requests for Amitiza® (lubiprostone), the recipient must be female.

b. The requested dose is appropriate based on indication and age.

1. Linzess® (linaclotide): 290 µg daily.

2. Amitiza® (lubiprostone): 16 µg daily.

3. Trulance® (plecanatide): 3 µg daily.

2. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):

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

b. The requested dose is appropriate based on indication and age.

1. Lotronex® (alosetron): 0.5 mg twice daily or 1 mg twice daily.

2. Viberzi® (eluxadoline): 75 mg twice daily or 100 mg twice daily.

3. Xifaxan® (rifaximin): 550 mg three times a day for 14 days.

b. Prior Authorization Guidelines

1. Prior authorization approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

c. Zelnorm® (tegaserod)

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

a. The recipient has a diagnosis of IBS-C; and

b. The recipient is female; and

c. The recipient is less than 65 years of age; and

d. The recipient has had trial and failure, contraindication, or intolerance to one of the following:

1. Lactulose; or

2. Polyethylene glycol.

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

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

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be for six weeks.

b. Recertification approval will be 12 months.

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

3. Opioid-Induced Constipation Agents

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

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

2. The requested medication is being used for an FDA approved indication; and

3. The recipient must meet the following criteria:

a. There is documentation in the recipient's medical record of an inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative drug classes:

1. Bulk forming laxatives;

2. Osmotic laxatives;

3. Saline laxatives;

4. Stimulant laxatives.

4. And, requests for methylnaltrexone bromide that exceed the quantity limit must meet all the following criteria:

   a. The recipient has opioid-induced constipation in advanced illness, is receiving palliative care, and is not enrolled in DHCFP's hospice program; and

   b. The requested dose is 0.15 mg/kg; and

   c. The recipient's current weight is >114 kg.

b. Prior Authorization Guidelines

   1. Prior authorization approval will be for one year.

   2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

XX. Xartemis® XR (oxycodone and acetaminophen)

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: January 22, 2015

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

1. Coverage and Limitations

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

a. The recipient is 18 years or older; and

b. A diagnosis code of Acute Pain is documented on the prescription and transmitted on the claim; or

c. An approved prior authorization documenting the recipient meeting the following criteria:

1. The recipient is 18 years or older; and

2. A diagnosis code of Acute Pain is documented on the Prior Authorization form.

2. Prior Authorization Guidelines

a. More than two fills of a quantity of 60 each, within six months requires an approved prior authorization documenting the reason to exceed the prescribing limit.

b. Prior authorization approval will be for six months.

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

YY. GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: April 26, 2018

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

1. Coverage and Limitations

   a. This prior authorization criteria only applies to recipients who are under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:

      1. The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and

         a. The requested dose and frequency is based on FDA-approved guidelines; and

         b. The medication is being prescribed by or in consultation with a pediatric endocrinologist; and

         c. There is an onset of secondary sex characteristics before age eight years (females) or nine years (males); and

         d. The recipient is currently less than 11 years of age (females) or 12 years of age (males).

      2. The recipient has a diagnosis of gender dysphoria, formerly known as gender identity disorder; and

         a. The medication is being prescribed for suppression of puberty; and

         b. The provider indicates a demonstrable knowledge what gonadotropins medically can and cannot do and their social benefits and risks; and

         c. One of the following:

            1. A documented real-life experience (living as the other gender) for at least three months prior to the administration of gonadotropin; or

            2. A period of psychotherapy for a duration specified by the mental health professional after the initial evaluation (usually a minimum of three months).

d. The member must meet the definition of gender dysphoria (see definition below):

1. Gender ~~Disphoria~~Dysphoria:

a. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).

b. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

c. The disturbance is not concurrent with a physical intersex condition.

d. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

e. The transsexual identity has been present persistently for at least two years.

f. The disorder is not a symptom of another mental disorder or a chromosomal abnormality.

3. The recipient has a diagnosis of endometriosis, and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The recipient has had an inadequate response, adverse reaction, or contraindication to an NSAID; and

c. The recipient has had an inadequate response, adverse reaction, or contraindication to a hormonal contraceptive.

4. The recipient has a diagnosis of uterine leiomyomata (fibroids), and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The recipient is symptomatic; and

c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rational why surgical intervention is not required.

5. The recipient has a diagnosis of prostate cancer, and

a. The requested dose and frequency is based on FDA-approved guidelines.

2. Prior Authorization Guidelines

a. Prior authorization approval will be given for an appropriate length of therapy based on the diagnosis~~,~~ unless the prescriber indicates a shorter duration of approval.

1. CPP: One year, or until the member reaches the age of 11 years (female) or 12 years (male).

2. Endometriosis: One year.

3. Uterine Leiomyomata (fibroids): One month or until the time of the documented surgery (maximum of three months).

4. Prostate Cancer: One year.

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

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: January 18, 2024~~October 20, 2022~~

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

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

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

      1. The recipient has a diagnosis of narcolepsy; or

         a. Obstructive Sleep Apnea (OSA); or

         b. Excessive sleepiness associated with shift work disorder.

   b. For treatment of OSA:

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

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

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

            2. Both the following:

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

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

                  1. Daytime sleepiness; or

                  2. Nonrestorative sleep; or

                  3. Fatigue; or

                  4. Insomnia; or

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

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

7. Observed apnea; and

c. Both the following:

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

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

c. Recertification Request:

1. Documentation of positive clinical response to therapy.

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

d. Prior Authorization Guidelines:

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

~~2. Xyrem® (sodium oxybate)~~

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

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

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

~~d. Prior Authorization Guidelines~~

~~1. Prior authorization approvals will be for 12 months.~~

~~3~~2. Sunosi® (solriamfetol)

a. For treatment of Narcolepsy

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

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

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

1. modafinil; and

2. armodafinil.

2. Recertification Request:

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

b. For treatment of OSA

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

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

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

2. Both the following:

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

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

1. Daytime sleepiness; or

2. Nonrestorative sleep; or

3. Fatigue; or

4. Insomnia; or

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

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

7. Observed apnea; and

c. Both the following:

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

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

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

1. Modafinil; and

2. Armodafinil.

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

a. Documentation of positive clinical response to therapy; and

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

3. Prior Authorization Guidelines

a. Initial request will be approved for six months.

b. Recertification request will be approved for six months.

