MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

April 25, 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 January 19, 2023, by the Drug Utilization Review (DUR) Board and to add new prior authorization criteria for Physician-Administered Drugs (PADs). The proposed changes include the adoption of new prior authorization criteria for Nucala® (mepolizumab) and Dupixent® (dupilumab) for the treatment of Hypereosinophilic Syndrome (HES), and Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), within the Respiratory and Allergy Biologics section; addition of new criteria within the Hematopoietic/Hematinic Agents Section; addition of new PAD-specific prior authorization criteria for Ocrevus® (ocrelizumab) within the Multiple Sclerosis (MS) Agents section; addition of new prior authorization criteria for penicillamine within the new Antirheumatics section; addition of new prior authorization criteria for Rayaldee® (calcifediol) within the new Vitamins section; addition of new prior authorization criteria for Relyvrio® (sodium phenylbutyrate/taurursodiol) within the new Amyotrophic Lateral Sclerosis (ALS) section; addition of new PAD-specific clinical prior authorization criteria for Prolia® (denosumab) and Xgeva® (denosumab) within the Osteoporosis Agents section; addition of new PAD-specific prior authorization criteria and quantity limits for Abraxane® (paclitaxel protein-bound particles) within the Taxane Chemotherapy Section; addition of new PAD-specific prior authorization criteria and quantity limits for Bavencio® (avelumab) and Imfinzi® (durvalumab) within the Anti-PD-1 Monoclonal Antibodies section; addition of new PAD-specific prior authorization criteria and quantity limits for Beovu® (brolucizam-dbll) within the Ophthalmic-Macular Degeneration section; addition of new PAD-specificprior authorization criteria and quantity limits for Avastin®, Myasi®, Zirabev™, Alymsys®, Vegzelma™ (Bevacizumab) within the ANP-Human Vascular Endothelial Growth Factor Inhibitors Rec-MC Antibody; addition of new PAD-specific prior authorization criteria and quantity limits for Darzalex® (daratumumab) within the Antineoplastic section; addition of new PAD-specific prior authorization criteria and quantity limits for Darzalex Easpro® (daratumumab and hyaluronidase-fihj) within the Antineoplastic - CD38 Specific Recombinant Monoclonal Antibody Agent section; addition of PAD-specific prior authorization criteria and quantity limits for Elaprase® (idursulfase) within the Lysosomal Enzymes section; addition of new PAD-specific related prior authorization criteria and quantity limits for Eylea® (aflibercept) within the Anti-angiogenic ophthalmic agents section; addition of new PAD-specific prior authorization criteria and quantity limits for Immune Globulins (immunoglobulin) within the Immune Globulins section; addition of new PAD-specific prior authorization criteria and quantity limits for Jemperli® (dostarlimab-gxly) and Keytruda® (pembrolizumab) within the Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1) section; addition of new PAD-specific prior authorization criteria and quantity limits for Kadcyla® (adotrastuzumab emtansine) within the Antineoplastic-Antibody Drug Conjugates (ADCs) section;

addition of new PAD-specific prior authorization criteria and quantity limits for Aranesp® (darbepoetin alfa) within the Recombinant Human Erythropoietin's section; addition of new PAD-specific prior authorization criteria and quantity limits for Pegfilgrastim/Colony Stimulating Factors within the Colony Stimulating Factors section.

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 May 1, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A MSM Chapter 1200 - Prescribed Drugs	MTL N/A MSM Chapter 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section H	**Hematopoietic/Hematinic Agents**	Added new criteria for Epoetin Alfa (Epogen®) within the and updated the recertification criteria within this section.
Appendix A Section P	**Respiratory and Allergy Biologics**	Added new prior authorization criteria for Nucala® (mepolizumab) for treatment of Hypereosinophilic Syndrome (HES), Chronic Rhinosinusitis with Nasal Polyps, and new prior authorization criteria for Dupixent® (dupilumab) for the Diagnosis of Chronic Rhinosinusitis with Nasal Polyps, Diagnosis of Eosinophilic Esophagitis (EoE), and Diagnosis of Prurigo Nodularis (PN).
Appendix A Section CC	**Multiple Sclerosis (MS) Agents**	Added new PAD-related prior authorization criteria for Ocrevus® (ocrelizumab).
Appendix A Section SS	**Colony Stimulating Factors (POS Claims Only)**	Updated existing criteria for this section pertaining to PAD-related clinical criteria
Appendix A Section OO	**Osteoporosis Agents**	Added new PAD-related clinical criteria for Prolia®.
Appendix A Section EEEE	**Penicillamine**	Added new prior authorization criteria for penicillamine and revised the title to create new section named Antirheumatics.
Appendix A Section FFFF	**Rayaldee**	Added new prior authorization criteria for Rayaldee® (calcifediol) and revised the title to create new section named Vitamins.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section GGGG	**Amyotrophic Lateral Sclerosis (ALS)**	Added new prior authorization criteria for Relyvrio® (sodium phenylbutyrate/taurursodiol).
Appendix B Section 5	**Physician Administered Drugs**	Created a new section specific to Physician-Administered Drugs to represent a fee schedule for a select subset of specialty physician-administered drugs (PADs) while streamlining utilization management tools such as quantity limits and clinical prior authorization criteria for an effective and comprehensive management of PADs.
Appendix B Section 5	**Taxane Chemotherapy**	Created new section for PAD prior authorization criteria and quantity limits for Abraxane® (paclitaxel protein-bound particles).
Appendix B Section 5B	**Anti-PD-1 Monoclonal Antibodies**	Created new Section. PAD prior authorization criteria and quantity limits for Bavencio® (avelumab) and Imfinzi® (durvalumab).
Appendix B Section 5C	**Ophthalmic-Macular Degeneration**	Created new section for PAD prior authorization criteria and quantity limits for Beovu® (brolucizam-dbll).
Appendix B Section 5D	**ANP-Human Vascular Endothelial Growth Factor Inhib Rec-MC Antibody**	Created new section for PAD prior authorization criteria and quantity limits for Avastin®, Myasi®, Zirabev™, Alymsys®, Vegzelma™ (Bevacizumab).
Appendix B Section 5E	**Antineoplastic**	Created new section for PAD prior authorization criteria and quantity limits for Darzalex® (daratumumab).
Appendix B Section 5F	**Antineoplastic - CD38 Specific Recombinant Monoclonal Antibody Agent**	Created new section for PAD prior authorization criteria and quantity limits for Darzalex Easpro® (daratumumab and hyaluronidase-fihj).
Appendix B Section 5G	**Lysosomal Enzymes**	Created new section for PAD prior authorization criteria and quantity limits for Elaprase® (idursulfase).
Appendix B Section 5H	**Anti-angiogenic ophthalmic agents**	Created new section for PAD prior authorization criteria and quantity limits for Eylea® (aflibercept).
Appendix B Section 5I	**Immune Globulins**	Created new section for PAD prior authorization criteria and quantity limits for Immune Globulins (immunoglobulin).

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix B Section 5J	**Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)**	Created new section for PAD prior authorization criteria and quantity limits for Jemperli® (dostarlimab-gxly) and Keytruda® (pembrolizumab).
Appendix B Section 5K	**Antineoplastic-Antibody Drug Conjugates (ADCs)**	Created new section for PAD prior authorization criteria and quantity limits for Kadcyla® (adotrastuzumab emtansine).
Appendix B Section 5L	**Recombinant Human Eyrhthropoietins**	Created new section for PAD prior authorization criteria and quantity limits for Aranesp® (darbepoetin alfa).
Appendix B Section 5M	**Colony Stimulating Factors**	Created new section for PAD prior authorization criteria and quantity limits for Pegfilgrastim/Colony Stimulating Factors.

H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)
Last Reviewed by the DUR Board: January 19, 2023~~October 17, 2019~~

This policy applies in all settings with the exception of inpatient facilities. Hematopoietics and Hematinics are subject to prior authorizations 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. The recipient has been evaluated for adequate iron stores; and

b. Recent laboratory results are required for prior authorization, i.e. serum hemoglobin, within seven days of prior authorization request; and

c. Recipients must meet one of the following criteria for coverage:

1. Achieve and maintain hemoglobin levels in one of the following conditions:

a. Treatment of anemia secondary to myelosuppressive anticancer chemotherapy, Hb levels should not exceed 10 g/dL.

b. Treatment of anemia related to zidovudine therapy in HIV-infected patients. Hb levels should not exceed 12 g/dL.

c. Treatment of anemia secondary to ESRD. Hb levels should not exceed 11 g/dL if on dialysis or 10 g/dL if not on dialysis.

d. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) has adequate iron stores as demonstrated by serum ferritin greater than or equal to 100 ng/mL (mcg/L) and transferrin saturation (TSAT) greater than or equal to 20% (measured within the previous three months for renewal)~~does not have this indication~~.

2. Non-Covered Indications

a. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding or bone marrow fibrosis.

b. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) or erythroid cancers.

c. Anemia of cancer not related to cancer treatment.

d. Any anemia associated only with radiotherapy.

e. Prophylactic use to prevent chemotherapy-induced anemia.

f. Prophylactic use to reduce tumor hypoxia.

g. Patients with erythropoietin-type resistance due to neutralizing antibodies.

h. Anemia due to cancer treatment if patients have uncontrolled hypertension.

3. Recertification Request

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

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

2. Previous dose was administered within the past 60 days; and

3. Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; and

4. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pure red cell aplasia severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in recipients with cancer, severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), etc.; and

b. Anemia Due to Myelodysplastic Syndrome (MDS):

1. Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

c. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis:

1. Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct) less than 30%.

d. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria.

e. Anemia Due to Chronic Kidney Disease (Non-Dialysis Patients):

1. Pediatric patients: Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%.

2. Adult patients: Hemoglobin (Hb) less than 11 g/dL and/or Hematocrit (Hct) less than 33%.

4. ~~3.~~ Prior Authorization Guidelines

a. Prior approval will be given for a one month period.

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

P. Respirator and Allergy Biologics

Therapeutic Class: Respirator and Allergy Biologics
Last Reviewed by the DUR Board: January 19, 2023~~April 28, 2022~~

Respirator and Allergy Biologics 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. 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 150mg or 300mg 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 nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]

4. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

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.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

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

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 greater than or equal to 150 cells/microliter; or

2. Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter 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., greater than 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 greater than or equal to six 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, long-acting beta-2 agonist [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. Prior Authorization Guidelines:

a. Initial authorization will be approved for six months.

b. Recertification will be approved for 12 months.

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

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

c. The recipient is currently receiving corticosteroid therapy; and

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).

