MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

November 24, 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, Appendix A, to reflect recommendations approved on July 23, 2020 by the Drug Use Review (DUR) Board. The proposed changes include revisions to the existing prior authorization criteria for psychotropic medications for children and adolescents, addition of new prior authorization criteria for Somavert®(pegvisomant), and addition of new prior authorization criteria for Valtoco® (diazepam). Furthermore, the DHCFP is proposing revisions to the existing prior authorization criteria within the Anti-Migraine Medication agents, to correct duplicative criteria.

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

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

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

These changes are effective November 30, 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MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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	**Various**	Updated prior authorization throughout Sections D, N, S, AA, BB, EEE, and BBBB.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section D	**Growth Hormones**	Updated last reviewed date. Added new prior authorization criteria for Somavert® (pegvisomant)..
Appendix A Section N	**Psychotropic Medications for Children and Adolescents**	Updated last reviewed date.
Appendix A Section S	**Anti-Migraine Medication**	Removed policy language for "Episodic Migraines" and "Chronic Migraines" as the clinical criteria was duplicative.
Appendix A Section AA	**Savella® (milnacipran)**	Updated last reviewed date.
Appendix A Section BB	**Substance Abuse Agents**	Updated last reviewed date. Added "Buprenorphine" for clarification as the clinical criteria applies to both the single agent and the combination.
Appendix A Section EEE	**Anti-lipidemic Agents – PCSK9 Inhibitors**	Updated last reviewed date.
Appendix A Section BBBB	**Anticonvulsants**	Updated last reviewed date. Added new prior authorization criteria for Valtoco® (diazepam).

D. Growth Hormones

Therapeutic Class: Growth Hormone
Last Reviewed by the DUR Board: July ~~25, 2019~~23, 2020

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

1. Coverage and Limitations

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

1. Children (with open epiphyses and with remaining growth potential) must meet all of the following:

a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy; and

b. The recipient has had an evaluation ruling out all other causes for short stature; and

c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones.

The recipient must then meet one of the following:

1. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is at least two standard deviations below the mean or below the fifth percentile for the patient's age and gender and the bone age is less than 16 years for male recipients or less than 14 years for female recipients; or

2. The recipient has a diagnosis of Prader-Willi Syndrome; or

3. The recipient has a diagnosis of Turner Syndrome, is female and has a bone age of less than 14 years; or

4. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute), and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

5. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and the height

is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

6. The recipient is a newborn infant with evidence of hypoglycemia, and has low growth hormone level (<20 ng/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP) 3 (no stimulation test required for infants); or

7. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender and their bone age is less than 16 years for male or less than 14 years for female.

   And recipient must meet one of the following:

   a. The recipient has failed two growth hormone stimulation tests (<10 ng/mL); or

   b. The recipient has failed one growth hormone stimulation test (<10 ng/mL) and one IGF-1 or IGFBP-3 test; or

   c. The recipient has failed one growth hormone stimulation test (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), adrenocorticotropic hormone (ACTH) or antidiuretic hormone (ADH)).

2. Adults (with closed epiphyses, and no remaining growth potential) must meet all of the following:

   a. The recipient is being evaluated by an endocrinologist; and

   b. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones; and

   c. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation); and

The recipient must then meet one of the following:

1. The recipient has failed two growth hormone stimulation tests (<5 ng/mL); or

2. The recipient has failed one growth hormone stimulation test (<5 ng/mL) and one IGF-1 or IGFBP-3 test; or

3. The recipient has failed one growth hormone stimulation test (<5 ng/mL) or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH), and has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.

3. Continued authorization will be given for recipients (up to age 21, with remaining growth potential) who meet all of the following:

   a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age or Turner Syndrome; and

   b. The recipient's epiphyses are open; and

   c. The recipient's growth rate on treatment is at least 2.5 cm/year; and

   d. The recipient does not have evidence of an expanding lesion or tumor formation; and

   e. The recipient has not undergone a renal transplant.

4. Continued authorization will be given for recipients (age 21 years and older, with closed epiphyses and no remaining growth potential) who meet all of the following:

   a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease; and

   b. There is documentation of improvement in clinical manifestations associated with growth hormone deficiency.

