MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

June 27, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES
CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to clarify coverage limitations of drugs without an FDA-approved indication. The proposed changes also identify drug classes that are exempt from Nevada Medicaid Preferred Drug List (PDL) restrictions under Nevada Revised Statute (NRS) 422.4025. In addition, the proposed revisions update the current prior authorization criteria for Ponvory® (ponesimod) to reflect trial and failure requirements of one Multiple Sclerosis (MS) disease-modifying therapy as recommended and approved by the Drug Utilization Review Board (DUR).

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 July 3, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A MSM Chapter 1200 - Prescribed Drugs	MTL 08/20, 18/17, 16/18 MSM Chapter 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Section 1203.1	**Coverage and Limitations**	Updated language to clarify coverage limitations. Added language concerning excluded drug classes from the PDL. Updated broken links.
Appendix A Section CC	**Multiple Sclerosis (MS) Agents**	Updated clinical criteria for Ponvory® (poensimod).

1203 POLICY

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

1203.1 COVERAGE AND LIMITATIONS

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

1. Section 1927(d)(1)(B)(i) of the SSA allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication~~.~~, including any prescription dietary supplement/vitamin/mineral (other than prescription pre-natal vitamins or fluoride) without an FDA-approved indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug, which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:

   a. American Hospital Formulary Service Drug Information;

   b. United States Pharmacopeia;

   c. DRUGDEX Information System; or

   d. Peer-reviewed medical literature.

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

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

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

PDL, but within drug classes reviewed by the Silver State Scripts Board, require prior authorization, unless exempt under NRS or federal law or excluded through recommendations of the ~~Silver State Scripts Board~~SSSB or excluded by the DHCFP.

a. Per NRS 422.4025 the following drug classes are excluded from any PDL restrictions:

1. Prescribed drugs for the treatment of human immunodeficiency virus (HIV/AIDS);

2. Antirejection medications for organ transplants; and

3. Antihemophilic medications.

Additionally, the PDL must include the following drug classes as covered and preferred:

4. Any prescription essential for treating sickle cell disease and its variants; and

5. Prescribed drugs to prevent the acquisition of HIV/AIDS.

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

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

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

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

B. Standard ~~Preferred Drug List~~ PDL Exception Criteria
Drugs that have a "non-preferred" status are a covered benefit for recipients if they meet the coverage criteria.

1. Coverage and Limitations

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

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

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

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

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

f. An indication which is unique to a non-preferred agent, and is supported by peer-reviewed literature or a FDA-approved indication;

g. Psychotropic, Antidepressant Medication – Continuity of Care;

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

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

2. Prior Authorization forms are available ~~at~~ through the Nevada Medicaid Pharmacy Portal at https://nevadamedicaid.magellanrx.com/home ~~:~~.
~~http://www.medicaid.nv.gov/providers/rx/rxforms/aspx~~

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight loss.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

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

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

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

7. Agents used for impotence/erectile dysfunction.

8. Prescription dietary supplements/vitamins/minerals (other than prescription pre-natal vitamins or fluoride) without an FDA-approved indication.

D. Refills

A refill is a prescription subject to the limitations below:

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

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

E. Early Refills

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: January 19, 2023

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

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

    a. The recipient has a diagnosis of MS.

2. Ampyra® (dalfampridine)

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

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

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

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

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

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

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

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

    b. Prior Authorization Guidelines

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

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

3. Relapsing Forms of MS Agents:

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

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

b. Lemtrada® (alemtuzumab)

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

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

1. Both the following:

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

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

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Mavenclad (cladrivine)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

c. Both the following:

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

b. The recipient has had at least 12 months elapsed or will have elapsed since the most recent treatment course with alemtuzumab; and

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

2. Prior Authorization Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

c. Mavenclad® (cladribine)

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

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

1. Both the following:

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

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

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone®/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Lemtrada® (alemtuzumab)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

2. Both the following:

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

d. Ocrevus® (ocrelizumab)

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

a. Recipient is at least 18 years of age (unless otherwise specified); and

b. Recipient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment and does not have active disease (i.e., positive HBsAg and anti-HBV tests); and

c. Recipient has had baseline serum immunoglobulins assessed; and

2. Universal Criteria

a. Recipient will not receive live or live-attenuated vaccines while on therapy or within four weeks prior to initiation of treatment; and

b. Recipient does not have an active infection; and

3. Multiple Sclerosis

a. Recipient must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); and

b. Must be used as single agent therapy; and

1. Recipient has a diagnosis of relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)]; or

2. Recipient has a diagnosis of primary progressive MS (PPMS); and

a. Recipient is less than 65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of less than or equal to 6.5.

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

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

b. Recipient has not received a dose of ocrelizumab within the past five months; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy malignancy, hypogammaglobulinemia, immune-mediated colitis, etc.; and

d. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities, or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].

1. Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as greater than or equal to one relapse, greater than or equal to two unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

e. PPMS

1. Recipient continues to ambulatory, defined as an EDSS score of less than 7.5.

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 months.

b. Recertification approval will be for 12 months.

e. Zeposia® (ozanimod)

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

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

b. One of the following:

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

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

a. Avonex® (interferon beta-1a)

b. Betaseron® (interferon beta-1b)

c. Copaxone®/Glatopa® (glatiramer acetate)

d. Tecfidera (dimethyl fumarate); and

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

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

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

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

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

f. Ponvory® (ponesimod)

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

a. Recipient has a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease [RRMS]; active secondary progressive MS [SPMS]+, or clinically isolated syndrome [CIS]); and

b. Recipient will NOT be initiating therapy after previous treatment with alemtuzumab; and

c. Ponesimod will be prescribed by, or in consultation with, neurologist; and

d. One of the following:

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

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

a. Avonex® (interferon beta-1a); or

b. Betaserone® (interferon beta-1b); or

c. Copaxone®/Glatopa® (glatiramer acetate); or

d. Tysabri® (natalizumab); or

e. Tefidera® (dimethyl fumarate); or

f. Aubagio® (teriflunomide); or

g. Gilenya® (fingolimod)

2. Recertification Request:

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

b. Ponesimod will be prescribed by, or in consultation with, neurologist.

3. Prior Authorization Guidelines:

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