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 months.

b. Recertification request will be approved 12 months.

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

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

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

a. Recipient is greater than or equal to 12 years old; and

b. Recipient has a diagnosis of uncontrolled HES for greater than or equal to six months defined by both of the following:

1. History of greater than or equal to two flares over the past 12 months; and

2. Baseline (pre-treatment) blood eosinophil count greater than or equal to 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. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification will be given for 12 months.

f. Nucala® (mepolizumab) for treatment of Chronic Rhinosinusitis with Nasal Polyps

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

a. Recipient is greater than or equal to 18 years old.

b. Recipient has a diagnosis of Chronic Rhinosinusitis with Nasal Polyps (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. Prior Authorization Guidelines:

a. Initial prior authorization will be given for 12 months.

b. Recertification approval will be given for 12 months.

e. Fasenra® (benralizumab)

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

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

b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthamtic 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., greater than 500 mcg fluticasone propionate equivalent/day) and an 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)).

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, long-acting beta-2 agonist (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. Prior Authorization Guidelines:

a. Initial prior authorization will be for 12 months.

b. Recertification request will be for 12 months.

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

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® (pimecromulus) 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 greater than or equal to 150 cells per microliter; 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 inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (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, long-acting beta-2 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 (budenoside/formoterol)

3. Prescribed by or in consultation with an allergist/immunologist/otolaryngologist/ENTs.

c. Diagnosis of Chronic Rhinosinusitis with Nasal Polyps

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

a. Recipient is at least 18 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 greater than or equal to 12 years old; and

b. Recipient weighs greater than or equal to 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. Prior Authorization Guidelines:

a. Prior authorization 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 greater than or equal to 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. Prior Authorization Guidelines:

   a. Prior authorization will be approved for 12 months.

   b. Recertification requests will be approved for 12 months.

   ~~c. Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) and all the following:~~

      ~~1. Unless contraindicated, the recipient has had an inadequate response to two months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [Document drugs(s), dose, duration, and date of trial]; and~~

      ~~2. The medication will not be used in combination with another agent for CRSwNP; and~~

      ~~3. Prescribed by or in consultation with an allergist/immunologist~~

~~2. Recertification Request:~~

~~a. Diagnosis of moderate to severe atopic dermatitis and all the following:~~

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

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

   a. Both an ICS and additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 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))

   c. Prescribed by or in consultation with a pulmonologist or Allergy/immunology specialist.

3. Prior Authorization Guidelines:

   a. Initial prior authorization will be for 12 months.

   b. Recertification request will be for 12 months.

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

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: January 19, 2023~~July 28, 2022~~

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

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

   a. The recipient has a diagnosis of MS.

2. Ampyra® (dalfampridine)

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

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

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

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

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

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

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

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

   b. Prior Authorization Guidelines

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

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

3. Relapsing Forms of MS Agents:

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

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

b. Lemtrada® (alemtuzumab)

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

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

1. Both the following:

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

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

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Mavenclad (cladrivine)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

c. Both the following:

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

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

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

2. Prior Authorization Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

c. Mavenclad® (cladribine)

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

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

1. Both the following:

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

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

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone®/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Lemtrada® (alemtuzumab)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

2. Both the following:

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

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

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

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

d. Ocrevus® (ocrelizumab)

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

~~The recipient has a diagnosis of a relapsing form of MS (e.g.,~~

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

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

c. Recipient has had baseline serum immunoglobulins assessed; and

2. Universal Criteria

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

b. Recipient does not have an active infection; and

3. Multiple Sclerosis

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

b. Must be used as single agent therapy; and

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

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

a. Recipient is less than 65 years; and

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

~~a. relapsing-remitting MS, secondary-progressive MS with relapses); and~~

~~b.~~

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

~~d.~~

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

~~f.~~

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

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

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

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

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

d. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR),

development of new/worsening T2 hyperintensities, or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].

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

e. PPMS

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

~~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., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and~~

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

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 months.

b. Recertification approval will be for 12 months.

~~e.~~ 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

OO. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: ~~October 22, 2020~~January 19, 2023

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

b. Prolia® (denosumab)

1. Criteria for Physician Administered Drugs (PAD)

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

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

2. Recipient must not have hypocalcemia; and

3. Coverage is provided in the following conditions:

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

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

c. Pregnancy ruled out prior to starting therapy in women of childbearing potential; and

~~1.~~2. 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

a. One of the following:

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

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

a. Vertebral compression fracture

b. Fracture of the hip

c. Fracture of the distal radius

d. Fracture of the pelvis

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

3. 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]); 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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. ~~3.~~ For Postmenopausal Osteoporosis or Osteopenia

a. Criteria for Physician Administered Drugs (PAD)

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

a. Recipient must be a woman; and

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

1. Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to negative two and a half and/or forearm DXA at the 33% (one-third) radius site; or

2. T-score less than or equal to negative one or low bone mass and a history of fragility fracture to the hip or spine; or

3. T-score between negative one and negative two and a half with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%; and

c. 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

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

~~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~~ 12 months.

2. Recertification approval will be for ~~24~~ 12 months.

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

4. Glucocorticoid-Induced Osteoporosis

a. Criteria for Physician Administered Drugs (PAD)~~Approval will be given if all criteria is met and documented~~:

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

a. Recipient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to greater than or equal to 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least six months; and

b. 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

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

~~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).~~

5. Osteoporosis treatment and prevention in prostate cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

a. Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to negative one (or recipient meets the diagnostic criteria for osteoporosis above); and

b. Recipient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

6. Osteoporosis treatment and prevention in breast cancer patients

a. Criteria for Physician Administered Drugs (PAD)

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

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

b. Recertification Request:

1. 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~~ 12 months.

2. Recertification request will be approved for ~~24~~ 12 months.

3. Prior Authorization forms are available at: https://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:

SS. Colony Stimulating Factors (POS Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: January 19, 2023~~April 28, 2016~~

Colony Stimulating Factors 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. Coverage and Limitations

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

a. The requested agent is being used for an FDA-approved indication.

b. The requests for a diagnosis of nonmyeloid malignancy must meet one of the following criteria:

1. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neuropenia risk of ≥ 20%; or

2. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age > 65 years, absolute neutrophil count (ANC) < 100 cells/µL or the expected duration of neutropenia is > 10 days); or

3. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

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

EEEE. Penicillamine

Therapeutic Class: Antirheumatics
Last reviewed by DUR Board: January 19, 2023

Penicillamine is 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. Wilson's Disease

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

      1. Recipient has diagnosis of Wilson's Disease; and

      2. Medication prescribed by or in consultation with gastroenterologist, hepatologist, rheumatologist, or liver transplant physician.

   b. Recertification Request:

      1. Recipient continues to meet above criteria; and

      2. Recipient has demonstrated positive clinical response to therapy.

   c. Prior Authorization Guidelines:

      1. Initial approval will be given for 12 months.

      2. Recertification approval will be given for 12 months.

2. Cystinuria

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

      1. Recipient has diagnosis of Cystinuria; and

      2. Recipient has a history of failure, contraindication, or intolerance to conservative treatment measures (e.g., use of urinary alkalinization such as potassium citrate, high fluid intake, sodium, and protein restriction) [initial criteria only]; and

      3. Medication is prescribed by or in consultation with nephrologist or urologist.

   b. Recertification Request:

      1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

3. Rheumatoid Arthritis

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

1. Recipient has diagnosis of severe, active rheumatoid arthritis; and

2. Recipient has contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate, leflunomide, or azathioprine) [initial criteria only].

3. Medication is prescribed by or in consultation with a rheumatologist.

b. Recertification Request:

1. Recipient continues to meet above criteria; and

2. Recipient has demonstrated positive clinical response to therapy.

c. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

FFFF. Rayaldee® (calcifediol)

Therapeutic Class: Vitamins
Last reviewed by DUR Board: January 19, 2023

Rayaldee® (calcifediol) is 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. Rayaldee® (calcifediol)

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

      1. Recipient is greater than or equal to 18 years of age; and

      a. Recipient has a diagnosis of secondary hyperparathyroidism (HPT); and

      3. Recipient has both of the following:

         a. serum total 25-hydroxyvitamin D level less than 30 ng/mL; and

         b. serum corrected total calcium below 9.8 mg/d; and

      4. Recipient has Chronic Kidney Disease (CKD) Stage 3 or 4

      5. Recipient does not have CKD Stage 5 or end stage renal disease on dialysis

      6. Recipient has a history of failure, contraindication, or intolerance to adequate trial of all of the following:

         a. Calcitriol

         b. Doxercalciferol

         c. Paricalcitol

      7. Medication is prescribed by or in consultation with nephrologist or endocrinologist.

2. Recertification Request:

   a. Recipient has demonstrated positive response to treatment as defined by increase in serum total 25-hydroxyvitamin D level and/or decrease in intact parathyroid hormone (iPTH).

   b. Medication is prescribed by or in consultation with nephrologist or endocrinologist.

3. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be approved for six months.

GGGG. Relyvrio® (sodium phenylbutyrate/taurursodiol)

Therapeutic Class: Amyotrophic Lateral Sclerosis (ALS)
Last reviewed by DUR Board: January 19, 2023

Relvyrio® (sodium phenylbutyrate/taurusodiol) is 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. Relyvrio® (sodium phenylbutyrate/taurusodiol)

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

      1. Recipient is greater than or equal to 18 years of age; and

      2. Recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

      3. Recipient must have an adequate trial of riluzole for greater than or equal to eight weeks or contraindication to therapy; and

      4. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R); and

      5. Recipient does not require permanent assisted ventilation; and

      6. Therapy prescribed by or in consultation with neurologist; and

   b. Recertification Request:

      1. Recipient must continue to meet the above criteria; and

      2. Recipient must have disease stabilization or improvement in the slope of decline as demonstrated on an objective measure/tool (e.g., ALSFRS-R); and

      3. Recipient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure).

   c. Prior Authorization Guidelines:

      1. Initial approval will be given for six months.

      2. Recertification will be approved for six months.

5. PHYSICIAN ADMINISTERED DRUGS (PADs) REQUIRING PRIOR AUTHORIZATION AND/OR QUANTITY LIMITATIONS

A. Abraxane® (paclitaxel protein-bound particles)

Therapeutic Class: Taxane Chemotherapy
Last Reviewed by the DUR Board: N/A

Physician Administered Drugs (PAD) are subject to prior authorization 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 of age; and

    b. Breast Cancer

        1. Recipient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy; and

            a. Previous chemotherapy included an anthracycline unless clinically contraindicated; or

