MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

August 25, 2020

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CODY L. PHINNEY, DEPUTY ADMINISTRATOR

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

The DHCFP is proposing revisions to Medicaid Services Manual (MSM), Chapter 1200 – Prescribed Drugs, to reflect recommendations approved on April 30, 2020 by the Drug Use Review (DUR) Board. The proposed changes include revisions to the existing prior authorization criteria to the Proton Pump Inhibitors (PPIs) Agents, revisions to the existing prior authorization criteria for Toradol® (ketorolac tromethamine) tablets, addition of new prior authorization criteria for Ubrelvy® (ubrogepant), Emgality® (galcanezumab-gnlm), Aimovig® (erenumab-aooe) and Ajovy® (fremanezumab-vfrm), addition of a new Sickle Cell Anemia Agents' section to include new prior authorization criteria for Adakveo® (crizanlizumab-tmca) and Oxbryta® (voxelotor), addition of new prior authorization criteria for Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and lastly, addition of new prior authorization criteria for Wakix® (pitolisant).

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: August 31, 2020.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL OL MSM Ch 1200 – Prescribed Drugs	MTL NA MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section A	**Proton Pump Inhibitors (PPIs)**	Removed "The recipient is not on concomitant therapy of an H2 antagonist or sucralfate." from existing prior authorization criteria.
Appendix A Section R	**Toradol ®**	Added maximum dosage limit to the existing prior authorization criteria.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section S	**Anti-Migraine Medications**	Added new prior authorization criteria for Ubrelvy®, Emgality®, Aimovig® and Ajovy®.
Appendix A Section T	**Tobacco Cessation Products**	Revised last reviewed by DUR Board date.
Appendix A Section W	**Reserved for Future Use**	Revised section title to "Sickle Cell Anemia Agents". Added new prior authorization criteria for Adakveo® and Oxbryta®.
Appendix A Section LL	**Kalydeco®**	Revised section title to "Cystic Fibrosis Agents". Added new prior authorization criteria for Trikafta®. Relocated Orkambi® and Symdeko® to this section.
Appendix A Section AAA	**Narcolepsy Agents**	Added new prior authorization criteria for Wakix®.
Appendix A Section HHH	**Orkambi®**	Relocated Orkambi® prior authorization criteria to section LL. This section is now reserved for future use.
Appendix A Section VVV	**Symdeko®**	Relocated Symdeko® prior authorization criteria to section LL. This section is now reserved for future use.

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 24, 2014~~April 30, 2020

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

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

a. The recipient is not exceeding once daily dosing (quantity limit of one unit/day). ~~Prior Authorization is not required for once per day treatment if the following criteria is met:~~

~~1. The recipient is not on concomitant therapy of an H2 antagonist or sucralfate.~~

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

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

b. 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. ~~2.~~ Prior Authorization Guidelines

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

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

R. Toradol® (ketorolac tromethamine) tablets

Therapeutic Class: Nonsteroidal Anti-inflammatory Drugs~~,~~ (NSAIDs~~S~~)
Last Reviewed by the DUR Board: ~~Not Available~~April 30, 2020

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

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

   a. Oral treatment ~~is~~ must be indicated only as continuation therapy to IV/IM therapy.

   b. Oral treatment ~~is~~ 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.
   ~~The prior authorization must be initiated by the prescriber. The approved prior authorization must be available if requested.~~

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

S. Anti-Migraine Medications

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

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: ~~October 18, 2018~~April 30, 2020

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

1. Serotonin 5-HT1 Receptor Agonists (triptans)

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

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

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

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

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

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

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

b. Prior Authorization Guidelines

1. Approval for exceeding the quantity limits on trip~~i~~tans will be ~~given~~provided for a two month time period.

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

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

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

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

1. Episodic Migraines

a. ~~1.~~ Initial request:

1. ~~a.~~ The recipient must have a documented diagnosis of episodic migraines; and

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

3. ~~c.~~ The recipient must have four to 14 migraine days per month, but no more than 14 headache days per month; and

4. ~~d.~~ One of the following:

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

2. ~~2.~~ The recipient has a contraindication to both Elavil® (amitriptyline) and Effexor® (venlafaxine); and

5. One of the following:

a. ~~1.~~ The recipient has documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); or

b. ~~2.~~ The recipient has a contraindication to both Depakote®/Depakote ER (divalproex) and Topamax® (topiramate); and

6. ~~f.~~ One of the following:

a. ~~1.~~ The recipient has a history of failure (after at least a two-month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; or

b. ~~2.~~ The recipient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol and metoprolol; and

7. ~~g.~~ The medication must not be used in combination with another CGRP Inhibitor.

