MEDICAID SERVICES MANUAL TRANSMITTAL LETTER

October 26, 2021

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: JESSICA KEMMERER, HIPAA PRIVACY AND CIVIL RIGHTS OFFICER

SUBJECT: MEDICAID SERVICES MANUAL CHANGES

CHAPTER 1200 - PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on July 22, 2021 by the Drug Use Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria for Ergot Derivatives within the Anti-Migraine Medications Section, and addition of new prior authorization criteria for Viltepso® (viltolarsen) within the Duchenne Muscular Dystrophy (DMD) Agents.

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

Entities Financially Affected: No entities are financially affected.

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

These changes are effective November 1, 2021.

MATERIAL TRANSMITTED

MTL OL MSM CH 1200 - Prescribed Drugs		MTL N/A MSM CH 1200 - Prescribed Drugs	
Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates	
Appendix A, Section S.	Anti-Migraine Medications	Updated last review date. Added Prior Authorization criteria for Ergot Derivatives.	
Appendix B, Section MMM.	Duchenne Muscular Dystrophy (DMD) Agents	Updated last review date. Added Prior Authorization criteria for Viltepso® (viltolarsen).	

MATERIAL SUPERSEDED

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S. Anti-Migraine Medications

Therapeutic Class: Serotonin 5-HT1 receptor agonists (triptans)

Last Reviewed by the DUR Board: July 25, 2019

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications

Last Reviewed by the DUR Board: April 22, 2021

Therapeutic Class: Ergot Derivitives

Last Reviewed by the DUR Board: July 22, 2021

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

- 1. Serotonin 5-HT1 Receptor Agonists (triptans)
 - a. An approved prior authorization is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:
 - 1. The recipient's current medication history documents the use of prophylactic medications for migraine headache, or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or
 - 2. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.
 - a. Recipient's current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).
 - b. Recipients whose current medication history indicates the use of propranolol will NOT be granted prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.
 - c. Prior authorization will NOT be given to patients with ischemic heart disease.
 - b. Prior Authorization Guidelines:
 - 1. Approval for exceeding the quantity limits on triptans will be provided for a two-month period.

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- 2. The prior authorization must be initiated by the prescriber. The approved prior authorization must be available if requested.
- 3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.
- 2. Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
 - a. CGRP General Criteria Approval will be given if the following criteria are met and documented:
 - 1. CGRP General Criteria Approval will be given if the following criteria are met and documented:
 - a. The recipient must have one of the following:
 - 1. Both the following:
 - a. The recipient has a diagnosis of episodic migraines; and
 - b. The recipient has four to 14 migraine days per month, but not more than 14 headache days per month: or
 - 2. All the following:
 - a. The recipient has a diagnosis of chronic migraines; and
 - b. The recipient has greater than or equal to 15 headache days per month, of which at least eight must be migraine days for at least three months; and
 - c. The recipient has been considered for medication overuse headache (MOH) and potentially offending medication(s) have been discontinued; and
 - b. The recipient is 18 years of age or older; and
 - c. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist; and
 - d. The recipient must meet two of the following:
 - 1. One of the following:
 - a. The recipient has documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or

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- b. The recipient has had a decrease in use of acute migraine medications (e.g., NSAIDs, triptans) since the start of CGRP therapy; and
- c. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist; and
- d. For chronic migraine only: The recipient continues to be monitored for MOH.
- 3. Prior Authorization Guidelines:
 - a. Initial request will be approved for six months.
 - b. Recertification request will be approved for 12 months.
 - c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.
- b. 3. CGRPs for Acute Migraines
 - 1. a. Ubrelvy® (ubrogepant), Nurtec® ODT (rimegepant).
 - a. 1.—Approval will be given if all the following criteria are met and documented:
 - 1. a. Recipient must have a diagnosis of acute migraine with or without aura; and
 - 2. b. Recipient is 18 years of age or older; and
 - 3. e. The prescribed dose will not exceed two doses per migraine and treating no more than eight migraine episodes per 30 days; and
 - 4. d. The recipient has had at least one trial and failure of triptan agent; and
 - 5. e. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.
 - b. 2.—Recertification Request:
 - 1. a. The recipient must have a documented positive response to the CGRP therapy; and
 - 2. b.—The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.
 - c. 3. Prior Authorization Guidelines:

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- 1. a. Initial request will be approved for six months.
- 2. b. Recertification request will be approved for 12 months.
- 3. e. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

42. CGRPs for Episodic Cluster Headache

- a. Emgality® (galcanezumab-gnlm)
 - 1. Approval will be given if all the following criteria are met and documented
 - a. The recipient has a diagnosis of episodic cluster headache; and
 - b. The recipient has experienced at least two cluster periods lasting from seven days to 365 days, separated by pain-free periods lasting at least three months.
 - c. The recipient is 18 years of age or older.
 - d. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

2. Recertification Request:

- a. The recipient has documented positive response to Emgality® therapy, demonstrated by a reduction in headache frequency and/or intensity; and
- b. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

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:

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

- 3. Ergot Derivatives
 - a. Brand D.H.E. 45 (dihydroergotamine mesylate) injection, Generic dihydroergotamine mesylate injection, Brand Migranal nasal spray, or Generic dihydroergotamine mesylate nasal spray
 - 1. Approval will be given if all criterias are met and documented:
 - a. The recipient has a diagnosis of headahces with or without aura; and
 - b. The medication will be used for the acute treatment of migraine; and
 - c. The recipient is 18 years of age or older; and
 - d. One of the following:
 - 1. The recipient has tried and failed or has intolerance to two triptants (e.g., eletriptan, rizatriptan, sumatriptan); or
 - 2. The recipient has contraindication to all triptans; and
 - e. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist; and
 - f. If the recipient has more than four headache days per month, they must meet at least one of the following:
 - 1. The recipient is currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications; or
 - 2. The recipient is currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications; or



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3. The recipient is currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications; and

2. Recertification Request:

- a. The recipient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and
- b. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. Prior Authorization Guidelines:

- a. Initial request will be approved for three months.
- b. Recertication requests will be approved for 12 months.
- c. Prior Authorization forms are available at:
 https://www.medicaid.nv.gov/providers/rx/rxforms.
 aspx.
- b. Brand D.H.E. 45 injection or Generic dihydroergotamine mesylate injection
 - 1. Approval will be given if all criterias are met and documented:
 - a. The recipient has a diagnosis of cluster headache; and
 - b. The recipient is 18 years of age or older; and
 - c. The recipient has had a trial and failure, contraindication, or intolerance to sumatriptain injection; and
 - d. The medication is prescrived by or in consulation with either a Neurologist, a Pain Specialist, or a Headache Specialist.
 - 2. Recertification Request:

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- a. The recipient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and
- b. The medication is prescrived by or in consulation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. Prior Authorization Guidelines:

- a. Initial authorization will be approved for three months.
- b. Recertification requests will be approved for 12 months.
- c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents Last Reviewed by the DUR Board: July 22, 2021 January 28, 2021

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

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- 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://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. Recipient experienced a benefit from therapy (e.g. disease amelioration compared to untreated patients); and
 - 3. 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://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:

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

