MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

February 23, 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

The DHCFP is proposing revisions to Medicaid Services Manual (MSM), Chapter 1200 – Prescribed Drugs, Appendix A, to reflect recommendations approved on October 22, 2020, by the Drug Use Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria for Doxepine Topical, the addition of new prior authorization criteria for Zeposia® (ozanimod), addition of new prior authorization for Evenity® (romosozumab-aqqg), Prolia® (denosumab), Forteo® (teriparatide) and Tymlos® (abaloparatide) within a new combined osteoporosis agents section, and addition of new prior authorization criteria for Orilissa® (elagolix) and Oriahnn® (elagolix, estradiol, and norethindrone) within a new Gonadorpin Hormone Receptor (GnRH) Antagonist and Combinations section. Additionally, the DHCFP is proposing revisions to the existing prior authorization criteria for psychotropic medications for children and adolescents, and revision to the existing clinical criteria for Epidiolex® (cannabidiol).

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 March 1, 2021.

MATERIAL TRANSMITTED	**MATERIAL SUPERSEDED**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 N	**Psychotropic Medications for Children and Adolescents**	Added new policy language criteria on which specific drug classes may bypass polypharmacy clinical criteria.
Appendix A Section W	**Reserved for Future Use**	Created a new section titled “Doxepin Topical.” Added new prior authorization criteria for doxepin topical.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section CC	**Multiple Sclerosis (MS) Agents**	Replaced "Lemtrada (alemtuzumab)" with Mavenclad (cladrivine) within the Lemtrada® (alemtuzumab) criteria to correct duplication. Added "Zimbryta (daclizumab)" as this was missing from criteria. Added "Zimbryta (daclizumab)" to within Mavenclad® (cladrivine) since it was missing from the criteria. Added new prior authorization criteria for Zeposia® (Ozanimod).
Appendix A Section OO	**Prolia® (Denosumab)**	Revised section title to "Osteoporosis Agents". Revised prior authorization criteria for Prolia® (Denosumab). Added new prior authorization criteria for Evenity® (romosozumab-aqqg), Forteo® (Teriparatide) and Tymlos® (Abaloparatide).
Appendix A Section PP	**Forteo® (Teriparatide)**	Revised section title to "Gonadotropin Releasing Hormone Receptor (GNRH) Antagonist and Combinations". Removed prior authorization criteria for Forteo ® (Teriparatide) as new revised criteria was under section OO. Added new prior authorization criteria for Orilissa® (Elagolix). Added new prior authorization criteria for Oriahnn® (Elagolix, Estradiol, and Norethindrone).
Appendix A Section BBBB	**Anticonvulsants**	Revised prior authorization criteria for Epidiolex® (Cannabidiol).

N. Psychotropic Medications for Children and Adolescents

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

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

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

1. Coverage and Limitations

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

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

1. Antipsychotics

2. Antidepressants

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

4. Sedative hypnotics

5. Antianxiety agents

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

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

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

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

a. For recipients who are in initial treatment (have not received any doses previously) or are continuing therapy but are considered

unstable (has had a dose change in the last three months), medical documentation must support a monthly or more frequent visit with the physician and/or prescriber. If the recipient was discharged from an institution on the medication, the follow-up visit(s) can be with their treating physician and/or prescriber.

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

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

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

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

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

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

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

4. Approval for polypharmacy may ~~polypharmacy 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, all psychotropic medications must be utilized for a medically accepted indication as established by the FDA, and/or peer reviewed literature.

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

d. For children under six years of age, in addition to the Coverage and Limitation requirements, all psychotropic medications require a prior authorization approval and must be utilized for a medically accepted indication as established by the FDA and/or peer-reviewed literature.

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

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

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

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

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

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

3. Prior Authorization Guidelines

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

W. ~~RESERVED FOR FUTURE USED~~Doxepin Topical

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

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

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

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

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

   c. Treatment must not exceed eight days.

2. Prior Authorization Guidelines:

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

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

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CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: January 23, 2020

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. Ampyria® (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.

2. 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. ~~Lemtrada (alemtuzumab)~~ 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)

2. 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

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

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.

1. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

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

d. Ocrevus® (ocrelizumab)

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

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

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

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

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

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

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

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 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.

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 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.

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

3. Primary Progressive Forms of Multiple Sclerosis (PPMS) Agents:

a. Ocrevus® (ocrelizumab)

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

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

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

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

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

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

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

c. The medication must not be used in combination with another B-cell target therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]); and

d. The medication must not be used with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

3. Prior Authorization Guidelines

a. ~~Initial p~~Prior authorization approval will be for 12 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

OO. Osteoporosis Agents~~Prolia® (Denosumab)~~

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: October 22, 2020~~October 25, 2012~~

Osteoporosis agents are ~~Prolia® (Denosumab) is~~ subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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

~~a. Postmenopausal Osteoporosis~~

~~1. The recipient has a T score ≤ -2.5; and~~

~~2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture; and~~

~~3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and~~

~~4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.~~

~~b. Male Osteoporosis~~

~~1. The recipient has a T score ≤ -2.5; and~~

~~2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture; and~~

~~3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and~~

~~4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.~~

~~c. Non-metastatic Prostate Cancer~~

~~1. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture;~~

~~2. The recipient is receiving treatment with androgen-deprivation therapy (e.g., anti-androgen or luteinizing hormone-releasing hormone agents);~~

~~3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and~~

~~4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.~~

~~d. Breast Cancer~~

~~1. The recipient has a history of osteoporotic fracture or has multiple risk factors for fracture;~~

~~2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane and letrozole);~~

~~3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and~~

~~4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.~~

~~2. Prior Authorization Guidelines~~

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

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

a. Evenity® (romosozumab-aqqg)

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

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. The recipient's Bone Mineral Density (BMD) T-score is -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. The recipient has documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); or

c. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. The recipient has a documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. The recipient has a documented trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

2. One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

a. The recipient has a major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions.

b. The recipient has a hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. The recipient has a documented trial and failure, contraindication, or intolerance to one of the following:

1. Forteo® (teriparatide)

2. Tymlos® (abaoparatide); and

d. Treatment duration of Evenity® (romosozumab-aqqg) has not exceeded a total of 12 months during the recipient's lifetime.

2. Prior Authorization Guidelines:

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

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

b. Prolia® (denosumab)

1. For bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.

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

1. The recipient has a diagnosis of nonmetastatic prostate cancer; and

2. The recipient is undergoing androgen deprivation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

3. One of the following:

a. The recipient is 70 years of age or older; or

b. Both the following:

1. The recipient is less than 70 years of age; and

2. One of the following:

a. BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

b. Documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal numerous; and

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

1. The recipient is undergoing androgen depravation therapy with one of the following:

a. Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]; or

b. Bilateral orchiectomy (i.e., surgical castration); and

2. The recipient has no evidence of metastases; and

3. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

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

2. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

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

1. The recipient has a diagnosis of breast cancer; and

2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole[JCB1]]); and

3. One of the following:

a. The recipient's BMD scan T-score is less than -1.0 (1.0 standard deviation or greater below the mean for young adults); or

b. Documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g. alendronate)

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

1. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]); and

2. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

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

3. For Postmenopausal Osteoporosis or Osteopenia

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

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

2. One of the following:

a. The recipient has a BMD scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. Both the following:

1. The recipient has a BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following FRAX 10-year probabilities:

a. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has a documented history of one of the following resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

3. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate).

b. Recertification Request:

1. Documentation that indicates the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 24 months.

2. Recertification approval will be for 24 months.

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

4. Glucocorticoid-Induced Osteoporosis

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

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient is initiating or continuing greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months; and

3. One of the following:

a. The recipient has a BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. One of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has a documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. The recipient has a documented trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate).

b. Recertification Request:

a. Documentation that the recipient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for 24 months.