        2. Recipient has recurrent unresectable (local or regional) or metastatic (Stage IV [M1]) disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

            a. Used a single agent or in combination with carboplatin in recipient with high tumor burden, rapidly progressing disease, and visceral crisis; and

            b. Disease is HER2-negative; and

                1. Disease is hormone receptor-negative; or

                2. Disease is hormone receptor-positive, and recipient is refractory to endocrine therapy or has a visceral crisis; or

            c. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; or

            d. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease; or

3. May be substituted for paclitaxel or docetaxel if the recipient has experienced hypersensitivity reactions despite premedication, or the patient has contraindication to standard hypersensitivity premedication.

c. Non-Small Cell Lung Cancer (NSCLC)

1. Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; or

2. May be substituted for paclitaxel or docetaxel if the recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications to standard hypersensitivity premedication; or

3. Used for recurrent, advanced, metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence or disseminated disease), or mediastinal lymph node recurrence with prior radiation therapy; and

a. Used as first-line therapy; and

1. Used in combination with carboplatin and pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); and

a. Used in recipients with tumors that have negative actionable molecular biomarkers; and

b. Used in recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

2. Used in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2); and

a. Used in recipients with tumors that have negative actionable molecular biomarkers and PD-L1 greater than or equal to one percent; or

b. Used in recipients with tumors that have negative actionable molecular biomarkers and PD-L1 less than one percent; or

c. Used in recipients who are positive for one of the following molecular mutations: EFGR exon 20, KRAS G12C, BRAD V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

b. Used as subsequent therapy; and

1. Used as a single agent (if not previously given) in recipients with a PS 0-2; and

a. Used for first progression after initial systemic therapy; or

b. Used in combination with carboplatin and pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in recipients with PS score of 0-1; and

1. Used in recipients who are positive for one the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

2. Used in recipients who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; or

c. Used in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2); and

1. Used in recipients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

2. Used in recipients who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or

L858R tumors, EGFR S7681, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; or

3. Used in recipients with PD-L1 expression-positive (greater than or equal to one percent) tumors that are negative for actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy.

d. Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal)

1. Recipient has recurrent or persistent disease; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); and

a. Used a single agent; and

1. Recipient has platinum-resistant disease; and

a. Used for progression on primary, maintenance, or recurrence therapy; or

b. Used for stable or persistence disease if not currently on maintenance therapy; or

c. Used for relapse disease less than six months after complete remission from prior chemotherapy; or

2. Recipient has platinum-sensitive disease; and

a. Used for radiographic and/or clinical relapse greater than or equal to six months after complete remission from prior chemotherapy; or

b. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; and

1. Used for relapse greater than or equal to six months after complete remission from prior chemotherapy; or

3. Recipient has recurrent low-grade serous carcinoma; and

a. Used as a single agent for platinum-sensitive or platinum-resistant disease; or

b. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; or

4. May be substituted for paclitaxel if the recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications to standard hypersensitivity premedication.

e. Pancreatic Adenocarcinoma

1. Used in combination with gemcitabine; and

a. Recipient has locally advanced or metastatic disease; and

1. Used as first-line therapy; or

2. Used an induction therapy followed by chemoradiation (locally advanced disease only); or

3. Used as subsequent therapy after progression with a fluoropyrimide-based therapy; or

4. Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); or

5. Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy (metastatic disease only); or

b. Recipient has recurrent disease in the pancreatic operative bed or metastatic disease, post-resection; and

1. Used greater than or equal to six months after completion of primary therapy; or

2. Used less than six months from completion of primary therapy with a fluoropyrimidine-based regimen; or

c. Used as neoadjuvant therapy; and

1. Recipient has resectable disease with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); or

2. Recipient has biopsy positive borderline resectable disease; or

2. Used in combination with gemcitabine and cisplatin; and

a. Recipient has metastatic disease; and

b. Recipient has ECOG PS 0-1; and

1. Used as first-line therapy; or

2. Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy.

f. Cutaneous Melanoma

1. Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; and

a. Used as subsequent therapy for disease progression; or

b. Used after maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.).

g. Uveal Melanoma

1. Used as a single agent for distant metastatic disease

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Used as a single agent therapy; and

2. Recipient has tried paclitaxel and treatment paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication, or there is a documented medical contraindication to recommended premedication; and

a. Recipient has endometroid adenocarcinoma; and

1. Used a primary treatment of disease not suitable for primary surgery; and

a. Recipient has suspected or gross cervical involvement (excluding recipients using a chemotherapy alone); or

b. Recipient has locoregional extrauterine disease; or

c. Recipient has distant metastases; or

2. Recipient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/de-differentiated carcinoma; and

a. Used for locoregional recurrence or disseminated metastases; or

b. Used as additional treatment of metastatic disease that is suitable for primary surgery; or

c. Used as primary treatment of metastatic disease that is not for primary surgery.

i. Hepatobiliary Adenocarcinoma (Intrahepatic /Extrahepatic Cholangiocarcinoma, Gallbladder)

1. Used in combination with gemcitabine for unresectable or metastatic disease; and

a. Used as a primary treatment; or

b. Used as a subsequent treatment for progression on or after systemic therapy.

j. Small Bowel Adenocarcinoma

1. Recipient has advanced or metastatic disease; and

2. Used as single agent or in combination with gemcitabine; and

a. Used as subsequent therapy; or

b. Recipient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; and

1. Used as initial therapy; or

2. Used as subsequent therapy in recipient who previously received initial therapy with nivolumab with or without ipilimumab, pembrolizumab, or dostarlimab-gxly.

k. Kaposi Sarcoma

1. Used as subsequent therapy; and

a. Used as a single agent for patients that do not have HIV; or

b. Used in combination with antiretroviral therapy (ART) for recipients with HIV; and

2. Recipient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

3. Disease has progressed on or not responded to first-line systemic therapy; and

4. Disease has progressed on alternative first-line systemic therapy.

l. Ampullary Adenocarcinoma

1. Used in combination with gemcitabine; and

2. Recipient has pancreatobiliary and mixed type disease; and

a. Used as neoadjuvant therapy for localized disease in high-risk recipients (i.e., imaging findings, markedly elevated CA 19-9, markedly elevated carcinoembryonic antigen [CEA], large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); or

b. Used as first-line therapy for unresectable localized or metastatic disease; or

c. Used as subsequent therapy for disease progression.

2. Dosing Limits

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

1. Abraxane® 100 mg powder for injection single dose vial: 9 vials per 21-day supply

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

a. Kaposi Sarcoma

1. 300 billable units per 28 days

b. All other indications

1. 900 billable units per 21 days

3. Recertification Request:

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

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count less than 1,500 cell/mm3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions (including anaphylactic reactions), etc.

4. Prior Authorization Guidelines:

a. Initial approval will be given for 6 months.

b. Recertification will be given for 6 months.

B. Anti-PD-1 Monoclonal Antibodies

Therapeutic Class: Anti-PD-1 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

Anti-PD-1 Monoclonal Antibodies are subject to prior authorization 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. Bavencio® (avelumab)

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

1. Recipient is at least 18 years of age, unless otherwise indicated; and

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab, nivolumab/relatlimab-rmbw, etc.), unless otherwise specified; and

3. Merkel Cell Carcinoma (MCC)

a. Recipient is at least 12 years of age; and

b. Used as single-agent therapy; and

c. Recipient has metastatic or recurrent disseminated disease.

4. Urothelial Carcinoma (Bladder Cancer)

a. Used as single-agent therapy; and

1. Recipient has one of the following diagnoses:

a. Locally advanced or metastatic urothelial carcinoma

b. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder

c. Metastatic or local bladder cancer recurrence post cystectomy

d. Metastatic upper genitourinary (GU) tract tumors

e. Metastatic urothelial carcinoma of the prostate

f. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes); and

2. Used for disease that progressed during or following platinum-containing chemotherapy; or

3. Used as second-line treatment after chemotherapy other than a platinum; or

b. Used for first-line maintenance treatment; and

1. Recipient has locally advanced or metastatic urothelial carcinoma (inclusive of bladder, upper GU tract, urethra, and/or prostate cancer); and

2. Recipient has not progressed with first-line platinum-containing chemotherapy.

4. Renal Cell Carcinoma (RCC)

a. Used in combination with axitinib; and

b. Used as first-line therapy; and

c. Used for the treatment of advanced, relapsed, or stage IV disease and clear cell histology.

5. Gestational Trophoblastic Neoplasia

a. Used a single-agent therapy for multiagent chemotherapy-resistant disease; and

1. Recipient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); and

a. Recipient has recurrent or progressive disease; and

b. Recipient was previously treatment with a platinum-based regimen; or

2. Recipient has high-risk disease (i.e., prognostic score greater than or equal to seven or FIGO stage IV disease).

6. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as single-agent therapy; and

b. Recipient has recurrent or metastatic disease; and

c. Used as second-line treatment for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

b. Dosing Limits

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

a. Bavencio 200 mg/10mL single dose vial: 4 vials per 14 days

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

a. 80 billable units (800 mg) every 14 days (all indications)

c. Recertification Request

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

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

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, hepatotoxicity, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE) when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

d. Prior Authorization Guidelines:

1. Initial approval will be given for 6 months.

2. Recertification will be given for 6 months.

2. Imfinzi® (durvalumab)

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

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

2. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)- directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, etc.) unless otherwise specified; and

3. Non-Small Cell Lung Cancer (NSCLC)

a. Recipient has a performance status (PS) of 0-1; and

1. Used as a single agent; and

a. Used as consolidation therapy: and

b. Recipient has unresectable stage II-III disease; and

c. Disease has not progressed after definitive chemoradiation; or

2. Used in combination with tremelimuab-actl and platinum-based chemotherapy; and

a. Used as first-line therapy for metastatic disease; and

b. Recipient had no EGFR mutations or ALK genomic tumor aberrations.

