Medicaid Services Manual
Transmittal Letter

February 25, 2025

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 incorporate recommendation approved on the July 18, 2024, and January 16, 2025, Drug Utilization Review (DUR) Board for Zynlonta®. Updates to Lyfgenia™, Elevidys, Tymlos® and Linzess®.

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 3, 2025.

Material Transmitted	Material Superseded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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section P	**Respirator and Allergy Biologics**	Added new section "Fasenra® (benralizumab) for treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)." Updated the age and weight criteria for Fasenra®. Updated age criteria for "Diagnosis of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)" under Dupixent®. Also, added new section "Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)." Added new section "Tezspire™".

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		Added new section "Adbry®".
Appendix A Section WW	**Functional Gastrointestinal Disorder Agents**	Updated diagnosis and the addition of Linzess for FC in pediatric recipients.
Appendix A Section MMM	**Duchenne Muscular Dystrophy (DMD) Agents**	Updated the age requirement for Elevidys. Removed the ambulatory requirement and exons.
Appendix A Section XXXX	**Sickle Cell**	Additional definition for severe cerebral vasculopathy for Lyfgenia®.
Appendix B Section G	**Elaprase® (idursulfase)**	Corrected the hierarchy within this section.
Appendix B Section S	**Zynlonta® (loncastuximab tesirine-lpyl)**	Removed advice to avoid exposure to direct natural or artificial sunlight. Added Universal Criteria. Updated Large B-Cell Lymphoma to B-Cell Lymphoma. Added "Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, or HHV8-positive DLBCL, not otherwise specified." Added "Histologic Transformation of Indolent Lymphomas (follicular lymphoma or marginal zone lymphoma) to DLBCL." Added "Monomorphic Post-Transplant Lymphoproliferative Disorders (PTLD)." Updated the Recertification Request.
Appendix B Section T	**Osteoporosis Agents**	Updated approval criteria for Tymlos® (abaloparatide).

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: ~~January 19, 2023~~July 18, 2024, and January 16, 2025

Respirator and Allergy Biologics 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. Coverage and Limitations

a. Xolair® (omalizumab)

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

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. All the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:

1. The recipient must be six years of age or older; and

2. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and

3. The prescriber must be either a pulmonologist or allergist/ immunologist; and

4. The recipient must have had an inadequate response, adverse reaction, or contraindication to inhaled, corticosteroids; and

5. The recipient must have had an inadequate response, adverse reaction, or contraindication to a leukotriene receptor antagonist; and

6. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and

7. The recipient's current weight must be recorded; and

8. The requested dose is appropriate for the recipient’s pre-treatment serum IgE and body weight (see Table 1).

2. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU):

a. The recipient is 12 years of age or older; and

b. The recipient must have had an inadequate response, adverse reaction, or contraindication to two different oral second-generation antihistamines; and

c. The recipient must have had an inadequate response, adverse reaction, or contraindication to an oral second-generation antihistamine in combination with a leukotriene receptor antagonist; and

d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist, or a rheumatologist regarding the diagnosis and treatment recommendations; and

e. One of the following:

1. The request is for initiation of therapy and the dose will be 150 mg every four weeks; or

2. The request is for initiation of therapy and the dose will be 300 mg every four weeks, and clinical rationale for starting therapy at 300 mg every four weeks has been provided (pharmacy review required); or

3. The request is for continuation of therapy and the dose will be 150 mg or 300 mg every four weeks.

3. All the following criteria must be met for diagnosis of Nasal Polyps (NP) and all the following:

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

b. The prescriber must be one of the following, or there is documentation in the recipient's medical record that a consultation regarding diagnosis and treatment recommendations was done by one of the following:

1. Allergist/Immunologist; or

2. Dermatologist; or

3. Rheumatologist; and

c. The recipient must have had an inadequate response, adverse reaction, or contraindication to at least 2 months of therapy with an intranasal corticosteroid and had inadequate response; and

d. One of the following:

1. The recipient will continue intranasal corticosteroid treatment along with omalizumab therapy; or

2. The prescriber has provided valid medical rationale for not continuing intranasal corticosteroid treatment along with omalizumab therapy; or

3. The request is for continuation of therapy and there is documentation of a positive clinical response to therapy (e.g., reduction in NP score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]

4. PA Guidelines:

a. PA approval will be for 12 months.