2. Chronic Migraines

a. ~~2.~~ Initial request:

1. ~~a.~~ The recipient has a documented diagnosis of chronic migraines; and

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

3. ~~c.~~ The recipient has been evaluated for medication overuse headache (MOH) and if the recipient is diagnosed with MOH, then treatment plan will include a taper off the offending medication; and

4. ~~d.~~ The recipient has ≥ 15 headache days per month, of which at least eight must be migraine days for at least three months; and

5. ~~e.~~ One of the following:

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

b. ~~2.~~ The recipient has a contraindication to both Elavil® (amitriptyline) and Effexor® (venlafaxine); and

6. ~~f.~~ One of the following:

a. ~~1.~~ The recipient has documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); or

b. ~~2.~~ The recipient has a contraindication to both Depakote®/Depakote ER (divalproex) and Topamax® (topiramate); and

7. ~~g.~~ One of the following:

a. ~~1.~~ The recipient has a history of failure (after at least a two-month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; or

b. ~~2.~~ The recipient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol and metoprolol; and

8. ~~h.~~ The medication will not be used in combination with another CGRP Inhibitor; and

9. ~~i.~~ The medication will not be used in combination with Botox (onabotulinumtoxinA).

b. ~~2.~~ Recertification Request:

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

2. ~~b.~~ The use of acute migraine medications (e.g., NSAIDs, triptans) has decreased since the start of CGRP therapy.

c. ~~3.~~ Prior Authorization Guidelines

1. ~~a.~~ Initial request ~~Prior authorization approvals~~ will be approved for three months.~~:~~

~~1. Initial prior authorization approval: three months.~~

2. Recertification request will be approved~~al~~ for~~:~~ 12 months.

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

3. Acute Migraines

a. Ubrelvy® (ubrogepant)

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

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

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

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

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

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

2. Recertification Request:

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

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

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

4. Episodic Cluster Headache

a. Emgality® (galcanezumab-gnlm)

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

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

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

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

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

2. Recertification Request:

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

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

3. Prior Authorization Guidelines:

   a. Initial request will be approved for three months.

   b. Recertification request will be approved for 12 months.

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

5. Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm) or Emgality® (galcanezumab-gnlm)

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

      1. The recipient must have one of the following:

         a. Both the following:

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

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

b. All the following:

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

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

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

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

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

4. The recipient must meet two of the following:

a. One of the following:

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

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

b. One of the following:

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

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

c. One of the following:

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

a. Atenolol; or

b. Propranolol; or

c. Nadolol; or

d. Timolol; or

e. Metoprolol; or

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

a. Atenolol; or

b. Propranolol; or

c. Nadolol; or

d. Timolol; or

e. Metoprolol.

b. Recertification Request:

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

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

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

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

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

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

T. Tobacco Cessation Products

Therapeutic Class: Tobacco Cessation Agents
Last Reviewed by the DUR Board: ~~Not Available~~April 30, 2020

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

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

W. ~~RESERVED FOR FUTURE USE~~ Sickle Cell Anemia Agents

Therapeutic Class: Sickle Cell Anemia Agents
Last Reviewed by the DUR Board: April 30, 2020

Sickle Cell Anemia 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. Adakveo® (crizanlizumab-tmca)

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

         a. The recipient has a documented diagnosis of Sickle Cell Disease; and

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

         c. The recipient has documentation of two vaso-occlusive events that requires medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism); and

         d. The recipient must have a trial and failure, contraindication, or intolerance to one of the following:

            1. Hydoxyurea; or

            2. L-glutamine (i.e., Endari); and

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

            1. Hematologist/Oncologist; or

            2. A specialist with expertise in the diagnosis and management of sickle cell disease.

      2. Recertification Request

         a. The recipient has documentation of positive clinical response to Adakveo® therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event).

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

B. Oxbryta® (voxelotor)

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

a. The recipient has a documented diagnosis of sickle cell disease; and

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

c. The recipient has documentation of 1 vaso-occlusive crisis (VOC) event within the past 12 months (e.g., sickle cell crisis, acute painful crisis, acute chest syndrome); and

d. The recipient has documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation; and

e. The recipient has documentation of trial and failure, contraindication, or intolerance to hydroxyurea; and

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

1. Hematology/Oncologist; or

2. A specialist with expertise in the diagnosis and management of sickle cell disease.

2. Recertification Request

a. The recipient has documentation of positive clinical response to Oxbryta® therapy (e.g., an increase in hemoglobin level of greater than or equal to one g/dL from baseline, decreased annualized incidence rate of VOCs); and

b. The recipient has documentation of hemoglobin level that does not exceed 10.5 g/dL.