4. Small Cell Lung Cancer (SCLC)

a. Recipient has extensive stage disease (ES-SCLC); and

1. Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; or

2. Used as single-agent maintenance therapy after initial therapy with etoposide and either carboplatin or cisplatin.

5. Hepatobiliary Cancers

a. Recipient has hepatocellular carcinoma (HCC); and

1. Used a first-line therapy as a single agent; and

a. Recipient has unresectable disease and is not a transplant candidate; or

b. Recipient has liver-confirmed disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or

c. Recipient has metastatic disease or extensive liver tumor burden; or

2. Used as first-line therapy in combination with tremelimumab-actl; and

a. Recipient has unresectable disease; and

b. Recipient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); and

1. Recipient has intermediate disease (i.e., multinodular, PS 0) and is not eligible for locoregional therapy; or

2. Recipient has advanced disease (i.e., portal invasion, regional lymph node metastasis, distant metastasis, PS 1-2); or

b. Recipient has biliary tract cancer (e.g., gallbladder cancer or intra-/extra- hepatic cholangiocarcinoma); and

1. Used in combination with cisplatin and gemcitabine; and

a. Used as primary treatment for unresectable, locally advanced, or metastatic disease; or

b. Used for recurrent disease greater than six months after surgery with curative intent and greater than six months after completion of adjuvant therapy.

b. Dosage Limits

1. Quantity Limits (max daily dose) [NDC Unit]:

a. Imfinzi 120 mg/2.4 mL single dose vial: four vials per 14 days

b. Imfinzi 500 mg/10 mL single dose vial: two vials per 14 days

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

a. NSCLC: 112 billable units (1,120 mg) every 14 days

b. SCLC: 150 billable units (1,500 mg) every 21 days x six disease, then 150 billable units (1,500 mg) every 28 days

c. Biliary Tract Cancer: 150 billable units (1,500 mg) every 21 days x eight doses, then 150 billable units (1,500 mg) every 28 days

d. Hepatocellular Carcinoma: 150 billable units (1,500 mg) every 28 days

c. Recertification Request

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

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

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe or life-threatening infusion-related reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, pancreatitis, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; and

4. NSCLC (single-agent use)

a. Recipient has not exceeded a maximum of 12 months of therapy

5. Hepatobiliary Cancers

a. Cases for recipients with HCC who use treatment as part of STRIDE and experience disease progression but who are clinically stable and still deriving clinical benefit will be reviewed on a case-by-basis.

6. Continuation Maintenance Therapy for SCLC

a. Refer to Section III for criteria.

d. Prior Authorization Guidelines:

1. Initial approval for Non-Small Cell Lung Cancer (single agent use) will be given for six months.

2. Recertification for Non-Small Cell Lung Cancer (single agent use) will be given for 12 months.

3. Initial approval for Non-Small Cell Lung Cancer (use in combination with tremelimumab-act] and platinum-based chemotherapy, Small Cell Lung Cancer and Hepatobiliary Cancers will be given for six months.

4. Recertification for Non-Small Cell Lung Cancer (used in combination with tremelimumab-act] and platinum-based chemotherapy, Small Cell Lung Cancer and Hepatobiliary Cancers will be for six months.

C. Beovu® (brolucizumab-dbll)

Therapeutic Class: Ophthalmic-Macular Degeneration
Last Reviewed by the DUR Board: N/A

Beovu® (brolucizumab-dbll) are subject to prior authorization 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 of age; and

   b. Universal Criteria

      1. Recipient is free of ocular and/or peri-ocular infections; and

      2. Recipient does not have active intraocular inflammation; and

      3. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, ranibizumab, pegaptanib, bevacizumab, faricimab-svoa, etc.); and

      4. Recipients best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; and

      5. Recipient has a definitive diagnosis of the following:

         a. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

         b. Diabetic Macular Edema (DME)

2. Dosing Limits

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

      1. Neovascular age-related macular degeneration (AMD):

         a. Six mg single-dose vial or pre-filled syringe for injection: one vial/syringe per eye every 25 days for three doses initially, then one vial/syringe every eight weeks

      2. Diabetic Macular Edema (DME)

         1. Six mg single-dose vial or pre-filled syringe for injection: one vial/syringe per eye every six weeks for five doses initially, then one vial/syringe every eight weeks.

3. Neovascular age-related macular degeneration (AMD)

a. MU for Initial Dosing

1. 12 billable units every 25 days x three doses

b. MU for Maintenance Dosing

1. 12 billable units every 56-84 days

4. Diabetic Macular Edema (DME)

a. MU for Initial Dosing

1. 12 billable units every six weeks x five doses

b. MU for Maintenance Dosing

1. 12 billable units every 56-84 days

3. Recertification Request

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity: endophthalmitis and retinal detachment, increase in intraocular pressure, arterial thromboembolic events, retinal vasculitis, and/or retinal vascular occlusion etc.; and

c. Continued administration is necessary for the maintenance treatment of the condition; and

d. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

1. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline corrected visual acuity (BCVA), etc.)); and

2. Decreasing the interval of maintenance doses from 12 weeks to eight weeks will be allowed if the recipient has received all three-loading disease and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 16:

a. Decrease in BCVA of greater than or equal to five letters compared to baseline; or

b. Decrease in BCVA of greater than or equal to three letters due to neovascular AMD disease activity compared with week 12; or

c. Decrease in BCVA of greater than or equal to five letters and central subfield thickness greater than or equal to 75 microns compared with week 12; or

d. New or worsening intra-retinal cysts or fluid compared with week 12.

e. Diabetic Macular Edema (DME)

1. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA, etc.); and

2. Decreasing the interval or maintenance doses from 12-weeks to either weeks will be allowed if the recipient has received all five loading doses and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 28:

a. Decrease in BCVA of greater than or equal to five letters compared to baseline; and

b. Increase in central subfield thickness compared to baseline.

4. Prior Authorization Guidelines:

a. Initial approval be given for 12 months.

b. Recertification will be approved for 12 months.

D. Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™ (Bevacizumab)

Therapeutic Class: ANP -Human Vascular Endothelial Growth Factor Inhib Rec-MC Antibody
Last Reviewed by the DUR Board: N/A

Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™(Bevacizumab) are subject to prior authorization 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 of age, unless otherwise specified; and

   b. Universal Criteria

      1. Recipient has no recent history of hemoptysis (i.e., the presence of greater than or equal to 2.5mL of blood in sputum); and

      2. Recipient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; and

   c. Ampullary Adenocarcinoma

      1. Used in combination with a fluoropyrimidine (e.g., five-fluorouracil/five-FU or capecitabine) based regimen for intestinal type disease; and

         a. Used as first-line therapy for unresectable localized or metastatic disease or as subsequent therapy for disease progression; and

            1. Recipient has poor performance status (ECOG PS 2); or

            2. Recipient has good performance status (ECOG 0-1, with good biliary drainage and adequate nutritional intake) and received prior oxaliplatin-based therapy.

   d. Adult Central Nervous System (CNS) Cancers

      1. Used for symptom management related to radiation necrosis, poorly controlled vasogenic edema, or mass effect as single-agent short-course therapy; and

         a. Recipient has a diagnosis of one of the following CNS cancers

            1. Glioma (WHO Grade 1)

            2. Primary CNS Lymphoma

3. Meningiomas

4. Brain or Spine metastases

5. Medulloblastoma

6. Glioblastoma/Gliosarcoma

7. IDH-mutant Astrocytoma (WHO Grade 2-4)

8. IDH-mutant, 1p19q co-deleted Oligodendroglioma (WHO Grade 2 or 3)

9. Intracranial or Spinal Ependymoma (excluding subependymoma); or

2. Used for recurrent disease; and

a. Recipient has a diagnosis of one of the following CNS cancers:

1. IDH-mutant, 1p19q co-deleted Oligodendroglioma (WHO Grade 3)

2. Glioblastoma/Gliosarcoma

3. IDH-mutant Astrocytoma (WHO Grade 3 or 4); and

b. Used as a single agent; or

c. Used in combination with carmustine, lomustine, or temozolomide; and

1. Recipient has failed bevacizumab monotherapy; or

3. Used as a single agent for progressive or recurrent Intracranial or Spinal Ependymoma (excluding subependymoma) after prior radiation therapy; or

4. Used as a single agent for recipients with surgically inaccessible recurrent or progressive Meningioma when radiation is not possible

e. Cervical Cancer

1. Recipient has persistent, recurrent, or metastatic disease; and

a. Disease has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology; and

1. Used in combination with paclitaxel and either cisplatin, carboplatin, or topotecan; or

2. Used in combination with pembrolizumab, paclitaxel, and cisplatin or carboplatin; and

a. Tumor expresses PD-L1 (Combined Positive Score [CPS] greater than or equal to 1) as determined by an FDA-approved or CLIA compliant test; or

3. Recipient has small cell neuroendocrine carcinoma of the cervix (NECC); and

a. Used as subsequent therapy; and

1. Used in combination with paclitaxel and either cisplatin, carboplatin, or topotecan; or

2. Used in combination with pembrolizumab, paclitaxel, and cisplatin or carboplatin; and

a. Tumor expressed PD-L1 (Combined Positive Score [CPS] greater than or equal to one) as determined by an FDA-approved or CLIA compliant test.

f. Colorectal Cancer (CRC)

1. Will not be used as part of adjuvant treatment; and

a. Used in combination with a fluoropyrimidine (e.g., five-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; or

b. Used in combination with a fluoropyrimidine-irinotecan-or fluoropyrimidine-oxaliplatin-based regimen (not used first line) as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab-containing regimen; or

c. Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease after progression on all available regimens.

g. Appendiceal Adenocarcinoma – Colon Cancer

1. Used as initial therapy for advanced or metastatic disease; and

a. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/5-FU or capecitabine) based regimen; or

2. Used as subsequent therapy for progression of advanced or metastatic disease; and

a. Used in combination with a fluoropyrimidine (e.g., five-fluorouracil/five-FU or capecitabine) or irinotecan-based regimen following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy; or

b. Used in combination with trifluridine and tipiracil after progression on all available regimens.