2. Recertification request will be approved for 24 months.

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

c. Forteo® (teriparatide)

1. For Postmenopausal Osteoporosis or Osteopenia, or Men with Primary or Hypogonadal Osteoporosis or Osteopenia at High Risk for Fracture

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

1. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia, or primary or hypogonadal osteoporosis or osteopenia; and

2. One of the following:

a. Both the following:

1. The recipient has a BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following

a. The recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Documented trial and failure, contraindication intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); or

b. Both the following:

1. The recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

2. One of the following:

a. Recipient has documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

b. Both the following:

1. Recipient has a documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

2. One of the following FRAX 10-year probabilities:

a. Major osteoporotic fracture at 20% or

more in the U.S., or the country-specific threshold in other countries or regions; or

b. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

3. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.

2. For Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

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

1. The recipient has a diagnosis of glucocorticoid-induced osteoporosis; and

2. The recipient has documented history of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to three months; and

3. One of the following:

a. BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site); or

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; or

c. The recipient has documented history of one of the following fractures resulting from minimal trauma:

1. Vertebral compression fracture

2. Fracture of the hip

3. Fracture of the distal radius

4. Fracture of the pelvis

5. Fracture of the proximal humerous; and

4. Documented trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate); and

5. The recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceed a total of 24 months during the patient's lifetime.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

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

d. Tymlos® (abaloparatide)

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

a. The recipient has a diagnosis of postmenopausal osteoporosis or osteopenia; and

b. One of the following:

1. Both the following:

a. BMD T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate,

risedronate, zoledronic acid, Prolia [denosumab]); or

2. Both the following:

a. Recipient has a BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site); and

b. One of the following:

1. Recipient has a documented history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm; or

2. Both the following:

a. Documented trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]); and

b. The recipient has one of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions; or

2. Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions; and

c. Recipient's treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during their lifetime.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 24 months.

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

PP. ~~Forteo® (Teriparatide)~~Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations

Therapeutic Class: GnRH Antagonist and Combinations~~Parathyroid/Bone Formation Stimulating Agent (Osteoporosis Agents)~~
Last Reviewed by DUR Board: October 22, 2020~~October 25, 2012~~

GnRH Antagonist and Combinations are ~~Forteo® (Teriparatide) is~~ subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. ~~Coverage and Limitations~~Orilissa® (elagolix)

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

~~a. The recipient has been diagnosed with Postmenopausal Osteoporosis, or Glucocorticoid-Induced Osteoporosis, or the recipient is male and diagnosed with Primary or Hypogonadal Osteoporosis;~~

~~b. The recipient has a T score of ≤ 2.5;~~

~~c. The recipient has a history of osteoporotic fracture or has multiple risk factors for fracture;~~

~~d. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate;~~

~~e. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and~~

~~f. The total duration of treatment with this agent has not exceeded two years.~~

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

1. The recipient has a diagnosis of moderate to severe pain associated with endometriosis; and

2. One of the following:

a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

1. Danazol; or

2. Combination (estrogen/progesterone) oral contraceptive; or

3. Progestins; or

b. The recipient has had surgical ablation to prevent occurrence; and

3. For Orilissa 200 mg request only, the treatment will not exceed six months.

b. Recertification Request (All criteria must be met and documented):

1. The recipient has documented improvement in pain associated with endometriosis improvement in dysmenorrhea and non-menstrual pelvic pain); and

2. Treatment duration has not exceeded a total of 24 months; and

3. The request is for Orilissa 150 mg.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for six months.

2. Recertification approval will be for six months.

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

2. ~~Prior Authorization Guidelines~~Oriahnn® (elagolix, estradiol, and norethindrone)

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

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

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

1. The recipient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and

2. One of the following:

a. The recipient has documented history of inadequate pain control response following a trial of at least three months or the recipient has documented history of intolerance or contraindication:

1. Danazol; or

2. Combination (estrogen/progesterone) oral contraceptive; or

3. Progestins; or

b. The recipient has had surgical ablation to prevent occurrence.

b. Recertification Request:

1. The recipient has documented improvement in menstrual bleeding; and

2. Treatment duration will not exceed a total of 24 months.

c. Prior Authorization Guidelines:

1. Prior authorization approval will be for six months.

2. Recertification approval will be for six months.

3. 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

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 or Tuberous Sclerosis Complex (TSC); and

b. The recipient is ~~two~~ one 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~~therapy.

c. Prior Authorization Guidelines:

1. Initial ~~authozition~~ authorization 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.