3. Wakix® (pitolisant)

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

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

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

b. Recertification Requests:

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

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

4. Xywav® (calcium, magnesium, potassium, and sodium oxybates), Xyrem–® (sodium oxybate), Lumryz® (sodium oxybate ER)

a. Narcolepsy with Cataplexy (Narcolepsy Type 1).

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

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

b. The recipient has present symptoms of cataplexy; and

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

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

e. Patient is FDA approved age for agent (≥ 7 years old Xywav, Xyrem; ≥ 18 years old Lumryz).

2. Recertification Request:

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

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

b. Narcolepsy without Cataplexy (Narcolepsy Type 2)

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

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

b. The recipient symptoms of cataplexy are absent; and

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

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

e. One of the following:

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

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

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

g. Patient is FDA approved age for agent (≥ 7 years old Xywav, Xyrem; ≥ 18 years old Lumryz).

2. Recertification Request:

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

c. Idiopathic Hypersomnia (Xywav® only)

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

a. Diagnosis of idiopathic hypersomnia with all of the following:

1. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; and

2. The absence of cataplexy; and

3. Fewer than two sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques, or no SOREMPs if the REM sleep latency on the preceding polysomnogram was < 15 minutes; and

4. One of the following:

   a. A mean sleep latency of ≤ 8 minutes; or

   b. Total 24-hour sleep time ≥ 660 minutes; and

5. Other causes of sleepiness have been ruled out; and

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

7. Patient is ≥ 18 years old.

2. Recertification Request:

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

3. Prior Authorization Guidelines:

   a. Initial request will be approved for six months.

   b. Recertification request will be approved for 12 months.

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

Therapeutic Class: Nonsteroidal Anti-inflammatory Drug/Anti-ulcer Agent Combinations
Last Reviewed by the DUR Board: April 23, 2015

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

1. Coverage and Limitations

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

a. The drug is being used for an FDA approved indication; and

b. The recipient's medical records documents one of the following risk factors for developing a NSAID-related ulcer:

1. Previous history of a major gastrointestinal bleed, perforation, or obstruction; or

2. Previous history of a peptic ulcer, hemorrhagic gastritis, hemorrhagic gastropathy or erosive esophagitis; or

3. Concomitant therapy for an anticoagulant or antiplatelet agent (including aspirin) or chronic oral corticosteroids; or

4. The recipient has had gastric bypass surgery (Roux-en-Y gastric bypass); and

c. The recipient is intolerant to a COX-2 inhibitor or has had a gastric or duodenal ulcer while taking a COX-2 inhibitor; and

d. The recipient has experienced an NSAID-associated ulcer in the past while taking a single-entity proton pump inhibitor (PPI) or prostaglandin agent concomitantly with an NSAID or the recipient is intolerant to both PPIs and prostaglandin agents; and

e. The recipient's medical records document an inadequate response or adverse reaction with concurrent therapy of an equivalent dose of the individual components.

2. Prior Authorization Guidelines

a. Prior authorization approvals will be for one year.

b. Prior Authorization forms available at: https://nevadamedicaid.magellanrx.com/provider/forms.

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL

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

CCC. Rayos® (prednisone ~~delayed-release~~delayed release)

Therapeutic Class: Corticosteroid, Systemic
Last Reviewed by the DUR Board: April 23, 2015

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

1. Coverage and Limitations

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

   a. The requested drug is being used for ~~a~~an FDA approved indication; and

   b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate–release tablets.

2. Prior Authorization Guidelines

   a. Prior authorization approvals will be:

      1. Initial therapy: three months.

      2. Recertification: one year.

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

DDD. Corlanor® (ivabradine)

Therapeutic Class: Cardiovascular Agent
Last Reviewed by the DUR Board: September 3, 2015

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

1. Coverage and Limitations

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

   a. A diagnosis of chronic heart failure; and

   b. A left ventricular ejection fraction (LVEF) $\leq$ 35%; and

   c. A resting heart rate $\geq$ 70 bpm; and

   d. The recipient is $\geq$ 18 years of age; and

   e. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted regarding the diagnosis and treatment recommendations; and

   f. The recipient is in a normal sinus rhythm; and

   g. The recipient is on a maximally tolerated dose of a beta-blocker or the recipient has a contraindication to beta-blocker use.

2. Prior Authorization Guidelines

   a. The extent of prior authorization approvals will be based on the appropriate use for the individual agents.

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

EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: Antilipemic Agent, PCSK9 Inhibitors
Last Reviewed by the DUR Board: July 23, 2020

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

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

   a. Initial Request:

      1. The recipient has an FDA-approved diagnosis; and

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

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

      4. For the treatment of homozygous familial hypercholesterolemia:

         a. With alirocumab (Praluent®)

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

         b. With evolocumab (Repatha®)

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

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

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

            1. The recipient has received therapy with atorvastatin $\geq$ 40 mg or rosuvastatin $\geq$ 20 mg for at least the past three months; and

            2. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

            3. The LDL-C after therapy for at least the past three months was $\geq$ 100 mg/dL (HeFH) for $\geq$ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

4. The statin therapy will be continued with PCSK-9 therapy.

b. Or, the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:

1. The recipient has an intolerance or contraindication to high intensity statin therapy; and

2. The recipient has received therapy with:

a. atorvastatin 10 to 20 mg; or

b. rosuvastatin 5 to 10 mg; or

c. simvastatin > 20 mg; or

d. pravastatin >40 mg; or

e. lovastatin 40 mg; or

f. fluvastatin XL 80 mg; or

g. fluvastatin 40 mg twice daily; or

h. pitavastatin > 2 mg

for at least the past three months; and

3. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

4. The LDL-C after therapy for at least the past three months was $\geq$ 100 mg/dL (HeFH) or $\geq$ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

5. Statin therapy will be continued with PCSK-9 therapy.

c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.

d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.

2. Recertification Request (The recipient must meet all criteria (a-d))

a. The recipient has been adherent with PCSK-9 inhibitor therapy; and

b. The recipient has been adherent with statin therapy, or the recipient has a labeled contraindication to statin therapy; and

c. The recipient is continuing a low-fat diet and exercise regimen; and

d. The recipient has achieved a reduction in LDL-C level.

3. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification approval will be approved for 12 months.

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

GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: January 27, 2017
Previously reviewed: January 28, 2016

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

1. Coverage and Limitations

   a. For recipients 21 years of age or older:

      1. The prescriber has verified the recipient is enrolled in the hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care; and

      4. The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient; and

      5. The requested medication is not providing a curative or long-term prophylactic therapy.

   b. For recipients 20 years of age or younger:

      1. The prescriber has verified the recipient is enrolled in a hospice program; and

      2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

      3. The requested medication is not being used for palliative care.

      4. Medically necessary curative medications for this age group are covered by the DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for three months.

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

JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker
Last Reviewed by the DUR Board: October 26, 2021

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

1. Coverage and Limitations

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

a. The recipient has a diagnosis of chronic heart failure NYHA Class II to IV; and

b. The recipient has reduced left ventricular ejection fraction (LVEF); and

c. The recipient is one year of age or older; and

d. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted; and

e. The recipient has had a trial of an angiotensin converting enzyme (ACE) or an angiotensin receptor blocker (ARB) for at least four weeks prior to the initiation of therapy; and

f. The recipient will not concurrently receive an ACE inhibitor; and

g. The recipient is on an individualized dose of a beta blocker, or the recipient has a contraindication to beta blocker use; and

h. Entresto® will be given twice daily with a maximum dose of 97/103 mg.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for one year.

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

KKK. Neurokinin-1 Antagonists and Combinations

Therapeutic Class: Neurokinin-1 Antagonists and Combinations
Last Reviewed by the DUR Board: April 28, 2016

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

1. Coverage and Limitations

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

a. The requested medication is being used for an FDA-approved indication; and

b. The requested medication is being prescribed by an oncologist or in consultation with an oncologist; and

c. The recipient must meet one of the following criteria:

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

2. The recipient is 12 years of age or older, the requested medication is aprepitant (Emend®) and the recipient is diagnosed with nausea and vomiting caused by chemotherapy; and

d. It is medical necessity for the recipient to exceed the quantity limit (e.g., duration of chemotherapy cycle).

2. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

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

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: October 19, 2023

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

1. Exondys 51® (eteplirsen)

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

      1. Initial request:

         a. The recipient has a diagnosis of Duchenne muscular dystrophy (DMD); and

         b. There is documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping; and

         c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

         d. The prescribed dose does not exceed 30 milligrams per kilogram of body weight once weekly.

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

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

         b. The recipient has experienced clinically significant benefit; and

         c. The recipient is tolerating therapy; and

         d. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

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

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

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

            3. The recipient has experienced clinically significant benefit; and

4. The recipient is tolerating therapy; and

5. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

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

b. Prior Authorization Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

2. Emflaza® (deflazacort)

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

1. Initial request:

a. The recipient must have a diagnosis of (DMD); and

b. The recipient must be five years of age or older; and

c. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:

1. Documentation of a confirmed mutation of the dystrophin gene; or

2. Muscle biopsy confirming an absence of dystrophin protein; and

d. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and

e. The recipient has had at least a three-month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and

The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

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

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

2. The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

c. Prior Authorization Guidelines:

1. Initial prior authorization approval will be approved for 12 months.

2. Recertification request will be approved for 12 months.

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

3. Vyondys 53® (golodirsen)

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

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

a. The recipient has a diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

3. The dose will not exceed 30 milligrams per kilogram of body weight infused once weekly.

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

1. One of the following:

a. All the following:

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

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a neurologist who has experience treating children; or

b. All the following:

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

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

3. The recipient is tolerating therapy; and

4. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

4. Viltepso® (viltolarsen)

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

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

a. The recipient has a diagnosis of DMD; and

b. The recipient has documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly.

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

1. One of the following:

a. All of the following:

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

2. The recipient is tolerating therapy; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; or

b. All of the following:

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

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

3. The recipient is tolerating therapy; and

4. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a Neurologist who has experience treating children.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

5. Amondys 45® (casimersen)

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

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

b. Diagnosis of Dystrophy (DMD); and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 to exon 45 skipping; and

2. Prescribed by or in consultation with a neurologist who has experience treating children; and

3. Dose will not exceed 30 milligrams per kilograms of body weight infused once weekly.

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

1. The recipient is tolerating therapy; and

2. Dose will not exceed 30 milligrams per kilogram of body weight infused weekly; and

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

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

6. Elevidys™ (Delandistrogene Moxeparvovec-Rokl)

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

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

a. The recipient has a diagnosis of DMD; and

b. The recipient has confirmed mutation of the DMD gene between exons 1 to 71; and

c. The recipient does not have any deletion in exon 8 and/or exon 9 in the DMD gene; and

d. The recipient must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by ELISA.

NNN. Qutenza® (capsaicin)

Therapeutic Class: Topical Neuropathic Pain Agents
Last Reviewed by the DUR Board: January 27, 2022

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

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

   a. The recipient has a diagnosis of neuropathic pain associated with postherpetic neuralgia; or

   b. The recipient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet; and

   c. The recipient has history of failure or intolerance to over-the-counter capsaicin.

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

   a. At least three months have transpired since the last Qutenza® application/administration; and

   b. The recipient experienced pain relief with a prior course of therapy; and

   c. The recipient is experiencing a return of neuropathic pain.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification request will be approved for three months.

   c. The Prior Authorization forms are available at:
   https://nevadamedicaid.magellanrx.com/provider/forms.
   ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

OOO. Movement Disorder Agents

Therapeutic Class: Movement Disorder Agents
Last Reviewed by the DUR Board: April 28, 2022

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

1. Austedo® (deutetrabenazine)

   a. For treatment of Chorea Associated with Huntington's Disease.

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

         a. The recipient must have a diagnosis of chorea associated with Huntington's disease; and

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

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

      2. Recertification criteria:

         a. Documentation of positive clinical response to therapy.

      3. Prior Authorization Guidelines

         a. Initial prior authorization approval will be for 12 months.

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

   b. For the treatment of Tardive Dyskinesia (TD).