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Used as single agent therapy for recurrent or metastatic disease that has progressed or prior cytotoxic chemotherapy; or

2. Used in combination with carboplatin and paclitaxel for advanced and recurrent disease; or

3. Used in combination with paclitaxel and carboplatin as adjuvant therapy; and

a. Recipient has advanced and recurrent stage III-IV endometroid adenocarcinoma.

i. Hepatocellular Carcinoma (HCC)

1. Used as first-line therapy in combination with atezolizumab; and

2. Recipient has Child-Pugh Class A disease; and

a. Recipient has unresectable or metastatic disease; or

b. Recipient has liver confined disease inoperable by performance status, comorbidity or with minimal or uncertain extrahepatic-disease; or

c. Recipient has extensive liver tumor burden.

j. Malignant Peritoneal Mesothelioma (MPeM)

1. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Recipient has unresectable diffuse disease; or

2. Recipient has unresectable recurrent benign multi-cystic or well-differentiated papillary disease; or

2. Used as subsequent therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Immunotherapy was administered as first-line treatment; or

b. Used in combination with atezolizumab.

k. Malignant Pleural Mesothelioma (MPM)

1. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible) followed by single agent maintenance bevacizumab; and

1. Recipient has unresectable clinical stage I-IIIA disease and epithelioid histology; or

2. Recipient has clinical stage IIIB or IV disease, sarcomatoid or biphasic histology, or medically inoperable tumors; or

2. Used as subsequent therapy; and

b. Used in combination with pemetrexed and either cisplatin or carboplatin (if cisplatin ineligible); and

c. Immunotherapy was administered as first-line treatment.

l. Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

1. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

a. Used as first-line therapy; and

1. Used in combination with erlotinib for EGFR exon 19 deletion or L858R mutations; or

2. Used for one of the following:

   a. Recipients with a performance status (PS) less than or equal to one who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression less than one percent; or

   b. PD-L1 expression positive tumors (PD-L1 greater than or equal to one percent) that are negative for actionable molecular biomarkers; or

   c. Recipients with a PS less than or equal to one who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

3. Used in combination with one of the following:

   a. Carboplatin and paclitaxel; or

   b. Pemetrexed and either carboplatin or cisplatin in recipients with contraindications to PD-1 or PD-L1 inhibitor

   c. Atezolizumab, carboplatin, and paclitaxel; or

b. Used for subsequent therapy in recipients with a PS less than or equal to one; and

1. Used for one of the following:

   a. EGFR exon 19 deletion or L858R mutation, EGFR S7681, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement positive tumors and recipient received prior targeted therapy for those aberration

   b. BRAF V600E mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation or RET rearrangement positive tumors

   c. PD-L1 expression-positive (PD-L1 greater than or equal to one percent) tumors that are negative for

actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; and

2. Used in combination with one of the following:

a. Carboplatin and paclitaxel in recipient with contraindications to PD-1 or PD-L1 inhibitors

b. Pemetrexed and either carboplatin or cisplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors

c. Atezolizumab, carboplatin, and paclitaxel (excluding use in recipients who have received prior PD-1/PD-L1 inhibitor therapy or who have EGFR exon 19 deletions or L858R mutations or ALK rearrangement positive tumors); or

c. Used as continuation maintenance therapy (bevacizumab must have been included in the recipients first-line chemotherapy regimen) in recipients who achieved a tumor response or stable disease after first-line systemic therapy; and

1. Used as a single agent; or

2. Used in combination with pemetrexed following a first-line bevacizumab/pemetrexed/platinum chemotherapy regiment; or

3. Used in combination with atezolizumab following a first line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen; or

d. Used as continuation of therapy following disease progression on erlotinib with bevacizumab; and

1. Recipient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases; and

2. Recipient has T790M negative disease.

m. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

1. Recipient has malignant stage II-IV sex cord-stromal tumors

a. Used a single agent therapy for clinically relapsed disease; or

2. Recipient has epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

b. Recipient has persistent or recurrent disease; and

1. Bevacizumab has not been used previously; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); and

a. Recipient has platinum sensitive disease; and

1. Used as a single agent; or

2. Used in combination niraparib; or

3. Used in combination with carboplatin and either gemcitabine, paclitaxel, or PEGylated liposomal doxorubicin; or

b. Recipient has platinum resistant disease; and

1. Used as a single agent; or

2. Used in combination with one of the following: oral cyclophosphamide, PEGylated liposomal doxorubicin, paclitaxel, or topotecan; or

c. Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in recipients who have received no prior chemotherapy; or

d. Used as maintenance therapy; and

1. Used following primary therapy including bevacizumab; and

a. Used as a single agent in recipients that are BRCA1/2 wild-type or unknown and homologous recombination (HR) proficient or status unknown (grade 2/3 endometrioid and high-grade serous histology only); or

b. Used in combination with Olaparib; and

1. Recipient is BRCA1/2 wild-type or unknown and HR deficient (grade 2/3 endometrioid and high-grade serous histology only), or

2. Recipient has a germline or somatic BRCA1/2 mutation (grade 2/3 endometrioid, high grade serous, clear cell, carcinosarcoma histology only), or

2. Used a single agent following recurrence therapy with chemotherapy plus bevacizumab for platinum-sensitive disease; or

3. Used in combination with paclitaxel and carboplatin for stable disease following neoadjuvant therapy as continued treatment (grade 2/3 endometrioid and high-grade serous histology only); or

e. Used as neoadjuvant therapy in combination with paclitaxel and carboplatin (grade 2/3 endometrioid and high-grade serous histology only); and

1. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; or

f. Used as adjuvant therapy in combination with paclitaxel and carboplatin; and

1. Recipient has pathologic stage II-IV disease; or

2. Used after interval debulking surgery (IDS) in recipients with a response or stable disease to neoadjuvant therapy (grade 2/3 endometrioid and high-grade serous histology only); and

a. Recipient is a poor surgical candidate or has a low likelihood of optimal cytoreduction.

n. Pediatric Central Nervous System (CNS) Cancers

1. Recipient is less than or equal to 18 years of age; and

2. Recipient has diffuse high-grade glioma; and

3. Used for palliation of recurrent or progressive disease (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant).

o. Renal Cell Carcinoma (RCC)

1. Used in combination with interferon alfa for metastatic disease; or

2. Recipient has metastatic or relapsed disease with non-clear cell histology; and

a. Used as a single agent; or

b. Used in combination with everolimus; or

c. Used in combination with erlotinib in recipients with advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC.

p. Small Bowel Adenocarcinoma

1. Recipient has advanced or metastatic disease; and

2. Used in combination with fluoropyrimidine-based regimen.

q. Soft Tissue Sarcoma

1. Used as a single agent for angiosarcoma; or

2. Used in combination with temozolomide for solitary fibrous tumor.

r. Vulvar Cancer

1. Used in combination with paclitaxel and cisplatin; and

2. Recipient has squamous cell carcinoma or adenocarcinoma; and

3. Recipient has unresectable, locally advanced, metastatic, or recurrent disease.

2. Dosage Limits

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

1. 100 mg/4 mL single-dose vial: three vials 21 days

2. 400 mg/16 mL single-dose vial: four vials per 21 days

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

1. Oncology Indications (J9035/Q5107/Q5118/J999/Q5126):

a. Small Bowel Adenocarcinoma/Ampullary Adenocarcinoma:

1. 60 billable units per 14 days

b. NSCLC, Cervical Cancer, HCC, Vulvar Cancer, MPM, & MPeM:

1. 170 billable units per 21 days

c. All other indications:

1. 120 billable units per 14 days

3. Recertification Request:

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

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: gastrointestinal perforations and fistulae, surgical/wound healing complications, necrotizing fasciitis, hemorrhage, arterial and venous thromboembolic events (ATE & VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, proteinuria, severe infusion-related reactions, ovarian failure, congestive heart failure (CHF), etc.; and

d. Adult CNS Cancers – symptom management (short-course therapy):

1. Coverage may not be renewed

e. Adult CNS Cancers – Oligodendroglioma, Glioblastoma, or Astrocytoma (in combination with carmustine, lomustine, or temozolomide):

1. Refer to Section III for criteria

f. Colorectal Cancer (after first-line bevacizumab-containing regimen):

1. Refer to Section III for criteria

g. MPM and MPeM (maintenance therapy):

1. Refer to Section III for criteria

h. Non-Squamous Non-Small Cell Lung Cancer (maintenance therapy or continuation therapy in combination with erlotinib):

1. Refer to Section III for criteria

i. Ovarian Cancer (maintenance therapy):

1. Refer to Section III for criteria

4. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. For Adult CNS Cancers (symptom management), coverage will be provided for 12 weeks and may not be renewed.

c. Recertification will be given for six months.

E. Darzalex® (daratumumab)

Therapeutic Class: Antineoplastic
Last Reviewed by the DUR Board: N/A

Darzalex® (daratumumab) are subject to prior authorization 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 of age; and

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies (i.e., daratumumab and hyaluronidase-fihj, isatuximab, etc,); and

   c. Multiple Myeloma

      1. Used in the treatment of newly diagnosed disease in recipients who are eligible for autologous stem cell transplant (ASCT) in combination with one of the following regimens:

         a. Lenalidomine and dexamethasone; or

         b. Bortezomib, melphalan, and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipient who are eligible for autologous stem cell transplant (ASCT) in combination with one of the following regimens:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. Bortezomib, thalidomide, and dexamethasone (VTd); or

         c. Carfilzomib, lenalidomide, and dexamethasone; or

         d. Cyclophosphamide, bortezomib, and dexamethasone; or

      3. Used for disease relapse after six months following primary induction therapy with the same regimen in combination with one of the following regiments:

         a. Lenalidomide and dexamethasone for non-transplant candidates; or

b. Cyclophosphamide, bortezomib, and dexamethasone; or

4. Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and one of the following:

a. Lenalidomide; or

b. Bortezomib; or

c. Carfilzomib; or

d. Cyclophosphamide and bortezomib; or

e. Selinexor; or

5. Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (bortezomic, carfilzomib, etc.); or

6. Used as single agent therapy; and

a. Recipient received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); or

b. Recipient is double-refractory to a proteasome inhibitor and immunomodulatory agent; or

7. Used as maintenance therapy for symptomatic disease in transplant candidates; and

a. Used as single agent therapy; and

1. Used after response to primary myeloma therapy; or

2. Used for response or stable disease following an autologous hematopoietic cell transplant (HCT); or

3. Used for response or stable disease following a tandem autologous or allogeneic HCT for high-risk patients.

d. Systemic Light Chain Amyloidosis

1. Used as single agent therapy; and

2. Used for the treatment of relapsed/refractory disease.

2. Dosage Limits

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

1. Darzalex 100 mg single dose vial for injection: up to three vials per dose

a. Weekly Weeks 1 to 8, then every two weeks 9-24, then every four weeks-week 25 onwards; or

2. Darzalex 400 mg single dose vial for injections: up to four vial per dose

a. Weekly weeks one to eight, then every two weeks 9-24, then every four weeks – week 25 onwards; or

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

1. Up to 180 billable units per dose

a. Weekly week one to eight, then every two weeks, week 9-24, then every four weeks – week 25 onwards.

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

1. Up to 180 billable units per dose

a. Weekly week one to eight, then every two weeks, week 9-24, then every four weeks – week 25 onwards.

3. Recertification Request

a. 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

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia, etc.; and

d. Multiple Myeloma

1. Use for newly diagnosed disease in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

2. Use for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

3. Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

4. Use for newly diagnosed disease in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

4. Prior Authorization Guidelines:

a. Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

b. Use for newly diagnosed multiple myeloma in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

c. Use for newly diagnosed or relapsed multiple myeloma in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

d. Use for newly diagnosed multiple myeloma in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

e. Initial approval will be given for six months.

f. Recertification will be given for six months.