5. Prior Authorization Guidelines:

   a. Initial prior authorization will be for six months.

b. Recertification approval will be for 12 months.

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

b. Serostim® (somatropin)

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

a. ~~1.~~ The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and

~~a.~~b. The medication is indicated to increase lean body mass, body weight and physical endurance; and

~~b.~~c. The recipient is receiving and is compliant with antiretroviral therapy; and

~~c.~~d. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m²; and

~~d.~~e. The recipient has experienced an adverse event, allergy or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent; and

~~e.~~f. The recipient has experienced an adverse event, allergy or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone) or the recipient has a contraindication to treatment with these agents.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

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

c. Zorbtive® (somatropin)

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

a. The recipient has a diagnosis of short bowel syndrome; and

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

c. The medication is being prescribed by or following a consultation with a gastroenterologist; and

d. The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. Prior Authorization Guidelines:

a. ~~Prior authorization approval will be 12 weeks for Serostim® (somatropin).~~Initial authorization will be approved for six months.

b. ~~Prior authorization approval will be six months for initial authorization (for all somatropin products except for Serostim®).~~Recertification request will be approved for 12 months.

~~c. Prior authorization approval will be one year for continuing treatment (for all somatropin products except Serostim®).~~

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

d. Somavert® (pegvisomant)

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

a. The recipient has a diagnosis of acromegaly; and

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

c. One of the following:

1. The recipient has an inadequate response to one of the following:

a. Surgery; or

b. Radiation Therapy; or

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; or

2. The recipient is not a candidate for all the following:

a. Surgery; and

b. Radiation Therapy; and

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; and

d. The recipient has tried and failed, a contraindication, or intolerance to generic octreotide (a somatostatin analogue); and

e. The medication is prescribed by or in consultation with an endocrinologist.

2. Recertification Criteria:

a. The recipient must meet the following:

1. The recipient must have a documented positive clinical response to Somavert® therapy (e.g. biochemical control; decrease or normalization of IGF-1 levels).

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 weeks.

b. Recertification approval will be approved for 12 months.

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

N. Psychotropic Medications for Children and Adolescents

Therapeutic Class: Psychotropic Agents
Last Reviewed by the DUR Board: ~~September 3, 2015~~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~~poly-pharmacy~~. The DHCFP has adopted the following practice standards to strengthen treatment outcomes for our children and adolescents.

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

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

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

1. For psychotropic medications in this age group, when possible, be prescribed by or in consultation with a child psychiatrist.
2. Psychotropic medication must be part of a comprehensive treatment plan that addresses the education, behavioral management, living home environment and psychotherapy.
3. Physician and/or prescriber monitoring is required while the recipient is utilizing any psychotropic medication.

a. For recipients who are in initial treatment (have not received any doses previously) or are continuing therapy but are considered 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~~precsriber~~. 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~~Poly-pharmacy~~: Each psychotropic medication prescribed must be independently treating a specific symptom and/or diagnosis.

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

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

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

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

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

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

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

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

d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a prior authorization approval 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 ~~this criteria~~ for Anticonvulsants and ADD/ADHD ~~medications~~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:

1. 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: April 30, 2020

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

1. Serotonin 5-HT1 Receptor Agonists (triptans)

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

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

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

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

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

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

   b. Prior Authorization Guidelines:

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

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

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

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

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

~~1. Episodic Migraines~~

~~a. Initial request:~~

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

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

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

~~4. One of the following:~~

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

~~5. One of the following:~~

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

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

~~6. One of the following:~~

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

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

2. Chronic Migraines

a. Initial request:

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

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

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

5. One of the following:

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

6. One of the following:

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

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

~~7. One of the following:~~

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

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

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

~~b. Recertification Request:~~

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

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

~~c. Prior Authorization Guidelines~~

~~1. Initial request will be approved for three 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~~

1. ~~5. Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm) or Emgality® (galcanezumab-gnlm)~~CGRP General Criteria

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

a. ~~1.~~ The recipient must have one of the following:

1. ~~a.~~ Both the following:

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

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

2. ~~b.~~ All the following:

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

2. ~~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

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

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

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

5. ~~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.

2. 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.

3. 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.