Table 1: Dosing for Xolair® (omalizumab)

Pre-treatment Serum IgE (IU/mL)	**Body Weight (kg)**			
	30-60	**>60-70**	**>70-90**	**>90-150**
≥30-100	150 mg	150 mg	150 mg	300 mg
>100-200	300 mg	300 mg	300 mg	225 mg
>200-300	300 mg	225 mg	225 mg	300 mg
>300-400	225 mg	225 mg	300 mg	
>400-500	300 mg	300 mg	375 mg	
>500-600	300 mg	375 mg		
>600-700	375 mg	**DO NOT DOSE**		
Every 2 Weeks Dosing				
Every 4 Weeks Dosing				

b. Nucala® (mepolizumab), Cinqair® (reslizumab)

1. All the following criteria must be met and documented:

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; and

c. The recipient must be of FDA indicated appropriate age:

1. Mepolizumab: six years of age or older;

2. Reslizumab: 18 years of age or older; and

d. The prescriber must be either a pulmonologist or allergist/ immunologist; and

e. The recipient must be uncontrolled on current therapy including high dose corticosteroid and/or on a secondary asthma inhaler; and

f. There is documentation of the recipient's vaccination status; and

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks.

2. Reslizumab: 3 mg/kg via intravenous infusion of 20 to 50 minutes every four weeks.

3. PA Guidelines:

a. PA approval will be for 12 months.

c. Nucala® (mepolizumab) for the treatment of severe asthma

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

a. The recipient must have a diagnosis of severe asthma; and

b. The asthma is an eosinophilic phenotype as defined by one of the following:

1. Baseline (pre-treatment) peripheral blood eosinophil level ≥150 cells/microliter (μL); or

2. Peripheral blood eosinophil levels were ≥300 cells/ μL within the past 12 months; and

c. One of the following:

1. The recipient has had at least one or more asthma exacerbations requiring systemic corticosteroid within the past 12 months; or

2. The recipient has had prior intubation for an asthma exacerbation; or

3. The recipient has had prior asthma-related hospitalization within the past 12-months; and

d. The recipient is currently being treated with one of the following (unless there is a contraindication or intolerance to these medications)

1. Both the following:

a. High dose inhaled corticosteroid (ICS) (e.g., >500 mcg fluticasone propionate equivalent/day); and

b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist [LABA], theophylline); or

2. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera® [mometasone/formoterol], Symbicort® [budesonide/formoterol]); and

e. The recipient age is ≥6 years; and

f. The medication must be prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergist/Immunologist

2. Recertification request (the recipient must meet all the criteria)

a. Documentation of positive clinical response to therapy (e.g. reduction in exacerbations, improvement in forced expiratory volume in one second [FEV1], decreased use of rescue medications); and

b. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both the following:

a. ICS; and

b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera® [mometasone/formoterol], Symbicort® [budesonide/formoterol]); and

c. The medication must be prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergist/Immunologist

3. PA Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

d. Nucala® (mepolizumab) for the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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

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

b. The recipient is at least 18 years of age; and

c. The recipient's disease has relapsed or is refractory to standard of care therapy (i.e. corticosteroid treatment with or without immunosuppressive therapy); and

d. ~~c.~~ The recipient is currently receiving corticosteroid therapy; and

e. ~~d.~~ The medication must be prescribed or in consultation with one of the following:

1. Pulmonologist; or

2. Rheumatologist; or

3. Allergist/Immunologist.

2. Recertification Requests (the recipient must meet the following criteria)

a. Documentation of positive clinical response to therapy (e.g. increase in remission time).

b. The medication prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist.

3. PA Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification request will be approved for 12 months.

e. Nucala® (mepolizumab) for treatment of Hypereosinophilic Syndrome (HES)

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

1. History of ≥2 flares over the past 12 months; and

2. Baseline (pre-treatment) blood eosinophil count ≥1,000 cells/mL; and

c. No identifiable non-hematologic secondary cause of the HES; and

d. Recipient does not have FIP1L1-PDGFRa kinase-positive HES; and

e. Recipient is currently received a stable dose of background HES therapy (e.g., episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and

f. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

2. Recertification Request:

a. Documentation of positive clinical criteria response to therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroids requirements, and decreased eosinophil levels).

b. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

3. PA Guidelines:

a. Initial PA will be given for 12 months.

b. Recertification will be given for 12 months.

f. Nucala® (mepolizumab) for treatment of Chronic Rhinosinusitis with NP (CRSwNP)

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

a. Recipient is ≥18 years old.

b. Recipient has a diagnosis of CRSwNP; and

c. Unless contraindicated, the recipient has had an inadequate response to at least two months of treatment with an intranasal corticosteroid (initial approval only); and

d. Mepolizumab will be used as add-on medication to maintenance therapy (e.g. intranasal corticosteroid, saline nasal irrigations, systemic corticosteroids, antibiotics).