F. Darzalex Faspro® (daratumumab and hyaluronidase-fihj)

Therapeutic Class: Antineoplastic – CD38 Specific Recombinant Monoclonal Antibody Agent
Last Reviewed by the DUR Board: N/A

Darzalex Faspro® (daratumumab and hyaluronidase-fihj) are subject to prior authorization 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 of age; and

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies (i.e., daratumumab, isatuximab, etc.); and

   c. Multiple Myeloma

      1. Used in the treatment of newly diagnosed disease in recipients who are ineligible for autologous stem cell transplant (ASCT) in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone; or

         b. Bortezomib, melphalan and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipients who are eligible for autologous stem cell transplant (ASCT) in combination with one of the following regiments:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. Bortezomib, thalidomide, and dexamethasone (VTd); or

         c. Carfilzomib, lenalidomide, and dexamethasone; or

         d. Cyclophosphamide, bortezomib, and dexamethasone; or

      3. Used for disease relapse after six months following primary induction therapy with the same regimen in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone for non-transplant candidates; or

b. Cyclophosphamide, bortezomib, and dexamethasone; or

4. Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and one of the following:

a. Lenalidomide; or

b. Bortezomib; or

c. Carfilzomib; or

d. Cyclophosphamide and bortezomib; or

e. Selinexor; or

5. Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib); or

6. Used as singe agent therapy; and

a. Recipient received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); or

b. Recipient is double-refractory to a proteasome inhibitor and an immunomodulatory agent.

d. Systemic Light Chain Amyloidosis

a. Recipient must not have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease; and

1. Used in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd); and

a. Used for newly diagnosed disease; or

b. Used as a repeat of initial therapy for relapsed/refractory disease if the recipient has been relapse-free for several years; or

2. Used as single agent therapy for the treatment of relapsed/refractory disease.

2. Dosage Limits

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

1. Darzalex Faspro 1,800 mg/30,000 unit single dose vial for injection: 1 vial per dose

a. Weekly weeks one to eight, then every two weeks, weeks nine-24, then every four weeks – week 25 onwards.

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

1. Up to 180 billable units per dose

a. Weekly Weeks one to eight, then every two weeks Weeks nine-24, then every four weeks Week 25 onwards.

3. Recertification Request

a. 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

b. Disease response with treatment as defined by stabilization of disease and decrease in size of tumor of tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity and other administration reactions (e.g., systemic administration-related reactions, local injection-site reactions, etc.), neutropenia, thrombocytopenia, cardiac toxicity, etc.; and

d. Multiple Myeloma

1. Used for newly diagnosed disease in combination with bortezomib, thalidomide and dexamethasone may not be renewed.

2. Used for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of two years of maintenance therapy.

3. Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

4. Use for newly diagnosed disease in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for a maximum of 32 weeks.

e. Systemic Light Chain Amyloidosis (newly diagnosed disease)

1. Use for newly diagnosed disease or repeat of initial therapy for relapsed/refractory disease (after being relapse-free for several years) in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) may be renewed for a maximum of two years of therapy.

4. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be given for six months.

c. Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.

d. Used for newly diagnosed multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone may be renewed for a maximum of 32 weeks.

e. Use for newly diagnosed or repeat of initial therapy for relapsed/refractory (after being relapse-free for several years) systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone may be renewed for up to a maximum of two years.

G. Elaprase® (idursulfase)

Therapeutic Class: Lysosomal Enzymes
Last Reviewed by the DUR Board: N/A

Elaprase® (idursulfase) are subject to prior authorization 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 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 (6MWT), 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); and

      2. Recipients 16 months to less than five years of age: spleen volume, liver volume, FVC, six-MWT, and/or urinary glycosaminoglycan (uGAG); and

   c. Universal Criteria

      1. Recipient does not have severe cognitive impairment; and

      2. 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 six mg/three mL vial: 10 vials per seven days.

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

      2. 60 billable units every seven days.

3. Recertification Request

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions including anaphylaxis, antibody development and serious adverse reactions in Hunter Syndrome recipients with severe genetic mutations, acute respiratory complications, acute cardiorespiratory failure, etc.; and

c. Recipient has demonstrated a beneficial response to therapy compared to pretreatment age-appropriate baseline values in one or more of the following:

1. Recipients five years of age or greater: stabilization or improvement in percent predicted FVC and/or six-MWT, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index), and/or uGAG levels; or

2. Recipients 16 months to less than five years of age: reductions in spleen volume and/or liver volume or stabilization/improvement in FVC and/or 6-MWT, and/or uGAG levels.

4. Prior Authorization Guidelines:

a. Initial approval will be given for 12 months.

b. Recertification will be given for 12 months.

H. Eylea® (aflibercept)

Therapeutic Class: Anti-angiogenic ophthalmic agents
Last Reviewed by the DUR Board: N/A

Eylea® (aflibercept) are subject to prior authorization 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 of age; and

   b. Universal Criteria

      1. Recipient is free of ocular and/or peri-ocular infections; and

      2. Recipient does not have active intraocular inflammation; and

      3. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., brolucizumab-dbll, ranibizumab, pegaptanib, bevacizumab, faricimab-svoa, etc.); and

      4. Recipients best corrected visual activity (BCVA) is measured at baseline and periodically during treatment; and

      5. Recipient has a definitive diagnosis of one of the following:

   c. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

   d. Macular Edema following Retinal Vein Occlusion (RVO)

   e. Diabetic Macular Edema (DME)

   f. Diabetic Retinopathy (DR)

2. Dosage Limit

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

      a. 2 mg injection: one vial per eye every 28 days.

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

      1. Diagnosis

         a. Neovascular age-related macular degeneration (AMD)

1. MU for Initial Dosing

a. Four units every 28 days x three doses.

2. MU for Maintenance Dosing

a. Four units every 28-56 days.

b. Macular edema following retinal vein occlusion (RVO)

1. MU for Initial Dosing

a. Four units every 28 days.

2. MU for Maintenance Dosing

a. Four units every 28 days.

c. Diabetic Macular Edema (DME)/ Diabetic Retinopathy (DR)

1. MU for Initial Dosing

a. Four units every 28 days x five doses.

2. MU for Initial Dosing

a. Four units every 28-56 days.

3. Recertification Request:

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events: and

c. Recipient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition.

4. Prior Authorization Guidelines:

a. Initial approval will be given for 12 months.

b. Recertification will be given for 12 months.

I. Immune Globulins (immunoglobin)

Therapeutic Class: Immune Globulin
Last Reviewed by DUR Board: N/A

Immune Globulins (immunoglobulin) are subject to prior authorization 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 all the following criteria are met and documented:

   a. Baseline valyes for BUN and serum creatinine within 30 days of request; and

   b. Primary immunodeficiency (PID)/Wiskott – Aldrich Syndrome

      1. Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels, and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [list not all inclusive].

         a. Recipients IgG level is less than 200 mg/dL or both of the following:

            1. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

               a. Four or more ear infections within one year; or

               b. Two or more serious sinus infections; or

               c. Two or more months of antibiotics with little effect; or

               d. Two or more pneumonias within one year; or

               e. Recurrent or deep skin abscesses; or

               f. Need for intravenous antibiotics to clear infections; or

               g. Two or more deep-seated infections including septicemia; and

            2. The recipient has a deficiency in producing antibodies in response to vaccination; and

               a. Titers were drawn before challenging with vaccination; and

               b. Titers were drawn between four and eight weeks of vaccination.

c. IgG Subclass Deficiency

1. Recipient's IgG level is less than 400 mg/dL; and

2. Recipient has a history of recurrent infections; and

3. Recipient is receiving prophylactic antibiotic therapy.

d. Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP)

1. For acute disease state:

a. To manage acute bleeding due to severe thrombocytopenia (platelet count less than 30 x 10(9)/L); or

b. To increase platelet counts prior to invasive surgical procedures such as splenectomy (platelet count less than 20 x 10(9)/L).

c. Authorization will be given for one month only and cannot be renewed.

2. Chronic Immune Thrombocytopenia (CIT)

a. The recipient is at increased risk for bleeding as indicated by a platelet count less than 30 x 10(9)/L; and

b. History of failure, contraindication, or intolerance to corticosteroids; and

c. Duration of illness greater than six months.

e. Chronic Inflammatory Demyelination Polyneuropathy (CIDP)

1. Recipient's disease course is progressive or relapsing and remitting for greater than two months; and

2. Recipient has abnormal or absent deep tendon reflexes in upper or lower limbs; and

3. Electrodiagnostic testing indicating demyelination:

a. Partial motor conduction block in at least two motor nerves or in one nerve plus one other demyelination criterion listed here in at least one other nerve; or

b. Distal CMAP duration increase in at least one nerve plus one other demyelination criterion listed here in at least one other nerve; or

c. Abnormal temporal dispersion conduction must be present in at least two motor nerves; or

d. Reduced motor conduction velocity in at least two motor nerves; or

e. Prolonged distal motor latency in at least two motor nerves; or

f. Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least one other nerve; or

g. Prolonged F wave latency in at least two motor nerves; and

4. Recipient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; and

5. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

6. Initial approval will be given for three months.

f. Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

1. Recipient has severe disease (i.e., recipient requires assistance to ambulate); and

2. Onset of symptoms are recent (i.e., less than one month); and

3. Recipient has abnormal or absent deep tendon reflexes in upper or lower limbs; and

4. Recipient has diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; and

5. Approval will be granted for a maximum of two rounds of therapy within six weeks of onset.

6. Initial approval will be given for two months only and cannot be renewed.

g. Multifocal Motor Neuropathy

1. Recipient has progressive, focal, asymmetric limb weakness (without sensory symptoms) for greater than one month; and

2. Recipient has complete or partial conduction block or abnormal temporal dispersion conduction in at least two motor nerves; and

3. Recipient has normal sensory nerve conduction on all nerves tested: and

4. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

5. Initial approval will be given for three months.

h. HIV infected children: Bacterial control or prevention

1. Recipient age does not exceed 13 years of age; and

2. Recipients IgG level is less than 400 mg/dL.

i. Myasthenia Gravis

1. Recipient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; and

2. Recipient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); and

3. Recipient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); and

4. Recipient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.).

5. Initial approval will be valid for one course (one month) only and cannot be renewed.

j. Dermatomyositis/Polymyositis

1. Recipient has severe active disease; and

2. Recipient has proximal weakness in all upper and/or lower limbs; and

3. Diagnosis has been confirmed by muscle biopsy; and

4. Recipient has failed a trial of corticosteroids (i.e., prednisone); and

5. Recipient has failed a trial of an immunosuppressant (e.g., methotrexate, azathioprine, etc.); and

6. Must be used as part of combination therapy with other agents; and

7. Recipient has a documented baseline physical exam and muscular strength/function.

8. Initial approval will be given for three months.

k. Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas), and bone marrow transplant

1. Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation.