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

         a. The recipient must have a confirmed diagnosis of TD; and

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

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

         d. One of the following:

1. Persistent symptoms of TD despite a trial dose reduction, tapering or discontinuation of the offending medication; or

2. The recipient is not a candidate for trial dose reduction, tapering or discontinuation of the offending medication.

2. Recertification request:

a. Documentation of positive clinical response to therapy

3. Prior Authorization Guidelines

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

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

2. Ingrezza® (valbenazine)

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

2. Initial request:

a. The recipient must have a diagnosis of severe tardive dyskinesia (TD);

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

c. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and

d. One of the following:

1. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or

2. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.

b. Recertification Request:

1. Documentation of positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for three months.

2. Recertification will be approved for 12 months.

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

PPP. Brineura® (cerliponase alfa)

Therapeutic Class: Brineura® (cerliponase alfa)
Last Reviewed by the DUR Board: October 19, 2017

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

1. Coverage and Limitations

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

a. Initial request:

1. The recipient must have a diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis Type 2 (CLN2) also known as tripeptidyl peptidase 1 (TPP1) deficiency; and

2. The diagnosis must be confirmed by TPP1 enzyme detected by a dried blood spot test and CLN2 genotype analysis; and

3. The recipient must be three years of age or older; and

4. The drug must be prescribed by or in consultation with a neurologist with expertise in the diagnosis of CLN2; and

5. The drug must be administered by, or under the direction of, a physician knowledgeable in intraventricular administration; and

6. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

7. The recipient must not have a ventriculoperitoneal shunt.

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

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

a. The recipient must not have acute intraventricular access-related complications (e.g., leakage, device failure or device-related infections); and

b. The recipient must not have a ventriculoperitoneal shunt; and

c. Documentation of positive clinical response to Brineura®, (e.g., improvement in walking or crawling, or no evidence of disease progression).

c. Prior Authorization Guidelines

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

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

QQQ. Vuity® (pilocarpine) 1.25% Ophthalmic Solution

Therapeutic Class: Ophthalmic Agents, Intraocular Pressure (IOP)-Modifying

Last Reviewed by the DUR Board: April 28, 2022

Vuity® (pilocarpine) 1.25% Ophthalmic Solution is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

   a. The recipient has a diagnosis of presbyopia; and

   b. The medication prescribed by or in consultation with an ophthalmologist or optometrist; and

   c. The recipient is unable to use corrective lenses (e.g., eyeglasses or contact lenses) confirmed by medical records (e.g., chart notes); and

   d. Vuity will not be prescribed concurrently with any ophthalmic pilocarpine formulations.

2. Recertification Request:

   a. Documentation or positive clinical response to therapy (e.g., improvement in near vision in low light conditions without loss of distance vision); and

   b. Prescribed by or in consultation with an ophthalmologist or optometrist.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for one month.

   b. Recertification will be approved for six months.

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

TTT. Codeine and Tramadol for Children

Therapeutic Class: Opioid Analgesic
Last Reviewed by the DUR Board: October 19, 2017

Codeine, codeine with acetaminophen and tramadol, tramadol with acetaminophen ~~are~~is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Codeine, codeine with acetaminophen

1. All of the following criteria must be met:

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

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI > 30 kg/m^2), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy.

b. Tramadol, tramadol with acetaminophen

1. All of the following criteria must be met:

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

b. The lowest effective dose for the shortest period of time is being requested; and

c. The recipient must not be obese (BMI > 30 kg/m^2), have obstructive sleep apnea, or severe lung disease; and

d. The recipient is not being prescribed the drug for post-surgical pain following a tonsillectomy and/or adenoidectomy; and

e. The prescribed dose does not exceed 200mg/day and does not exceed a five-day supply.

2. Tramadol Extended Release (ER) will not be approved for children under 18 years of age and will be rejected at point of sale.

c. Prior Authorization Guidelines

1. Codeine, codeine with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

1. Prior authorization will be given for a one-month time period.

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

2. Tramadol, tramadol with acetaminophen

a. Prior authorization approval will be given for the lowest effective dose for the shortest period of time requested.

b. Prior authorization will be given for a one-month time period.

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

UUU. High Dollar Claim

Last Reviewed by the DUR Board: April 26, 2018

A High Dollar Claim is defined as a single point-of-sale claim that exceeds $10,000. A High Dollar Claim is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits. If other prior authorization criteria exists, it will supersede this criteria.

1. Coverage and Limitations

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

a. One of the following:

1. The medication is being prescribed for a Food and Drug Administration (FDA) approved indication; or

2. One of the following:

a. Diagnosis is supported as a use of American Society of Health-System Pharmacists Drug Information (AHFS DI); or

b. Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “Effective” or “Evidence Favors Efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table); or

4. Diagnosis is supported in any other section in DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

b. And one of the following:

1. The dosage/quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

a. American Hospital Formulary Service (AHFS) Compendium.

b. Thomson Reuters (Healthcare) Micromedex/DRUGDEX (not Drug Points) Compendium.

c. Elsevier Gold Standard Clinical Pharmacology Compendium.

d. National Comprehensive Cancer Network Drugs and Biologics Compendium.

c. Excluded:

1. Hemostatic coagulation factors used for the treatment of hemophilia are excluded from this criteria.

d. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

WWW. Botulinum Toxin

Therapeutic Class: Neurotoxic Protein
Last reviewed by the DUR Board: July 26, 2018

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

1. Policy

Botulinum toxin injections are a Nevada Medicaid covered benefit for certain spastic conditions including, but not limited to cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis. The injections may reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and ambulation, to allow improved range of motion, to permit better physical therapy and provide adequate perineal hygiene.

2. Coverage and Limitations

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

a. It is expected that physicians be familiar with and experienced in the use of botulinum toxin products and utilize FDA-approved product labeling, compendia and peer-reviewed scientific literature to select the appropriate drug and dose regimen for each recipient condition. A complete list of covered indications can be found within the "Provider Type 20, 24 and 77 Billing Guide" applicable to botulinum toxins.

b. Documentation must be provided that the recipient has been unresponsive to conventional methods of treatment (e.g., medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions); and

c. If maximum dose is reached and positive clinical response is not established, treatment must be discontinued; and

d. Documentation of medical necessity is required for treatment more frequent than every 90 days; and

e. Coverage will be approved for one injection per site. A site is defined as including muscles of a single contiguous body part, such as a single limb, eyelid, face or neck.

f. Coverage will not be provided for injections given for cosmetic or for investigational purposes.