2. Recertification Request:

a. Recipient continues to meet above criteria; and

b. Documentation of positive clinical response to Nucala® (mepolizumab).

3. PA Guidelines:

a. Initial PA will be given for 12 months.

b. Recertification approval will be given for 12 months.

~~e.~~g. Fasenra® (benralizumab)

1. All the following criteria must be met and documented:

a. The recipient must be ~~12~~ six years of age or older and medication dosed per FDA based on age and weight; and

b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

c. The recipient must have a diagnosis of severe eosinophilic phenotype asthma; and

d. One of the following:

1. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months; or

2. Any prior intubation for an asthma exacerbation; or

3. Prior asthma-related hospitalization within the past 12 months.

e. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. One maximally dosed combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera®

(mometasone/formoterol), Symbicort® (budesonide/ formoterol)).

f. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

2. Recertification Request: Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. There is documentation of a positive clinical response (e.g., reduction in exacerbation).

b. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both an ICS (5, E) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

2. A combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol)).

c. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

3. PA Guidelines:

a. Initial PA will be for 12 months.

b. Recertification request will be for 12 months.

h. Fasenra® (benralizumab) for treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

1. All the following criteria must be met and documented:

a. Recipient is at least 18 years of age; and

b. Recipient has a diagnosis of EGPA; and

c. Disease has relapsed or is refractory to standard of care therapy (i.e. corticosteroid treatment with or without immunosuppressive therapy); and

d. Recipient is currently receiving corticosteroid therapy; and

e. The medication is prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist

2. Recertification Request:

a. Documentation of positive response to Fasenra® therapy; and

b. The medication is prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist.

3. PA Guidelines;

a. Initial and recertification will be approved for 12 months.

i. ~~f.~~ Dupixent® (dupilumab)

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

a. The recipient has a diagnosis moderate of severe atopic dermatitis and all the following:

1. The medication is prescribed by or in consultation with a dermatologist or allergist/immunologist or an otolaryngologist; and

2. One of the following:

a. Trial and failure contraindication or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, triamcinolone); or

b. Trial and failure or intolerance to one of the following, unless the recipient is not a candidate for therapy (e.g. immunocompromised):

1. Elidel® (pimecrolimus) topical cream; or

2. Tacrolimus topical ointment; or

b. Diagnosis of moderate to severe asthma and all the following:

1. Recipient is six years of age or older; and

2. One of the following:

a. The recipient is currently dependent on oral corticosteroids for the treatment of asthma:

1. One or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.
2. Any prior intubation for an asthma exacerbation.

3. Prior asthma-related hospitalization within the past 12 months; or

b. All the following:

1. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥150 cells per μL; and

2. The recipient has one of the following:

a. One or more asthma exacerbations requiring systematic corticosteroid within the past 12 months.

b. Any prior intubation for an asthma exacerbation.

c. Prior asthma-related hospitalization within the past 12 months; and

3. Recipient is currently being treated with one of the following (or there is a contraindication or intolerance to all these medications):

a. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

b. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera® [mometasone/formoterol],

Symbicort®
[budesonide/formoterol]); and

4. Prescribed by or in consultation with a Pulmonologist or allergy/immunology specialist; or

3. Recertification Request:

a. Diagnosis of moderate to severe atopic dermatitis or severe eosinophilic asthma or oral corticosteroid-dependent asthma and all of the following:

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

2. Recertification Criteria for severe eosinophilic asthma or oral corticosteroid-dependent asthma:

a. Both an ICS and asthma controller medication (e.g., leukotriene, receptor agonist, LABA, theophylline); or

b. One maximally dosed combination ICS/LABA product combination ICS/LABA product (e.g., Advair (fluticasone, propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol)

3. Prescribed by or in consultation with an allergist/immunologist/otolaryngologist/ear, nose, and throat (ENT).

c. Diagnosis of CRSwNP

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

a. Recipient is at least ~~18~~ 12 years of age or older

b. Unless contraindicated, the recipient has had an inadequate response to two months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [Document drug(s), dose, duration, and date of trial]; and

c. The medication will not be used in combination with another agent for CRSwNP; and

d. Prescribed by or in consultation with an allergist/immunologist/otolaryngologists/ENTs.

