Medicaid Services Manual
Transmittal Letter

December 26, 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 to reflect recommendations approved on July 27, 2023, by the Drug Utilization Review (DUR) Board Meeting. The addition of Remicade® biosimilars Avolsa® (infliximab-axxq) and Ixifi® (infliximab-dyyb) and update Inflectra® infliximab) to Inflectra® infliximab-qbtx) and Renflexis® (infliximab) to Renflexis® (infliximab-abda) under Immunomodulator Drugs. The addition of Myfembree® under Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations). Also added were Strensiq® (asfotase alfa) for therapeutic class "Hypophosphatasia (HPP) Agents" and Tzield® (teplizumab-mzwv) for therapeutic class "Disease Modifying Agents for Type 1 Diabetes."

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 financially affected.

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

These changes are effective January 2, 2024.

Material Transmitted	Material Superseded
MTL N/A MSM 1200 – Prescribed Drugs	MTL N/A MSM 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section L	**Immunomodulator Drugs**	Updated last review date. Added Avolsa® (infliximab-axxq) and Ixifi® (infliximab-dyyb). Added prescription and prior authorization criteria

		and quantity limits for Remicade biosimilars. Updated the link to the Nevada Medicaid website.
Appendix A Section PP	**Gonadotropin Releasing Hormone Receptor (GnRH Antagonist and Combinations**	Updated last review date. Updated the link to the Nevada Medicaid website. Added prescription and prior authorization criteria and quantity limits for Myfembree®.
Appendix A Section IIII	**Strensiq® (asfotase alfa)**	Created new section for Strensiq® including prescription and prior authorization criteria and quantity limits.
Appendix A Section JJJJ	**Tzield® (teplizumab-mzwv)**	Created new section for Tzield® including prescription and prior authorization criteria and quantity limits.

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: July 27, 2023~~October 20, 2022~~

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Remicade® (infliximab)
Amevive® (alefacept)	Ilumya® (tildrakizumab)	Renflexis® (infliximab-abda)
Arcalyst® (rilonacept)	Inflectra® (infliximab-qbtx)	Siliq® (brodalumab)
Avolsa® (infliximab-axxq)	Ixifi® (infliximab-dyyb)	Simponi® (golimumab)
Cimzia® (certolizumab pegol)	Kevzara® (sarilumab)	Simponi® ARIA™ (golimumab)
Consentyx® (secukinumab)	Kineret® (ankinra)	Skyrizi® (risankizumab-rzaa)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Stelara® (ustekinumab)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Taltz® (ixekizumab)
Humira® (adalimumab)	Otezla® (apremilast)	Xeljanz® (tofacitinib)

Immunomodulator Drugs are subject to PA 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. For all recipients:

      1. The recipient has had a negative tuberculin test; and

      2. The recipient does not have an active infection or a history of recurring infections; and

      3. The approval will not be given for the use of more than one biologic at a time (combination therapy); and

      4. The requested medication is being prescribed for an FDA-approved indication or the prescriber has provided clinical justification for off-label usage; and

      5. Each request meets the appropriate diagnosis/agent-specific criteria (b-~~j~~k).

   b. Rheumatoid Arthritis (RA):

      1. The recipient has a diagnosis of moderately to severely active RA; and

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

      3. The recipient has had a rheumatology consultation, including the date of the visit; and one of the following:

         a. The recipient has had RA for less than six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

hydroxychloroquine, leflunomide, minocycline and sulfasalazine); or

b. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has moderate disease activity and has an inadequate response to a DMARD (methotrexate, hydroxychloroquine, leflunomide, minocycline or sulfasalazine); or

c. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has high disease activity.

c. Psoriatic Arthritis:

1. The recipient has a diagnosis of moderate or severe psoriatic arthritis; and

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

3. The recipient has had a rheumatology consultation including the date of the visit or a dermatology consultation including the date of the visit; and

4. The recipient had an inadequate response or a contraindication to treatment with any one nonsteroidal anti-inflammatory (NSAID) or to any one of the following DMARDs: methotrexate, leflunomide, cyclosporine or sulfasalazine.

d. Ankylosing Spondylitis:

1. The recipient has a diagnosis of ankylosing spondylitis; and

2. The recipient is 18 years or older; and

3. The recipient has had an inadequate response to NSAIDs; and

e. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

1. The recipient has a diagnosis of moderately or severely active juvenile RA or juvenile idiopathic arthritis; and

2. The recipient is at an appropriate age, based on the requested agent, and:

a. Abatacept: Six years of age or older.

b. Adalimumab, canakinumab, etanercept, tocilizumab: Two years of age or older.

3. And the recipient has at least five swollen joints; and

4. The recipient has three or more joints with limitation of motion and pain, tenderness or both; and

5. The recipient has had an inadequate response to one DMARD.

f. Plaque Psoriasis:

1. The recipient has a diagnosis of chronic, moderate to severe plaque psoriasis; and

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

3. The agent is prescribed by a dermatologist; and

4. The recipient has failed to adequately respond to a topical agent; and

5. The recipient has failed to adequately respond to at least one oral treatment.

g. Crohn's Disease:

1. The recipient has a diagnosis of moderate to severe Crohn's Disease; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Adalimumab, infliximab: Six years of age or older.

b. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to conventional therapy (e.g. sulfasalazine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or

4. The recipient has fistulizing Crohn's Disease.

h. Ulcerative Colitis (UC):

1. The recipient has a diagnosis of moderate to severe UC; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Infliximab: Six years of age or older.

b. Humira: five years of age or older.

c. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to one or more of the following standard therapies:

a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

4. Zeposia® (ozanimod) for diagnosis of UC

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

1. Prescribed by or in consultation with a gastroenterologist; and

2. Recipient has a diagnosis of moderately to severely active UC; and

3. Inadequate response after a 90-day trial of one of the following conventional therapies:

a. 6-mercaptopurine

b. Aminosalicylates (e.g., mesalamine, balsalazide, olsalazine)

c. Sulfasalzine

d. Azathioprine

e. Corticosteroids (e.g., budesonide, high dose steroids 40-60mg of prednisone daily); and

4. Recipient has tried and failed two preferred immunomodulator therapies indicated for moderately to severely active UC.

i. Cryopyrin-Associated Periodic Syndromes (CAPS): Familial Cold Autoinflammatory Syndromes (FCAS) or Muckle-Wells Syndrome (MWS):

1. The recipient has a diagnosis of FCAS or MWS; and

2. The recipient is at an appropriate age, based on the requested agent:

a. Canakinumab: Four years of age or older.

b. Rilonacept: 12 years of age or older.

j. Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID):

1. The recipient has a diagnosis of NOMID.

k. Remicade biosimilars (infliximab-axxq, infliximab-abda, infliximab-dyyb, infliximab-qbtx).

1. Medication prescribed for FDA-approved diagnosis and patient is appropriate age per FDA labeling.

2. Prescriber has provided documentation to justify that patient is not a candidate for unbranded/generic Infliximab (e.g. product-specific past intolerance or contraindication).

2. PA Guidelines:

a. PA approval will be for 12 months.

b. PA forms are available at:

c. https://nevadamedicaid.magellanrx.com/provider/forms. ~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

PP. Gonadotropin Releasing Hormone Receptor (GnRH) Antagonist and Combinations

Therapeutic Class: GnRH Antagonist and Combinations
Last Reviewed by DUR Board: July 27, 2023~~October 22, 2020~~

GnRH Antagonist and Combinations are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Orilissa® (elagolix)

   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.

      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:

https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

2. Oriahnn® (elagolix, estradiol, and norethindrone)

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:
https://nevadamedicaid.magellanrx.com/provider/forms.
~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

3. Myfembree®

a. Approval will be given if the two criteria below have been met and documented:

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

2. One of the following has occurred:

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

1. Danazol;

2. Combination (estrogen/progesterone) oral contraceptive;

3. Progestins;

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

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

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

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

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

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

2. One of the following has occured:

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

1. Danazol;

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

3. Progestins;

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

d. Recertification requests (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

~~1.~~2. Treatment duration will not exceed a total of 24 months.

~~1.~~4. Prior Authorization Guidelines

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

b. Prior Authorization forms are available at:

https://nevadamedicaid.magellanrx.com/provider/forms~~https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~.

IIII. Strensiq® (asfotase alfa)

Therapeutic Class: Hypophosphatasia (HPP) Agents
Last Reviewed by DUR Board: July 27, 2023

HPP are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

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

A recipient has a diagnosis of either perinatal/infantile or juvenile-onset HPP demonstrated by all of the following:

1. The recipient was 18 years of age or younger at onset;

2. The recipient experienced clinical manifestations of HPP (e.g., vitamin B6-responsive seizures, chest deformity, severe hypercalcemia, bowing of the long bones, failure to thrive);

3. The recipient obtained radiographic imaging to support diagnosis of HPP;

4. Genetic testing has been completed documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation; and

5. There has been reduced activity of unfractionated serum alkaline phosphatase (ALP);

b. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

c. The requested quantity is within FDA-labeled dosing requirement based on the recipient's weight.

2. Recertification request:

a. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

b. The requested quantity is within FDA-labeled dosing based on the recipient's weight.

3. Prior Authorization Guidelines:

a. Initial prior authorization will be for six months.

b. Recertification approval will be for 12 months.

JJJJ. Tzield® (teplizumab-mzwv)

Therapeutic Class: Disease Modifying Agents for Type 1 Diabetes
Last Reviewed by DUR Board: July 27, 2023

Disease Modifying Agents for Type 1 Diabetes are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

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

   a. The recipient is at least eight years of age;

   b. The recipient has a diagnosis of stage 2 type 1 diabetes, confirmed by:

      1. Documenting at least two positive pancreatic islet cell autoantibodies (e.g., glutamic acid decarboxylase 65 [GAD65], insulin autoantibody [IAA), insulinoma-associated antigen 2 autoantibody [IA-2A], zinc transporter 8 autoantibody [ZnT8A], islet cell autoantibody [ICA], and

      2. Documenting dysglycemia without overt hyperglycemia using an oral glucose tolerance test (an alternative method of diagnosis dysglycemia without overt hyperglycemia may be used if an oral glucose tolerance test is not available); and

   c. Prescriber has attested to the absence of acute Epstein-Barr virus (EBV) and cytomegalovirus (CMV) infection through laboratory or clinical evidence; and

   d. Prescriber has confirmed the absence of an active serious infection or chronic active infection, excluding localized skin infection;

   e. The recipient has received all age-appropriate vaccines, with live vaccines administered at least eight weeks before treatment, and inactivated vaccines and mRNA vaccines administered at least two weeks before treatment;

   f. The recipient is not pregnant or planning to become pregnant during the 14-day treatment course; and

   g. It has been prescribed by or in consultation with an adult or pediatric endocrinologist.

2. Quantity Limitations:

   a. 24 vials per 14-day course of therapy.

   b. Maximum one treatment course per lifetime.

   c. Coverage not renewable.