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

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

1. Documentation of a positive clinical response to Botulinum Toxin therapy.

4. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

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

XXX. Compounded Medications

Last Reviewed by the DUR Board: January 24, 2019

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

1. Coverage and Limitations

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

a. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and

b. The therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery; and

c. If any prescription ingredients require prior authorization and/or step therapy, all drug specific criteria must also be met; and

d. The compounded medication must not be used for cosmetic purpose; and

e. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (drugs withdrawn from the market due to safety or effectiveness); and

f. The recipient has tried and failed therapy or had an intolerance to at least two FDA-approved, commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

1. The recipient has a contraindication to commercially available products; or

2. One or no other therapeutic alternatives are commercially available; or

3. Compound medication is prepared in a different dosage form for a recipient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does not meet this criteria); or

4. The recipient has an allergy or sensitivity to inactive ingredients (e.g., dyes, preservatives, sugars, etc.) that are found in commercially available products.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for six months unless the provider requests for a shorter length of therapy.

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

YYY. Antibiotics

Last Reviewed by the DUR Board: July 26, 2018

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

The outpatient antibiotic class criteria apply to the following:

Third Generation Cephalosporins	**Fluoroquinolones**	**Oxazolidinones**
cefixime	ciprofloxacin	tedizolid
cefdinir	levofloxacin	linezolid
cefpodoxime	delafloxacin	
ceftibuten	moxifloxacin	
cefditorencefdotoren	ofloxacin	

If applicable, reference current Infectious Disease Society of America (IDSA) (or equivalent organization) guidelines to support the use of the following:

1. Coverage and Limitations for Third Generation Cephalosporins and Fluoroquinolones

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

   a. Culture and sensitivity-proven susceptibilities and resistance to other agents suggest the requested drug is necessary.

2. Coverage and Limitations for Oxazolidinones

   a. Sivextro® (tedizolid)

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

      1. Recipient has diagnosis of Acute Bacterial Skin and Skin Structure Infection; and

      2. Infection is caused by methicillin-resistant *Staphylococcus aureus* (MRSA); and

      3. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to:

trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, vancomycin, daptomycin, telavancin, clindamycin); or

4. Recipient started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy.

b. Zyvox® (linezolid)

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

1. Recipient has a diagnosis of vancomycin-resistant *enterococcus* (VRE) *faecium* infection or diagnosis of MRSA infection; and

2. Recipient has had a trial of or has a contraindication to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, tetracycline, clindamycin); or

3. Recipient started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy.

3. Exception Criteria (applies to antibiotic medications)

a. Prescribed by an infectious disease specialist or by an emergency department provider; or

b. Ceftriaxone prescribed as first line treatment for gonorrhea, pelvic inflammatory disease, epididymo-orchitis and as an alternative to benzylpenicillin to treat meningitis for those with a severe penicillin allergy; or

c. If cefixime is prescribed for gonococcal infection where ceftriaxone is unavailable; or

d. The recipient resides in one of the following:

1. Acute Care

2. Long-term Acute Care (LTAC)

3. Skilled Nursing Facility (SNF)

4. Prior Authorization Guidelines

a. Prior authorization approval will be for a single course.

b. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. References

ZZZ. Oral Oncology Agents

Therapeutic Class: Oral Oncology Agents
Last Reviewed by the DUR Board: January 24, 2019

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

1. Coverage and Limitations (this criteria only applies if other product-specific criteria is not available in MSM Chapter 1200 – Prescribed Drugs)

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

   a. The recipient has a diagnosis that is indicated in the FDA approved package insert or listed in nationally recognized compendia, for the determination of medically accepted indications; and

   b. If the oral oncology medication is not indicated as a first line agent, either in the FDA approved package insert or nationally recognized compendia, then documentation of previous therapies tried and failed is required; and

   c. The medication is prescribed by or in consultation with an oncologist or hematologist; and

   d. The recipient does not have any contraindications to the requested oral oncology medication; and

   e. The requested quantity and dosing regimen falls within the manufacturer's published dosing guidelines or nationally recognized compendia and is appropriate for the recipient's age; and

   f. The medication must be used in combination with other chemotherapeutic or adjuvant agents according to the FDA approved prescribing information; and

   g. One of the following:

      1. If an FDA-approved companion diagnostic test for the requested agent exists, then documentation that the test was performed to confirm the diagnosis is required; or

      2. If a test with adequate ability to confirm a disease mutation exists, then documentation that the test was performed to confirm the diagnosis is required.

2. Recertification Request

   a. Documentation of a positive clinical response to ~~the oral~~oral oncology treatment.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

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

AAAA. Pulmonary Arterial Hypertension Agents

Therapeutic Class: Pulmonary Arterial Hypertension Agents
Reviewed by the DUR Board: January 24, 2019

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

1. Coverage and Limitations

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

a. The recipient has a documented diagnosis of pulmonary arterial hypertension; or

b. The recipient has one of the following ICD-10 diagnosis codes submitted on the pharmacy claim:

ICD-10	Description
127.20	Pulmonary Hypertension, Unspecified
127.21	Secondary Pulmonary Arterial Hypertension
127.22	Pulmonary Hypertension Due to Left Heart Disease
127.23	Pulmonary Hypertension Due to Lung Diseases and Hypoxia
127.9	Pulmonary Heart Disease, Unspecified

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

GGGG. Relyvrio® (sodium phenylbutyrate/taurursodiol)

Therapeutic Class: Amyotrophic Lateral Sclerosis (ALS)
Last reviewed by DUR Board: October 19, 2023

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

1. Relyvrio® (sodium phenylbutyrate/taurursodiol)

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

      1. The recipient is greater than or equal to 18 years of age; and

      2. The recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

      3. The recipient must have an adequate trial of riluzole for greater than or equal to eight weeks or contraindication to therapy; and