2. Recertification Request:

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

b. Prescribed by or in consultation with an allergist/immunologist/otolaryngologists/ENTs

c. Medication will not be used in combination with another agent for CRSwNP.

d. Diagnosis of Eosinophilic Esophagitis (EoE)

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

a. Recipient is ≥12 years old; and

b. Recipient weighs ≥40 kg; and

c. Prescribed by or in consultation with an allergist or gastroenterologist; and

d. Recipient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor.

2. Recertification Request:

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

b. Prescribed by or in consultation with an allergist or gastroenterologist.

3. PA Guidelines:

a. PA will be approved for 12 months.

b. Recertification requests will be approved for 12 months.

e. Diagnosis of Prurigo Nodularis (PN)

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

   a. Recipient is ≥18 years old; and

   b. Prescribed by or in consultation with a dermatologist, allergist, or immunologist.

2. Recertification Request:

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

   b. Prescribed by or in consultation with a dermatologist, allergist, or immunologist.

3. PA Guidelines:

   a. PA will be approved for 12 months.

   b. Recertification requests will be approved for 12 months.

f. Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)

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

   a. Recipient is at least 18 years of age; and

   b. Recipient has confirmed diagnosis of inadequately controlled COPD with eosinophilic phenotype, defined by both of the following;

      1. History of ≥2 moderate or ≥1 severe exacerbations within the past 12 months; and

      2. Blood eosinophil count ≥300 cells/ µL; and

   c. Inadequate response, intolerable adverse effects, or contraindications to ≥3-month trial of all of the following treatments;

      1. Long-acting beta 2 agonist (LABA); and

2. Long-acting muscarinic antagonist/anticholinergic (LAMA); and

3. Inhaled corticosteroid (ICS)

[Note: trial of double therapy (LABA and LAMA) permitted if ICS is contraindicated]; and

d. Recipient will continue to receive maintenance therapy concomitantly with Dupixent®; and

e. Medication prescribed by, or in consultation with, a pulmonologist or an allergist/immunologist

2. Recertification Request:

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

b. Recipient continues to receive maintenance therapy concomitantly with Dupixent®; and

c. Medication prescribed by, or in consultation with, a pulmonologist or an allergist/immunologist.

3. PA Guidelines

a. Initial and recertification will be approved for 12 months.

j. Tezspire™ (tezepelumab-ekko)

1. Initial Requests:

a. The recipient has a diagnosis of severe asthma; and

1. The medication is prescribed by or in consultation with a pulmonologist or allergist/immunologist; and

2. The recipient is ≥12 years old; and

3. The recipient is currently being treated with one of the following, unless there is a contraindication or intolerance to these medications:

a. Both a high-dose ICS (e.g., >500 mcg fluticasone propionate equivalent/day) and an additional asthma-controlled medication (e.g., leukotriene receptor antagonist, LABA, theophylline); or

b. One maximally dosed combination ICS/LABA product [e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol); and

4. One of the following (initial request only):

a. At least one or more asthma exacerbations requiring systemic corticosteroid within the past 12 months; or

b. Any prior intubation for an asthma exacerbation; or

c. Prior asthma-related hospitalization within the past 12 months; and

5. Medication will not be used in combination with other monoclonal antibodies for asthma treatment.

2. Quantity limit:

a. One injection (210 mg/1.91mL) per 28 days

3. Renewal Requests:

a. The recipient continues to meet the above criteria; and

b. Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications)

4. PA Guidelines

a. Initial approval will be given for six months.

b. Recertification will be approved for 12 months.

k. Adbry™ (tralokinumab-ldrm)

1. Initial requests

a. Recipient is ≥12 years old; and

b. Recipient has a diagnosis of moderate to severe atopic dermatitis; and

c. The medication is prescribed by or in consultation with a dermatologist, allergist/immunologist, or otolaryngologist; and

d. One of the following:

1. Recipient has trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, triamcinolone); or

2. Recipient has trial and failure or intolerance to one of the following, unless the recipient is not a candidate for therapy (e.g. immunocompromised):

a. pimecrolimus topical cream; or

b. tacrolimus topical ointment

2. Renewal requests:

a. Documentation of positive clinical response to therapy; and

b. The medication is prescribed by, or in consultation with, a dermatologist/allergist/immunologist/otolaryngologist.

3. PA Guidelines:

a. Initial and recertification will be approved for 12 months.

WW. Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome (IBS) Agents, Opioid-Induced Constipation Agents
Last Reviewed by the DUR Board: ~~January 23, 2020~~July 18, 2024

Functional Gastrointestinal Disorder Agents are subject to PA 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 specific quantity limits.