2. Treatment of antibody-mediated rejection of solid organ transplantation.

3. Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus).

l. Stiff-Person Syndrome

1. Recipient has anti-glutamic acid decarboxylase (GAD) antibodies; and

2. Recipient has failed at least two of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam; and

3. Recipient has a documented baseline on physical exam.

m. Allogeneic Bone Marrow or Stem Cell Transplant

1. Used for prevention of acute Graft-Versus-Host-Disease (aGVHD) or infection; and

2. Recipient's bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; and

3. Recipients IgG level is less than 400 mg/dL.

4. Initial approval will be given for three months.

n. Kawasaki's Disease

1. Initial approval will be valid for one course (one month) only and cannot be renewed.

o. Fetal Alloimmune Thrombocytopenia (FAIT)

1. Recipient has a history of one or more of the following:

a. Previous FAIT pregnancy; or

b. Family history of the disease.

c. Screening reveals platelet alloantibodies.

2. Initial approval will be given through the delivery date only and cannot be renewed.

p. Neonatal Alloimmune Thrombocytopenia (NAIT)

1. Initial approval will be valid for one course (one month) only and cannot be renewed.

q. Auto-immune Mucocutaneous Blistering Diseases

1. Recipient has been diagnosed with one of the following:

a. Pemphigus Vulgaris

b. Pemphigus Foliaceus

c. Bullous Pemphigoid

d. Mucous Membrane Pemphigoid (a.k.a. Cicatricial Pemphigoid)

e. Epidermolysis Bullosa Aquisita

f. Pemphigus Gestationis (Herpes gestationis)

g. Linear IgA Dermatotis; and

2. Recipient has severe disease that is extensive and debilitating; and

3. Diagnosis has been confirmed by biopsy; and

4. Recipient's disease is progressive; and

5. Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); and

6. Recipient has a documented baseline on physical exam.

r. Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL)

1. Used for prevention of infection; and

2. Recipient's IgG level is less than 400 mg/dL.

s. Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia or Multiple Myeloma

1. Recipients IgG level is less than 200 mg/dL or both of the following:

a. Recipient has a history of multiple hard to treat infections as indicated by at least one of the following:

1. Four or more ear infections within one year; or

2. Two or more serious sinus infections within one year; or

3. Two or more months of antibiotics with little effect; or

4. Two or more pneumonias within one year; or

5. Recurrent or deep skin abscesses; or

6. Need for intravenous antibiotics to clear infections; or

7. Two or more deep-seated infections including septicemia; and

b. The recipient has a deficiency in producing antibodies in response to vaccination: and

1. Titers were drawn before challenging with vaccination; and

2. Titers were drawn between four and eight weeks of vaccination.

t. Toxic Shock Syndrome

1. Initial approval be given for one course (one month) only and cannot be renewed.

u. Management of Immune-Checkpoint-Inhibitor Related Toxicity

1. Recipient has been receiving therapy with immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, dostarlimab, etc.); and

2. Recipient has one of the following toxicities related to their immunotherapy:

a. Severe (G3) or life-threatening (G4) bullous dermatitis as an as an adjunct to rituximab

b. Stevens-Johnson Syndrome (SJS)

c. Toxic epidermal necrolysis (TEN)

d. Severe (G3-4) myasthenia gravis

e. Transverse myelitis

f. Myocarditis as further intervention if no improvement within 24-48 hours of starting pulse-dose methylprednisolone

g. Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-dose methylprednisolone

h. Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids

i. Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone

j. Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present

k. Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

v. Management of CAR T-Cell-Related Toxicity

1. Recipient has been receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene, maraleucel, tisagenlecleucel, etc.); and

a. Used for the management of G4 cytokine release syndrome that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); or

b. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels less than 600 mg/dL and serious, persistent, or recurrent bacterial infections; or

1. Used as prophylactic therapy prior to receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagen autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

2. Recipient has hypogammaglobulinemia as confirmed by serum IgG levels less than or equal to 400 mg/dL and serious persistent, or recurrent bacterial infections.

w. Supportive Care after Rethymic transplant

1. Used as immunoglobulin replacement therapy in pediatric recipients with congenital athymia after surgical implantation of Rethymic; or

2. Used as re-initiation of treatment two months after stopping immunoglobulin replacement therapy in pediatric recipients who have an IgG trough level lower than normal range for age.

2. Dosage Limits

a. Dosing should be calculated using adjusted body weight if one or more following criteria are met:

1. Recipient's body mass index (BMI) is 30 kg/m(2) or more; or

2. Recipient's actual body weight is 20% higher than his or her ideal body weight (IBW).

3. Recertification Request:

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include renal dysfunction and acute renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions/transfusion-related acute lung injury (TRALI), hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, volume overload, etc.; and

c. BUN and serum creatinine have been obtained within the last six months and the concentration and rate of infusion have been adjusted accordingly; and

d. Recipient meets the disease-specific criteria identified below:

e. Primary Immunodeficiency (PID)

1. Disease response as evidence by one or more of the following:

a. Decrease in the frequency of infection.

b. Decrease in the severity of infection.

f. IgG Subclass Deficiency

1. Disease response as evidenced by one or more of the following:

a. Decrease in the frequency of infection

b. Decrease in the severity of infection; and

2. Recipient is at a decreased risk of infection as a result of treatment necessitating continued therapy.

g. Chronic Immune Thrombocytopenia/ITP

1. Disease response as indicated by the achievement and maintenance of a platelet count of greater than or equal to 30 x 10(9)/L and at least doubling the baseline platelet count.

h. Chronic Inflammatory Demyelinating Polyneuropathy

1. Renewals will be authorized for recipients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

i. Guillain-Barre Syndrome (Acute Inflammatory polyneuropathy)

1. May not be renewed.

j. Multifocal Motor Neuropathy

1. Renewals will be authorized for recipients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

k. HIV infected children: Bacterial control or prevention

1. Disease response as evidenced by one or more of the following:

a. Decrease in the frequency of infection

b. Decrease in the severity of infection; and

2. Recipient continues to be at an increased risk of infection necessitating continued therapy as evidenced by an IgG level less than 400 mg/dL.

l. Myasthenia Gravis

1. May not be renewed.

m. Dermatomyositis/Polymyositis

1. Recipient had an improvement from baseline on physical exam and/or muscular strength and function.

n. Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas), and bone marrow transplant

1. Disease response as evidenced by one or more of the following:

a. Decrease in the frequency of infection

b. Decrease in the severity of infection; and

2. Recipient is at a decreased risk of infection as a result of treatment necessitating continued therapy.

o. Stiff Person Syndrome

1. Documented improvement from baseline on physical exam.

p. Allogeneic Bone Marrow or Stem Cell Transplant

1. Patients IgG trough is less than 400 mg/dL.

q. Kawasaki's Disease

1. May not be renewed.

r. Fetal Alloimmune Thrombocytopenia (FAIT)

1. Authorization is valid through the delivery date only and cannot be renewed.

s. Neonatal Alloimmune Thrombocytopenia

1. May not be renewed.

t. Auto-Immune Mucocutaneous Blistering Diseases

1. Documented improvement from baseline on physical exam.

u. Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), or Multiple Myeloma

1. Disease response as evidenced by one or more of the following:

   a. Decrease in the frequency of infection

   b. Decrease in the severity of infection; and

2. Recipient is at a decreased risk of infection as a result of treatment necessitating continued therapy.

v. Toxic Shock Syndrome

1. May not be renewed.

w. Management of Immune Checkpoint Inhibitor related Toxicity

1. May not be renewed.

x. Management of CAR T-Cell-Related Toxicity

1. Recipient is still receiving treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); and

2. Recipient has serum IgG levels less than 600 mg/dL.

y. Supportive Care after Rethymic transplant

1. Renewals for use as initial immunoglobulin replacement therapy will be authorized until all of the following criteria are met:

   a. Recipient is no longer on immunosuppression (at least ten percent of CD3+ T cells are naïve in phenotype); and

   b. Recipient is at least nine months post-treatment; and

   c. Recipient's phytohemagglutinin (PHA) response within normal limits; or

2. Renewals for use as re-initiation of treatment after stopping immunoglobulin replacement therapy for recipients with an IgG trough level lower than normal range will be continued for one year before being retested using the above guidelines.

4. Prior Authorization Guidelines:

a. Initial and renewal authorization periods vary by specific covered indication.

b. Unless otherwise specified, the initial approval will be given for six months.

c. Recertification will be approved for 12 months.

J. Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)

Therapeutic Class: Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1)
Last Reviewed by DUR Board: N/A

Antineoplastic-Anti-Programmed Cell Death Receptor-1 (PD-1) are subject to prior authorization 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. Jemperli® (dostarlimab-gwly)

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

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

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, nivolumab/relatlimab-rmbw, etc.), unless otherwise specified; and

3. Mismatch Repair Deficient (dMMR/Microsatellite Instability-High (MSI-H) Cancer

a. Recipient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or CLIA-compliant test; and

b. Used as a single agent; and

c. Recipient has, but is not limited to, one of the following cancers:

1. Endometrial Carcinoma

a. Recipient does not have endometrial sarcoma (excluding carcinosarcoma); and

b. Used for advanced or recurrent disease; and

c. Disease has progressed on or following prior treatment with a platinum-containing regimen.

2. Ampullary Adenocarcinoma

a. Used as subsequent therapy for recurrent or advance disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

3. Breast Cancer

a. Used for recurrent unresectable or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

4. Appendiceal Adenocarcinoma – Colon Cancer

a. Used as subsequent therapy for advanced or metastatic disease; and

b. Disease has progressed following treatment with oxaliplatin-, irinotecan- and/or fluropyrimidine-based therapy.

5. Colorectal Cancer (CRC)

a. Used as subsequent therapy for advanced or metastatic disease; and

b. Disease has progressed following treatment with oxaliplatin-, irinotecan- and/or fluoropyrimidine-based therapy.

6. Esophageal and Esophagogastric Junction Cancer

a. Used as subsequent therapy for recipients who are not surgical candidates or who have unresectable locally advanced, recurrent, or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

7. Gastric Cancer (adenocarcinoma)

a. Used as subsequent therapy for recipients with locoregional disease who are not surgical candidates or who have unresectable locally advanced, recurrent, or metastatic disease; and

b. Disease has progressed on or following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

8. Occult Primary/Cancer of Unknown Primary (CUP)

a. Used in symptomatic recipients with performance status (PS) 1-2 or asymptomatic recipients with PS 0 and aggressive recurrent or advanced disease; and

b. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

c. Disease has progressed on or following prior treatment; and

d. Recipient has no satisfactory alternative treatment options; and

e. Recipient has one of the following:

1. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated.