      4. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R); and

      5. The recipient does not require permanent assisted ventilation; and

      6. Therapy prescribed by or in consultation with neurologist; and

   b. Recertification Request:

      1. The recipient must continue to meet the above criteria; and

      2. The recipient must have disease stabilization or improvement in the slope of decline as demonstrated on an objective measure/tool (e.g., ALSFRS-R); and

      3. The recipient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure).

   a. Prior Authorization Guidelines:

      1. Initial approval will be given for six months.

      2. Recertification will be approved for six months.

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

2. Qalsody™ (Tofersen)

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

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

2. The recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

3. The recipient has a baseline measure of plasma neurofilament light chain (NfL) and

4. Prescribed by or in consultation with a neurologist; and

5. The recipient has the presence of a superoxide dismutase 1 (SOD1) gene mutation; and

6. Dosing is in accordance with FDA approved labeling.

B. Recertification Request:

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

2. The recipient must have stabilization or improvement in plasma NfL compared to baseline; and

4. The recipient has responded to therapy compared to pretreatment baseline with disease stability or mild progression (recipient has not experienced rapid disease progression while on therapy); and

5. Dosing is in accordance with FDA approved labeling.

C. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

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

KKKK. Vyjuvek™ (beremagene geperpavec-svdt)

Therapeutic Class: dystrophic epidermolysis bullosa (DEB)
Last reviewed by DUR Board: October 19, 2023

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

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

   a. The recipient is six months of age or older; and

   b. The recipient has not received a skin graft within the past three months; and

   c. The recipient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) with mutation in the COL7A1 gene; and

   d. Prescribed by or in consultation with pediatric dermatologist or other specialist with advanced knowledge of treating DEB; and

   e. The recipient has cutaneous wound(s) with are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

2. Recertification Request:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reaction resulting in discontinuation of therapy; and

   c. The recipient must have disease response as defined by improvement (healing) of treated wound(s); and

   d. The recipient requires continued treatment for new and/or existing open wounds.

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for six months.

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

LLLL. Hemgenix® (etranacogene dezaparvovec-drlb)

Therapeutic Class: hemophilia B;
Last reviewed by DUR Board: October 19, 2023

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

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

   a. The recipient is at least 18 years of age; and

   b. Prescribed by or in consultation with a hematologist; and

   c. The recipient has a diagnosis of moderately severe or severe congenital factor IX deficiency (e.g., pre-treatment factor IX less than or equal 2%), as confirmed by blood coagulation testing; and

   d. The recipient has one or more of the following:

      1. Currently uses factor IX prophylaxis therapy; or

      2. Current or historical life-threatening hemorrhage; or

      3. Repeated, serious spontaneous bleeding episodes; and

   e. The recipient has been recently tested (within two weeks prior to administration of Hemgenix and found negative for factor IX inhibitors; and

   f. The recipient does not have active hepatitis B and/or hepatitis C infection; and

   g. The recipient does not have uncontrolled HIV infection; and

   h. Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and elastography have been performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and

   i. The recipient has not received previous gene therapy for Hemophilia B; and

   j. Prescriber attestation that factor IX activity will be monitored periodically per package insert (e.g., weekly for three months) post-administration.

2. Recertification Request:

   a. Coverage not renewable.

3. Prior Authorization Guidelines:

   a. Limited to one treatment per lifetime.

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

MMMM. Roctavian™ (valoctocogene roxaparvovec-rvox)

Therapeutic Class: hemophilia A
Last reviewed by DUR Board: October 19, 2023

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

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

    a. The recipient is at least 18 years of age; and

    b. Prescribed by or in consultation with a hematologist; and

    c. The recipient has a diagnosis of severe congenital factor VIII deficiency (e.g., pre-treatment factor VIII activity less than 1 IU/dL), as confirmed by blood coagulation testing; and

    d. The recipient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; and

    e. The recipient does not have an active infection, either acute (e.g., acute respiratory infection or acute hepatitis) or uncontrolled chronic (e.g., chronic active hepatitis B); and

    f. The recipient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; and

    g. The recipient has not received prior hemophilia adeno-associated virus (AAV)-vector-based gene therapy; and

    h. The recipient is AAV serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA compliant test; and

    i. The recipient has been tested and found negative for active factor VIII inhibitors (e.g., results from a Bethesda assay or Bethesda assay with Nijmegen modification of under 0.6 Bethesda Units {BU} on two consecutive occasions greater than or equal to one week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba); and

    j. Prescriber attestation that factor VIII activity will be monitored periodically post-administration; and

        1. The recipients with factor VIII activity levels greater than 5 IU/dL should discontinue routine prophylactic exogenous factor VIII; or

2. If factor VIII activity levels decrease and/or if bleeding is not controlled, assess presence of factor VIII inhibitors, and assess the need for hemostatic phrophylaxis.

2. Recertification Request:

   a. Coverage not renewable.

3. Prior Authorization Guidelines:

   a. Limited to one treatment per lifetime.

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

NNNN. Evkeeza™ (evinacumab-dgnb)

Therapeutic Class: Antihyperlipidemic – Angiopoietin-like protein 3 (ANGPTL3)
Last reviewed by DUR Board: October 19, 2023

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

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

    a. The recipient is at least five years of age; and

    b. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

    c. The recipient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) by any of the following:

        1. Documented DNA test for functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality; or

        2. Untreated LDL-C levels >500mg/dL or treated LDL-C ≥ 300 mg/dL; and

            a. Cutaneous or tendon xanthoma before age 10 year; or

            b. Untreated LDL-C levels in both parents consistent with HeFH; and

    d. The recipient does not have heterozygous familial hypercholesterolemia (HeFH); and

    e. Baseline LDL cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment; and

    f. The recipient has been receiving stable background lipid lowering therapy for ≥ 4 weeks; and

    g. Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PKSK (inhibitors, lomitapide, LDL apheresis; and

    h. The recipient has tried and failed at least a 3-month trial of adherent therapy with ezetimibe used in combination with the highest available or maximally tolerated dose of atorvastatin or rosuvastatin, unless contraindication to statin or ezetimibe; and

    i. The recipient has tried and failed at least a 3-month trial of adherent therapy with combination therapy consisting of the highest available or maximally tolerated dose

of atorvastatin OR rosuvastatin, ezetimibe, and a PCSK9 inhibitor indicated for HoFH (I.E., evolocumab), unless contraindicated; and

j. Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL-C is ≥ 100 mg/dL or ≥ 70 mg/dL for recipients with clinical atherosclerotic cardiovascular disease; and

k. Female recipients must have a negative pregnancy test and have been counselled to use effective contraception during treatment.