1. ~~CIC~~ Chronic Constipation Agents

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

      1. The requested drug must be FDA approved for the recipient's age; and

      2. Must have a diagnosis of one of the following:

         a. CIC; ~~and~~ or

         b. Function Constipation (FC) in pediatric recipients (Linzess® only)

      ~~2.~~3. Recipient has trial and failure, contraindication or intolerance to either lactulose or polyethylene glycol (MiraLAX®); and

      ~~3.~~4. Recipient has trial and failure, contraindication or intolerance to at least one stimulant laxative, such as sennosides (Ex-Lax®, Senokot®), bisacodyl (Dulcolax®) or cascara sagrada; and

      ~~4.~~5. The maximum allowable doses for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2 mg, once daily

         d. Trulance® (plecanatide): 2 mg, once daily

      6. The maximum allowable dose for FC indication is as follows:

         a. Linzess® (linaclotide) 72 mcg, once daily

   b. PA Guidelines

      1. PA approval will be for one year.

2. IBS Agents

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: ~~October 19, 2023~~July 18, 2024

DMD agents 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. 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 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 mgs per kg of body weight once weekly.

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

         a. The recipient has been on therapy for <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 30mgs per kg 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

4. The recipient is tolerating therapy; and

5. The prescribed dose will not exceed 30 mgs per kg of body weight once weekly; and

6. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

b. PA Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

2. Emflaza® (deflazacort)

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

1. Initial request:

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

b. The recipient must be five years of age or older; and

c. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:

1. Documentation of a confirmed mutation of the dystrophin gene; or

2. Muscle biopsy confirming an absence of dystrophin protein; and

d. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and

e. The recipient has had at least a three-month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and

The dose will not exceed 0.9 mgs per kg of body weight once daily.

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

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 mgs per kg of body weight once daily.

c. PA Guidelines:

1. Initial PA approval will be approved for 12 months.

2. Recertification request will be approved for 12 months.

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 mgs per kg 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 <12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 mgs per kg 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. The recipient 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 30 mgs per kg 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. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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 mgs per kg of body weight infused once weekly.

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

1. One of the following:

a. All of the following:

1. The recipient has been on therapy for <12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 80 mgs per kg 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 mgs per kg 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. PA Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

5. Amondys 45® (casimersen)

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. Diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 to exon 45 skipping; and

2. Prescribed by or in consultation with a neurologist who has experience treating children; and

3. Dose will not exceed 30 mgs per kg of body weight infused once weekly.

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

1. The recipient is tolerating therapy; and

2. Dose will not exceed 30 mgs per kg of body weight infused weekly; and

3. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

c. PA Guidelines:

1. PA will be approved for six months.

2. Recertification request will be approved for 12 months.

6. Elevidys™ (delandistrogene moxeparvovec-rokl)

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. The recipient has confirmed mutation of the DMD gene ~~between exons 1 to 71~~; and

c. The recipient does not have any deletion in exon 8 and/or exon 9 in the DMD gene; and

d. The recipient must have a baseline anti-AAVrh74 total binding antibody titer of <1:400 as measured by enzyme-linked immunosorbent assay (ELISA).

2. Age four ~~through five years old~~and older; and

3. Prescribed by or in consultation with pediatric neuromuscular specialist with advanced knowledge in treating DMD; and

~~4. The recipient is ambulatory as confirmed by prescriber attestation; and~~

~~5.~~4. The recipient is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen); and

~~6.~~5. The recipient does not have an active infection, including clinically important localized infections; and

~~7.~~6. The recipient has been on a stable dose of corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); and

~~8.~~7. The recipient's troponin-I levels will be monitored at baseline and subsequently as clinically indicated; and

~~9.~~8. The recipient will have liver function assessed prior to and following therapy for at least three months as indicated; and

~~10.~~9. The recipient is receiving physical and/or occupational therapy; and

~~11.~~10. The recipient has never previously received Elevidys™ treatment in their lifetime.

b. Recertification requests:

1. Coverage not renewable.

XXXX. Sickle Cell

Therapeutic Class: Sickle Cell
Last reviewed by DUR Board: ~~April~~ July 18, 2024

Sickle Cell is 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. Lyfgenia® (lovotibeglogene autotemcel):

    a. Initial request:

        1. The recipient is ≥12 years of age; and

        2. The recipient has had genetic testing confirming diagnosis of severe sickle-cell disease (SCD) genotype (βS/βS or βS/βO or βS/β+); and