3. Prior Authorization Guidelines

a. Initial request will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

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

LL. ~~Kalydeco® (ivacaftor)~~Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: ~~July 26, 2018~~April 30, 2020

~~Kalydeco® (ivacaftor) is~~ 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. ~~Coverage and Limitations~~ 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 six months of age or older; and

         b. The recipient has a diagnosis of ~~cystic fibrosis~~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 ~~cystic fibrosis~~CF care center.

      2. 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:~~

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

      3. Prior Authorization Guidelines

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

         b. Recertification request will be for 12 months.

         c. ~~b.~~ Prior Authorization forms are available at: http://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 cystic fibrosis; and

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

c. The recipient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CTFR) ~~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~~12 months.

b. Prior Authorizaition forms are available at: http://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 six years of age or older; and

2. The recipient has a documented diagnosis of ~~cystic fibrosis (~~CF~~)~~; and

3. The medication must be prescribed by or in consultation with either a Pulmonolist or a specialist associated with a CF care center. ~~one of the following:~~

~~Pulmonologist.~~

~~Specialist affiliated 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 ~~cystic fibrosis~~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 CF transmembrane conductance regulator (CFTR) gene as detected by FDA cleared ~~cystic fibrosis~~CF mutation test or CLIA approved facility.

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

~~Authorization for continued use shall be reviewed at least every 12 months when the following criteria is met:~~

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 ~~Prior authorization approval~~ will be approved~~given~~ for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: http://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 12 years of age and older; and

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

c. The recipient has at least one F508del mutation in the CFTR gene 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 Pulmanologist or a specialist affiliated with a CF care center.

2. Recertification Request

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

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: ~~January 23, 2020~~April 30, 2020

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

1. Coverage and Limitations

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

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

a. The recipient has a diagnosis of narcolepsy.

2. Xyrem® (sodium oxybate):

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

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

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

3. Prior Authorization Guidelines

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

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

b. Sunosi® (solriamfetol)

1. For treatment of Narcolepsy

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

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

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

a. modafinil; and

b. armodafinil.

b. Recertification Request

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

c. Prior Authorization Guidelines

1. Initial request ~~Authorization~~ will be approved for 12 months.

2. Recertification request ~~approval~~ will be approved for 12 months.

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

2. For treatment of Obstructive Sleep Apnea (OSA)

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

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

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

b. Both the following:

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

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

a. Daytime sleepiness; or

b. Nonrestorative sleep; or

c. Fatigue; or

d. Insomnia; or

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

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

g. Observed apnea; and

2. Both the following:

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

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

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

a. Modafinil; and

b. Armodafinil.

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

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

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

c. Prior Authorization Guidelines

1. Initial ~~prior authorization~~request will be approved~~al~~ for ~~is~~ for six months.

2. Recertification request will be approved~~al is~~ for six months.

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

c. Wakix® (pitolisant)

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

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

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

2. Recertification Requests

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

3. Prior Authorization Guidelines

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

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

HHH. ~~Orkambi® (lumacaftor/ivacaftor)~~(RESERVED FOR FUTURE USE)

~~Therapeutic Class: Cystic Fibrosis Agent~~
~~Last Reviewed by the DUR Board: January 26, 2017~~
~~Previously reviewed November 5, 2015~~

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

~~1. Coverage and Limitations~~

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

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

~~b.a. The recipient is two years of age or older; and~~

~~c.a. The recipient is homozygous for the F508del mutation in the CFTR gene; and~~

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

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

~~2.1.Prior Authorization Guidelines~~

~~a. Prior authorization approvals will be for one year.~~

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

VVV. ~~Symdeko® (tezacaftor/ivacaftor)~~(RESERVED FOR FUTURE USE)

~~Last Reviewed by the DUR Board: July 26, 2018~~

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

~~1. Coverage and Limitations~~

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

~~a. Initial Request:~~

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

~~2.1. The recipient has a documented diagnosis of cystic fibrosis (CF); and~~

~~3.1. The medication must be prescribed by or in consultation with one of the following:~~

~~a. Pulmonologist.~~

~~b. Specialist affiliated with a CF care center.~~

~~4.1. One of the following:~~

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

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

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

~~1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria is met:~~

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

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