2. Recertification Requests

a. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

b. The recipient has had a documented reduction in LDL-C when compared to the initial baseline labs; and

c. The recipient continues to adhere to diet and background lipid lowering therapy (e.g., statin, ezetimibe, PCSK9 inhibitor).

3. Prior Authorization Guidelines:

a. Initial approval will be given for three months.

b. Recertification will be approved for six months.

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

OOOO. Joenja® (Leniolisib)

Therapeutic Class: activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)
Last reviewed by DUR Board: October 19, 2023

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

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

    a. The recipient is at least 12 years of age; and

    b. The recipient weighs at least 45 kg; and

    c. The recipient has a diagnosis of Activated Phosphoinositide 3-kinase Delta Syndrome (APDS) confirmed genetic mutation of either the PIK3CD or PIK3R1 gene; and

    d. Prescribed by or in consultation with immunologist; and

    e. The recipient has nodal and/or extra-nodal lymphoproliferation, with the presence of ≥ 1 measurable nodal lesion as confirmed by prescriber attestation of palpable diagnosis (and/or on computed tomography (CT) or magnetic resonance imaging (MRI); and

    f. The recipient has clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction [e.g., lung, liver]); and

    g. Pregnancy status will be confirmed in female recipients of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment; and

    h. The recipient is not on concurrent immunosuppressive therapy (e.g., mammalian target of rapamycin (mTOR) inhibitors, B-cell depleters, glucocorticoids [doses > 25 mg/day of prednisone equivalent.

2. Recertification request:

    a. The recipient must continue to meet the above criteria; and

    b. The recipient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells, decrease in disease-related hospitalizations); and

    c. The recipient has not experienced any treatment-restricting adverse effects (e.g.,

severe neutropenia: absolute neutrophil count [ANC] < 500 cells/µL)

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

   c. Prior Authorization forms are available at:
   https://nevadamedicaid.magellanrx.com/provider/forms.
   ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

PPPP. Daybue™ (trofinetide)

Therapeutic Class: Rett syndrome
Last reviewed by DUR Board: October 19, 2023

Daybue™ (trofinetide) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. The recipient is two years of age or older; and

   b. The recipient has a diagnosis of typical Rett Syndrome and a documented MECP2 gene mutation confirmed by genetic testing; and

   c. Prescribed by or in consultation with neurologist, geneticist, or developmental pediatrician; and

   d. Prescriber has assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression-Improvement [CGI-I] score, Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale); and

   e. The recipient does not have progressive weight loss prior to initiation of therapy; and

   f. The recipient does not have moderate or severe renal impairment (e.g., eGFR < 45 mL/min/1.73m^2).

2. Recertification request:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced on objective measure or tool (e.g., Rett Syndrome Behavior Questionnaire [RSBQ], CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor scale); and

   c. The recipient has NOT experienced any treatment-restricting adverse effects (e.g., severe diarrhea or dehydration, significant weight loss).

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

c. Prior Authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

QQQQ. Elfabrio® (pegunigalsidase alfa-iwxj)

Therapeutic Class: treats Fabry disease
Last reviewed by DUR Board: October 19, 2023

Elfabrio (pegunigalsidase alfa-iwxj) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

    a. The recipient is 18 years of age or older; and

    b. The recipient has a documented diagnosis of Fabry disease (α -galactosidase A [α-Gal A] deficiency) with biochemical/genetic confirmation by one of the following:

        1. α-Gal-A activity in plasma, isolated leukocytes, and/or cultured cells (males only); or

        2. Detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing; and

    c. Prescribed by or in consultation with a neurologist, geneticist, or other specialist with advanced knowledge in treating Fabry disease; and

    d. The recipient must have a baseline value for plasma GL-3 and/or GL-3 inclusions, plasma or urinary globotriaosylceramide (Gb3/GL-3); or plasma globotriaosylsphingosine (lyso- Gb3); and

    e. Recipient must not be taking migalastat (Galafold) or agalsidase beta (Fabrazyme) during pegunigalsidase alfa-iwxj (Elfabrio) therapy; and

    f. Medication is dosed per FDA labeling of 1 mg/kg (based on actual body weight) administered by IV infusion every two weeks.

2. Recertification requests:

    a. Recipient must continue to meet the above criteria; and

    b. Recipient must have experienced a disease response with treatment as defined by a reduction or stabilization in ≥ 1 of the following, as compared to pre-treatment baseline:

        1. plasma GL-3 and/or GL-3 inclusions

        2. plasma or urinary Gb3/GL-3

        3. plasma lyso-Gb3; or

c. The recipient must have experienced a disease response with treatment as defined by an improvement or stabilization in the rate of decline of the estimated glomerular filtration rate (eGFR); and

d. The recipient has not experienced unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, glomerulonephritis).

3. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be approved for 12 months.

c. Prior Authorization forms are available at:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

RRRR. Xiaflex® (collagenase clostridium histolyticum)

Therapeutic Class: treats Dupuytren's contracture and Peyronie's disease
Last reviewed by DUR Board: October 19, 2023

Xiaflex® (collagenase clostridium histolyticum) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Dupuytren's Contracture:

    a. Approval will be given if the following criteria are met and documented:

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Dupuytren's Contracture with a palpable cord; and

        3. The recipient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days; and

        4. Documentation that the flexion deformity is causing functional limitations; and

        5. Treatment is administered no sooner than four-week interval (up to three cycles in total).

    b. Recertification requests:

        1. Recipient continues to meet the above criteria.

    c. Prior Authorization Guidelines:

        1. One treatment cycle.

        2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

2. Peyronie's Disease

    a. Approval will be given if the following criteria are met and documented:

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Peyronie's Disease (PD) with a palpable plaque; and