        3. The recipient does not have disease with >2 α-globin gene deletions; and

        4. The recipient has symptomatic disease with hydroxyurea or alternative approved agent unless contraindicated; and

        5. The recipient experienced ≥4 vaso-occlusive events/crises (VOE/VOC) in the previous 24-months;

        6. Medication prescribed by or in consultation with Hematologist; and

        7. Prescriber attestation that the recipient is candidate for autologous hematopoietic stem cell transplant (HSCT); and

        8. The recipient has not previously received an allogeneic transplant; and

        9. The recipient has not previously received any other SCD gene therapy (e.g. Casgevy®); and

        10. The recipient has been counseled and verbalized understanding the hematologic malignancy (blood cancer) has occurred in clinical studies with Lyfgenia® treatment (black box warning); and

        11. The recipient does not have any of the following conditions:

            a. Positive for presence of HIV-1 or HIV-2, HBV, HCV; or

            b. Clinically significant and active bacterial, viral, fungal, or parasitic infection; or

            c. Advanced liver disease; or

d. Inadequate bone marrow function as defined by an absolute neutrophil count of <1000/µL (<500/µL for subjects on HU treatment) or a platelet count <100,000/µL; or

e. Any history of severe cerebral vasculopathy (defined by overt or hemorrhagic stroke; abnormal transcranial Doppler [≥200 cm/sec] needing chronic transfusions, or occlusion or stenosis in the polygon of Willis; or presence of Moyamoya disease; and

12. Prescriber attestation that all necessary preparations prior to Lyfgenia® administration will be followed per package insert (including scheduled transfusions to target required Hb and HbS levels and management of other concomitant medications; and

b. Renewal requests:

1. Coverage not renewable.

2. PA Guidelines:

a. Max one treatment course per lifetime.

2. Casgevy® (exagamglogene autotemcel)

a. Universal criteria:

1. The recipient is ≥12 years of age; and

2. Medication prescribed by or in consultation with Hematologist; and

3. Prescriber attestation that patient is candidate for autologous HSCT; and

4. The recipient has not previously received an allogeneic transplant; and

5. The recipient has not received other gene therapy for sickle-cell disease or beta-thalassemia (e.g., Lyfgenia®, Zynteglo®); and

6. The recipient does not have any of the following conditions:

a. Positive for presence of HIV-1 or HIV-2, HBV, or HCV; or

b. Clinically significant and active bacterial, viral, fungal, or parasitic infection; or

c. Advanced liver disease.

b. Renewal requests:

1. Max 1 treatment course per lifetime.

G. Elaprase® (idursulfase)

Therapeutic Class: Lysosomal Enzymes
Last Reviewed by the DUR Board: April 18, 2024

Elaprase® (idursulfase) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage is provided in the following conditions:

   a. Recipient is at least 16 months of age; and

   b. Documented baseline age-appropriate values for one or more of the following have been obtained:

      1. Recipients five years of age or greater: six-minute walk test (6-MWT), percent predicted forced vital capacity (FVC), joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ), and/or urinary glycosaminoglycan (uGAG); or

      2. Recipients 16 months to <5 years of age: spleen volume, liver volume, FVC, 6-MWT, and/or uGAG; and

   c. Universal Criteria

      1. Therapy is being used to treat non-central nervous system manifestations of the disease and patient does not have severe, irreversible cognitive impairment; and

   d. Hunter syndrome (Mucopolysaccharidosis II; MPS II)

      1. Recipient has a definitive diagnosis of MPS II as confirmed by one of the following:

         a. Deficient or absent iduronate 2-sulfate (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; or

         b. Detection of pathogenic mutations in the IDS gene by molecular genetic testing.

2. Dose Limits

   a. Quantity Limit (max daily dose) [NDC Unit]:

      1. Elaprase® 6 mg/3 mL vial: 10 vials per seven days.

S. Zynlonta® (loncastuximab tesirine-lpyl)

Therapeutic Class: Miscellaneous Antineoplastics
Last Reviewed by the DUR Board: ~~N/A~~July 18, 2024

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

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

   a. Recipient is at least 18 years old; and

   ~~b. Recipient advised to minimize or avoid exposure to direct natural or artificial sunlight including exposure through glass windows; and~~

   ~~c.~~b. Universal Criteria

      1. Used as single agent therapy; and

      2. Recipient has not received prior anti-CD19 therapy, (e.g., tafasitamab, axicabtagene, tisagenlecleucel, etc.~~CAR-T~~) or recipient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; and