AA. Savella® (milnacipran)

Therapeutic Class: Fibromyalgia Agents: Serotonin-NorepinephrineNorephinephrine Reuptake Inhibitor
Last Reviewed by DUR Board: July 23, 2020June 3, 2010

Savella® (milnacipran) is subject to prior authorization.

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

a. 1. The recipient has a Ddiagnosis of Fibromyalgia:

1. a. 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:
http://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~~April 25, 2019~~

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. ~~Coverage and Limitations~~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~~one year~~.

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

b. Lucemyra™ (lofexidine)

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

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

b. The requested quantity ~~does not~~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: http://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:

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

EEE. Anti-lipidemic Agents – PCSK9 Inhibitors

Therapeutic Class: AntilipemicAntilepemic Agent, PCSK9 Inhibitors
Last Reviewed by the DUR Board: July 23, 2020January 28, 2016

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

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

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

   a. Initial Request:

      1. The recipient has an FDA-approved diagnosis; and

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

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

      4. For the treatment of homozygous familial hypercholesterolemia:

         a. With alirocumab (Praluent®)

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

         b. With evolocumab (Repatha®)

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

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

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

            1. The recipient has received therapy with atorvastatin $\geq$ 40 mg or rosuvastatin $\geq$ 20 mg for at least the past three months; and

            2. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

3. The LDL-C after therapy for at least the past three months was ≥ 100 mg/dL (HeFH) for ≥ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

4. The statin therapy will be continued with PCSK-9 therapy.

b. Or, the recipient has had an inadequate response to moderate intensity statin therapy defined as all of the following:

1. The recipient has an intolerance or contraindication to high intensity statin therapy; and

2. The recipient has received therapy with:

a. atorvastatin 10 to 20 mg; or

b. rosuvastatin 5 to 10 mg; or

c. simvastatin > 20 mg; or

d. pravastatin >40 mg; or

e. lovastatin 40 mg; or

f. fluvastatin XL 80 mg; or

g. fluvastatin 40 mg twice daily; or

h. pitavastatin > 2 mg

for at least the past three months; and

3. The recipient has received add-on therapy with ezetimibe to the maximum tolerable dose of statin for at least the past two weeks or the recipient has a contraindication to ezetimibe therapy; and

4. The LDL-C after therapy for at least the past three months was ≥ 100 mg/dL (HeFH) or ≥ 70 mg/dL (clinical atherosclerotic cardiovascular disease); and

5. Statin therapy will be continued with PCSK-9 therapy.

c. Or the recipient experienced an adverse reaction to at least two statins, the statins and adverse reactions must be documented in the recipient's medical record.

d. Or the recipient has a labeled contraindication to all statins, the contraindication is documented in the recipient's medical record.

2. Recertification Request (The recipient must meet all criteria (a-d))

   a. The recipient has been adherent with PCSK-9 inhibitor therapy; and

   b. The recipient has been adherent with statin therapy or the recipient has a labeled contraindication to statin therapy; and

   c. The recipient is continuing a low-fat diet and exercise regimen; and

   d. The recipient has achieved a reduction in LDL-C level.

3. Prior Authorization Guidelines:

   a. ~~Prior authorizaiton approvals will be for:~~Initial authorization will be approved for six months.

   ~~a.~~b. Recertification approval will be approved for 12 months.

   ~~1. Initial request: six months~~

   ~~2. Recertification request: one year~~

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

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: July 23, 2020~~January 23, 2020~~

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

1. Cannabinoid

   a. Epidiolex® (cannabidiol)

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

         a. The recipient has a diagnosis of Lennox-Gastaut syndrome or Dravet Syndrome; and

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

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

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

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

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

      2. Recertification Request:

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

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

      3. Prior Authorization Guidelines:

         a. Initial prior authorization will be for three months.

         b. Recertification approval will be for 12 months.

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

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

2. Nayzilam® (midazolam)

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

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

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

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

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

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

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

c. Prior Authorization Guidelines:

1. Initial prior authorization will be for six months.

2. Recertification approval will be for 12 months.

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

3. Valtoco® (diazepam)

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

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years and older; and

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

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

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

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

b. Prior Authorization Guidelines:

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

c. Prior Authorization Guidelines:

1. Initial authozition will be approved for six months.

2. Recertification approval will be approved for 12 months.

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