3. The recipient has curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy and stable disease defined by symptoms (i.e. penile curvature and pain) for at least six months (initial request only); and

4. Xiaflex is NOT being used for sexual or erectile dysfunction associated with Peyronie's Disease; and

5. Must be used in conjunction with penile modeling procedure; and

6. Treatment is administered no sooner than 6-week interval (up to 4 cycles in total).

b. Recertification requests:

1. The recipient continues to meet above criteria; and

2. Curvature deformity remains greater than 15 degrees (curvature <15 degrees does not warrant subsequent treatment cycle).

c. Prior Authorization Guidelines:

1. One treatment cycle.

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

SSSS. Skyclarys® (Omaveloxolone)

Therapeutic Class: Friedreich ataxia
Last reviewed by DUR Board: October 19, 2023

Skyclarys® (Omaveloxolone) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Approval will be given if the following criteria are met and documented:

   a. The Recipient is at least 16 years of age; and

   b. The recipient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; and

   c. The recipient by or in consultation with neurologist, geneticist, or other specialist with advanced knowledge in treating Friedreich's ataxia; and

   d. The recipient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates); and

   e. The recipient has baseline Modified Friedreich's Ataxia Rating Scale (mFARS) score $\geq$ 20 and $\leq$ 80; and

   f. The recipient B-Type Natriuretic Peptide (BNP) is $\leq$ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; and

   g. Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:

      1. Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin; and

      2. Lipid parameter.

   h. The recipient does not have severe hepatic impairment (Child-Pugh C); and

   i. The recipient has the ability to swallow capsules; and

   j. The recipient of reproductive potential has been advised to use non-hormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation.

2. Recertification requests:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have disease improvement as defined by stabilization or slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; and

   c. The recipient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction).

3. Prior Authorization Guidelines:

   a. Initial approval will be given for 12 months.

   b. Recertification will be approved for 12 months.

   c. Prior Authorization forms are available at:
   https://nevadamedicaid.magellanrx.com/provider/forms.
   ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

TTTT. Voxzogo™ (vosoritide)

Therapeutic Class: Treatment of achondroplasia

Last reviewed by DUR Board: January 18, 2024

Voxzogo™ (vosoritide) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Voxzogo™ (vosoritide)

a. Initial requests:

1. Patient <18 years of age; and

2. Patient has diagnosis of confirmed achondroplasia based on one of the following:

a. Submission of records documenting:

1. Clinical manifestations of achondroplasia (e.g. proximal shortening of arms, large head, narrow chest, short fingers) and radiographic (e.g., ilia and horizontal acetabula, narrow sacrosciatic notch, proximal radiolucency of the femurs, generalized metaphyseal abnormality, decreasing interpedicular distance caudally); and

2. Radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphysis, and short and narrow chest); or

b. Genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene; and

3. Medication prescribed by or in consultation with endocrinologist, pediatric endocrinologist, clinical geneticist, or other specialist with advanced knowledge in treating achondroplasia; and

4. Patient has open epiphyses; and

5. Medication dosed per FDA label based on patient's actual body weight; and

6. Prescriber attestation that patient body weight, growth, and physical development will be monitored and assessed every three to six months; and

7. Patient has not had (within the previous 18 months) nor will they receive limb lengthening surgery.

b. Renewal requests:

1. Patient continues to meet above criteria; and

2. Documentation of positive clinical response to therapy as demonstrated by improvement in annualized growth velocity compared to pre-treatment baseline.

c. Prior Authorization Guidelines

1. Prior authorization approval will be for 12 months.

2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms

UUUU. Saphnelo® (anifrolumab-fnia)

Therapeutic Class: Systemic Lupus Erythematosus
Last reviewed by DUR Board: January 18, 2024

Saphnelo (anifrolumab-fnia) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial request:
    a. Patient is ≥ 18 years of age; and
    b. Patient has documented diagnosis of moderate to severe systemic lupus erythematosus (SLE); and
    c. The medication is prescribed by or in consultation with a rheumatologist; and
    d. Patient does not have any of the following exclusions to therapy:
        1. Severe active central nervous system lupus;
        2. Severe active lupus nephritis; and
    e. Patient has failed to respond adequately to at least one standard therapy (e.g. anti-malarials, corticosteroids, or immunosuppressives) (initial request only);
    f. The medication will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); and
    g. Patient must not have a clinically significant active infection; and
    h. Patient will not receive a live or live-attenuated vaccine concurrently with treatment; and
    i. The medication will not be used in combination with other biologic therapies (including B-cell targeted therapies (e.g., belimumab [Benlysta®]), voclosporin [Lupkynis™], or cyclophosphamide).
2. Renewal requests:
    a. Patient continues to meet above criteria; and
    b. Documentation of positive clinical response to Saphnelo therapy.
3. Prior Authorization Guidelines:
    a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.

VVVV. Tavneos™ (avacopan)

Therapeutic Class: ANCA-associated vasculitis (GPA or MPA)
Last reviewed by DUR Board: January 18, 2024

Tavneos™ (avacopan) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Initial request:

   a. Patient is ≥ 18 years old; and

   b. Patient has severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis; and

      1. Patient has autoantibodies for proteinase 3 (PR3) or myeloperoxidase (MPO), as detected using indirect immunofluorescence (IIF) assay or antigen-specific enzyme-linked immunosorbent assays (ELISAs); or

      2. Disease is confirmed by tissue biopsy at the site of active disease; and

   c. Medication prescribed by or in consultation with Nephrologist, Pulmonologist, or Rheumatologist; and

   d. Prescriber has assessed baseline (pre-treatment) disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS]) (initial request only); and

   e. Tavneos will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab); and

   f. Patient does not have an active infection, including localized infections; and

   g. Patient does not have severe hepatic impairment (e.g., Child-Pugh C) or active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis); and

   h. Liver panel has been obtained before initiating Tavneos and will be repeat per package insert (every four weeks after start of therapy for first six months then as clinically indicated);

   i. Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment (initial criteria only).

2. Renewal requests:

   a. Patient continues to meet above criteria; and

b. Documentation of positive clinical response to Tavneos therapy.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 6 months.

b. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.