      3. Recipient does not have active graft-versus-host disease; and

      4. Recipient has not had an ASCT within 30 days or allogeneic stem cell transplant (AlloSCT) with 60 days, prior to start of therapy; and

      5. Recipient does not have active CNS lymphoma (includes leptomeningeal disease); and

      6. Recipient does not have a clinically significant active infection (e.g., Grade 3 or 4 infections); and

      7. Recipient does not have any clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath); and

   ~~d.~~c. ~~Large~~ B-Cell Lymphoma

      1. ~~Recipient has relapsed or refractory disease (includes~~ DLBCL not otherwise specified, DLBCL arising from low grade lymphoma, or HHV8 positive DLCBCL, not otherwise specified~~ and high-grade B-cell lymphoma); and~~

         ~~2.~~a. Recipient has received at least two prior lines of therapy; and~~.~~

b. Recipient has had no response or partial response or has relapsed, progressive, or refractory disease

2. Histological Transformation of Indolent Lymphomas (follicular lymphoma or marginal zone lymphoma to DLBCL

a. Recipient has no intention to proceed to transplant; and

b. Recipient has been previously treated with an anthracycline-based regimen; and

1. Used as additional therapy for partial response, no response, or progressive or relapsed disease following chemoimmunotherapy for histologic transformation after minimal or no prior therapy if the patient has histologic transformation to DLBCL after minimal or no prior treatment; or

2. Recipient has received multiple lines of prior therapies including ≥2 chemoimmunotherapy regimens for indolent or transformed disease

3. Monomorphic Post-Transplant Lymphoproliferative Disorders (PTLD)

a. Used as third-line and subsequent therapy for B-cell type disease; and

b. Patient has partial response, no response, relapsed, progressive, or refractory disease

2. Dosage Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Zynlonta® 10 mg powder for injection: two vials every 21 days for the first two doses followed by one vial every 21 days thereafter.

b. Max Units (per dose and over time) [HCPCS Unit]:

1. ~~Relapsed or Refractory~~ B-Cell Lymphoma

a. Cycle 1-2

1. 230 billable units (17.25 mg) per each 21-day cycle

b. Subsequent Cycles

1. 115 billable units (8.63 mg) per each 21-day cycle.

3. Recertification Request

a. Coverage may be renewed based upon the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirement (not including prerequisite therapy), performance status, etc. identified in Section III; and

2. Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread.

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe effusion and edema (e.g., pleural effusion, pericardial effusion, ascites, peripheral edema, and general edema, etc.), myelosuppression, (e.g., neutropenia, thrombocytopenia, anemia, etc.), serious infections, severe cutaneous reactions (e.g., photosensitivity reaction, rash, erythema, etc.), etc.~~; and~~

~~Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread.~~

4. PA Guidelines

a. Initial approval will be given for six months.

b. Recertification will be given for six months.

T. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: April 18, 2024

Osteoporosis agents are subject to PA based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

1. Coverage and Limitations

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 document 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 document 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 document 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 Fracture Risk Assessment Tool (FRAX) 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® (abaloparatide); and

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

2. PA Guidelines:

a. PA approval will be given for 12 months.

b. Prolia® and Jubbonti® (denosumab)

1. Criteria for PAD and Point of Sale (POS)

2. Prolia®

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age; and

b. Universal Criteria

1. Recipient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; and

2. Recipients must not have hypocalcemia; and

3. Recipients with advanced kidney disease (i.e., eGFR <30 mL/min/1.73 m2 and including dialysis-dependent recipients) will be monitored for the presence of CKD mineral and bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1.25 (OH)2 vitamin D prior to decisions regarding denosumab treatment; and

4. Pregnancy is ruled out prior to administration in biological females of childbearing potential; and

5. Will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; and

3. Osteoporosis in Men and Women

a. Biological female recipient must be post-menopausal; and

b. Recipient must be at a high risk for fracture; and

c. Recipient has a documented diagnosis of osteoporosis indicated by one or more of the following:

1. T-score by DXA of ≤-2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; or

2. History of fragility fracture to the hip or spine, regardless of T-score; or

3. T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; and

a. History of fracture of proximal humerus, pelvis, or distal forearm; or

b. FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; and

d. Recipient has one of the following:

1. Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV such as alendronate, risedronate, ibandronate, or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and IV bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

4. Glucocorticoid-Induced Osteoporosis

a. Recipient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥2.5mg of prednisone and is expected to remain on glucocorticoid therapy for at least three months; and

b. Recipient must be at an increased risk for fracture; and

1. Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to both oral bisphosphonates and IV bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid.

5. Osteoporosis treatment and prevention in prostate cancer patients

a. Recipient must be receiving androgen deprivation therapy and

b. Recipient must be at a high-risk for fracture

6. Osteoporosis treatment and prevention in breast cancer recipients

a. Recipient must be receiving adjuvant aromatase inhibitor therapy for breast cancer.

c. Xgeva® and Wyost®

1. Coverage is provided in the following conditions:

a. Universal Criteria

1. Recipient will receive calcium and vitamin D as necessary to treat or prevent hypocalcemia (Note: excludes when use is for hypercalcemia of malignancy); and

2. Recipient must not have hypocalcemia; and

3. Will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; and

b. Prevention of skeletal-related events in recipients with MM or bone metastases from solid tumors.

1. Recipient is at least 18 years of age; and

a. Recipient must try and have an inadequate response, contraindication, or intolerance to at least a three-month trial of zoledronic acid, or

b. Recipient has metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC).

2. Giant Cell Tumor of the Bone

a. Recipient must be an adult or at least 12 years of age and skeletally mature; and

1. Disease is unresectable or surgical resection is likely to result in severe morbidity; or

2. Disease is localized, recurrent, or metastatic and

a. Used as a single agent; or

b. Used in combination with serial embolization and/or radiation therapy.

3. Hypercalcemia of malignancy

a. Recipient is at least 18 years of age; and

b. Recipient must have a diagnosis of cancer (malignancy); and

1. Recipient must have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven-day trial on previous therapy with IV bisphosphonates such as ibandronate or zoledronic acid; or

2. Recipient has a documented contraindication or intolerance to IV bisphosphonates such as ibandronate or zoledronic acid.

4. Systemic Mastocytosis

a. Recipient has osteopenia or osteoporosis and coexisting bone pain; and

b. Used as second line therapy if the recipient is

1. Not responding to bisphosphonate therapy; or

2. Recipient is not a candidate for bisphosphonate therapy due to renal insufficiency.

c. PA Guidelines:

1. Coverage will be provided for 12 months and may be renewed.

5. Dosing Limits

a. Quantity Limit (max daily dose) [NDC Unit]:

1. Prolia® 60 mg/1 mL single-dose prefilled syringe: one syringe every six months.

2. Xgeva® 120 mg/1.7 mL single-dose vial:

a. Load: four vials for one 28-day cycle.

b. Maintenance: 1 vial monthly.

b. Max Units (per dose and over time) [NDC Unit]:

1. Prolia® – All indications:

a. 60 billable units every six months.

2. Xgeva® – Giant Cell Tumor of Bone and Hypercalcemia of Malignancy.

a. Loading Dose:
120 billable units on days 1, 8, 15, and 29.

b. Maintenance:
120 billable units every four weeks.

3. Xgeva® –Bone metastases from solid tumors, MM, and Systemic Mastocytosis.

a. 120 billable units every four weeks.

6. Recertification Request:

a. Coverage can be renewed based on the following criteria:

1. Recipient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; and

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain, etc.; and

b. Prolia® and Jubbonti®

1. Beneficial disease response as indicated by one or more of the following:

a. Absence of fractures.

b. Increase in bone mineral density compared to pretreatment baseline; and

2. Osteoporosis in Men and Women only:

a. After five years of treatment, Recipient will have a repeat DXA performed; and

1. Recipients with low-to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms.

3. Glucocorticoid-Induced Osteoporosis

a. After two years of treatment, recipient will have a repeat DXA performed; and

b. Recipients with low to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms.

c. Xgeva® and Wyost®

1. Beneficial disease response as indicated by the following:

a. MM or Bone metastases from solid tumors: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression).

b. Giant Cell Tumor of the Bone: stabilization of disease or decrease in size of tumor or spread of tumor.

c. Hypercalcemia of Malignancy: corrected serum calcium ≤11.5 mg/dL (2.9 mmol/L).

d. Systemic Mastocytosis: improvement or resolution of bone pain as compared to pretreatment baseline.

d. 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 recipient'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 ≥5 mg/day for ≥3 months; and

3. One of the following:

a. BMD T-score ≤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 humerus; 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 exceeded a total of 24 months during the recipient's lifetime.

3. PA Guidelines:

a. PA approval will be for 24 months.

e. 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 is one of the following:

1. Postmenopausal female at high risk for fracture or has failed or is intolerant to other available osteoporosis therapy; or

2. Male at high risk for fracture or has failed or is intolerant to other available osteoporosis therapy; 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,