2. Lung nodules or breast marker-negative pleural effusion.

3. Resectable liver disease.

4. Peritoneal mass or ascites with non-ovarian histology.

5. Retroperitoneal mass of non-germ cell histology in selected recipients.

6. Unresectale liver disease or disseminated metastases.

9. Ovarian, Fallopian Tube, and Primary Peritoneal Cancers

a. Recipient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Mullerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; and

1. Recipient has persistent, recurrent, or advanced disease; and

2. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); or

b. Recipient has Low-Grade Serous Carcinoma; and

1. Recipient has recurrent or advanced tumors.

10. Small Bowel Adenocarcinoma

a. Used for advanced or metastatic disease; and

1. Used for initial therapy in recipient with prior oxaliplatin exposure in the adjuvant treatment setting or with a contraindication to oxaliplatin; or

2. Used as subsequent therapy in recipients without prior oxaliplatin exposure in the adjuvant treatment setting and without a contraindication to oxaliplatin.

b. Dosage Limits

1. Administer 500 mg intravenously every three weeks for doses one through four, followed by subsequent doses of 1,000 mg every six weeks (dose five begins three weeks after the fourth dose) until disease progression or unacceptable toxicity.

c. Recertification Request:

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

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

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

d. Prior Authorization Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

2. Keytruda® (pembrolizumab)

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

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

2. Universal Criteria

a. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplumab, avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab-rmbw, etc.), unless otherwise specified; and

3. Anal Carcinoma

a. Recipient has metastatic squamous cell carcinoma; and

b. Used as a single agent for subsequent therapy.

4. Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

a. Used as single agent; and

1. Recipient is at least six months of age; and

2. Recipient has relapsed or refractory disease; and

3. Recipient does not require urgent cytoreductive therapy; or

b. Used in combination with brentuximab vedotin; and

1. Recipient is at least six months to 39 years of age; and

2. Used as consolidation/additional therapy in recipients who achieve a partial response after therapy for relapsed or refractory disease.

5. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

1. Recipient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasice bladder cancer (NMBIC) defined as one of the following:

a. Persistent disease despite adequate BCG therapy

b. Disease recurrence after an initial tumor free state following an adequate BCG course of therapy

c. T1 disease following a single induction course of BCG therapy; and

d. Recipient has carcinoma in situ (CIS); and

e. Recipient is ineligible for or has elected not to undergo cystectomy; or

2. Recipient has one of the following diagnoses:

a. Locally advanced or metastatic urothelial carcinoma; or

b. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder

c. Metastatic or local bladder cancer recurrence post-cystectomy

d. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)

e. Primary carcinoma of the urethra that is stage T3-4 cN1-2 or cN1-2 with palpable inguinal lymph nodes (first-line therapy only)

f. Metastatic upper genitourinary (GU) tract tumors

g. Metastatic urothelial carcinoma of the prostate; and

h. Used for disease that progressed during or following platinum-containing chemotherapy; or

i. Used as second-line treatment after chemotherapy other than a platinum; or

j. Used as first-line therapy in cisplatin-ineligible recipients; and

1. Recipient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible).

6. Triple-Negative Breast Cancer

a. Recipient has recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used in combination with chemotherapy; and

2. Tumor expresses PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has high-risk early-stage disease; and

1. Used as neoadjuvant therapy in combination with chemotherapy; and

2. Used as adjugvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy.

7. Adult Central Nervous System (CNS) Cancer

a. Used as a single agent; and

b. Primary tumor is due to BRAF non-specific melanoma or PD-L1 positive non-small cell lung cancer (NSCLC); and

1. Used as initial treatment in recipients with small asymptomatic brain metastases; or

2. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

3. Used for recurrent limited brain metastases; or

4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options.

8. Pediatric Central Nervous System (CNS) Cancers

a. Recipient is less than or equal to 18 years of age; and

b. Recipient has hypermutated diffuse high-grade glioma; and

1. Used for recurrent or progressive disease as a single agent (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); or

2. Used as adjuvant therapy (excluding diffuse midline glioma, H3 K27-altered or pontine location); and

a. Recipient is less than three years of age and used as a single agent; or

b. Recipient is greater than or equal to three years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide.

9. Cervical Cancer

a. Recipient has persistent, recurrent, or metastatic disease; and

b. Tumor expressed PD-L1 (CPS greater than or equal to one) as determined by an FDA-approved or CLIA-compliant test; and

1. Used as a single agent; and

a. Disease has progressed on or after chemotherapy; or

2. Used in combination with chemotherapy.

10. Esophageal or Gastroesophageal Junction Cancer:

a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

1. Used in combination with platinum-and fluoropyrimidine-based chemotherapy; and

   a. Used as first-line therapy; or

2. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

   a. Used as first-line therapy for HER2-positive disease; and

   b. Recipient has adenocarcinoma; or

      1. Used as a single agent; and

         a. Recipient has squamous cell carcinoma; and

         1. Tumor expresses PD-L1 (CPS greater than or equal to 10) as determined by an FDA-approved or CLIA compliant test; and

         2. Recipient progressed after one or more prior lines of systemic therapy.

11. Gastric Cancer

   a. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; and

   b. Recipient has adenocarcinoma; and

   c. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and

   d. Used as first-line therapy for HER2-positive disease.

12. Gestational Trophoblastic Neoplasia

   a. Used as a single agent or multiagent chemotherapy-resistant disease; and

      1. Recipient has intermediate placental site trophoblastic (PSTT) or epithelioid trophoblastic tumor (ETT); and

         a. Used for recurrent or progressive disease; and

         b. Recipient has previously treated with a platinum-based regimen; or

2. Recipient has high risk disease (i.e., greater than or equal to seven prognostic score or stage IV disease).

13. Squamous Cell Carcinoma of the Head and Neck (SCCHN)

a. Recipient has Cancer of the Nasopharynx; and

1. Used in combination with cisplatin and gemcitabine; and

b. Recipient has Very Advanced Head and Neck Cancer; and

1. Recipient has nasopharyngeal cancer; and

a. Recipient has a performance status 0-1; and

b. Used in combination with cisplatin and gemcitabine; and

c. Used for one of the following:

1. Unresectable locoregional recurrence with prior radiation therapy (RT)

2. Unresectable second primary with prior RT

3. Unresectable persistent disease with prior RT

4. Recurrent/persistent disease with distant metastases; or

2. Recipient has NON-nasopharyngeal cancer; and

a. Recipient is unfit for surgery or has locally advanced disease; and

1. Used as a single agent as first-line therapy in recipients with a performance status (PS) 3; and

2. Tumor expresses PD-L1 (CPS greater than or equal to one) as determined by an FDA-approved or CLIA-compliant test; or

b. Recipient has unresectable, recurrent, persistent, or metastatic disease; and

1. Used as a single agent; and

a. Tumor expresses PD-L1 (CPS greater than or equal to one) as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; or

2. Used in combination with fluorouracil and a platinum chemotherapy agent or in combination with docetaxel and either carboplatin or cisplatin; and

a. Recipient has a performance status zero through one.

14. Hepatocellular Carcinoma (HCC)

a. Used as a single agent; and

b. Recipient was previously treated with sorafenib; and

c. Recipient has Child-Pugh Class A liver impairment (i.e., excluding Child-Pugh Class B and C).

15. Adult Classical Hodgkin Lymphoma (cHL)

a. Recipient has relapsed or refractory disease; and

1. Used as a single agent; or

2. Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin); or

b. Used as a palliative therapy in recipients greater than 60 years of age; and

1. Recipient has relapsed or progressive disease after high-dose therapy (HDT)/autologous stem cell transplantation (ASCT); or

2. Recipient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; or

3. Recipient is post-allogeneic stem-cell transplant.

16. Pediatric Classical Hodgkin Lymphoma

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

b. Used as a single agent; and

1. Recipient has refractory disease; or

2. Recipient has relapsed disease; and

a. Used after two or more prior lines of therapy; or

b. Used as subsequent therapy in recipients heavily pretreated with platinum or anthracycline-based chemotherapy; or

c. Used as subsequent therapy in recipients with an observed decreased in cardiac function.

17. Renal Cell Carcinoma (RCC)

a. Recipient has clear cell histology; and

1. Used in combination with axitinib or lenvatinib; and

a. Used as first-line therapy for advanced, relapsed, or stage IV disease; or

b. Used as subsequent therapy for relapsed or stage IV disease; or

2. Used as a single agent; and

a. Used as adjuvant therapy; and

1. Recipient has undergone a nephrectomy prior to receiving treatment; and

a. Recipient has stage II disease with grade four tumors (with or without sarcomatoid features); or

b. Recipient has stage III disease; or

2. Recipient has a metastasectomy within one year of having undergone a nephrectomy for relapsed or stage IV disease; or

a. Recipient has non-clear cell histology; and

b. Used as single agent for relapsed or stage IV disease.

18. Cutaneous Melanoma

a. Used as first-line therapy as a single agent for unresectable or metastatic disease; or

b. Used as initial treatment of limited resectable disease; and

1. Used as a single agent; and

a. Recipient has stage III disease with clinical satellite/in-transit metastases; or

b. Recipient has local satellite/in-transit recurrence; or

c. Used as subsequent therapy for unresectable or metastatic disease after disease progression or maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafen/binimetinib, etc.); and

1. Used as a single agent; and

a. Anti-PD-1 therapy was not previously used; or

b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior anti-PD-1 therapy, but subsequently have disease progression/relapse greater than three months after treatment discontinuation; or

2. Used in combination with ipilimumab; and

a. Used after progression on single-agent anti-PD-1 therapy and combination ipilimumab/anti-PD-1 therapy was not previously used; or

b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination ipilimumab/anti-PD-1 therapy, but subsequently have disease progression/relapse greater than three months after treatment discontinuation; or

e. Used as a single agent for adjuvant treatment; and

1. Recipient has stage IIB or IIC melanoma following complete restriction; and

a. Recipient is at least 12 years of age; or

2. Recipient has stage III disease; and

a. Used following complete resection; and

1. Recipient is at least 12 years of age; or

b. Recipient has lymph node involvement and has undergone complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; or

c. Recipient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision; or

3. Recipient has local satellite/in-transit recurrence and has NED after complete excision; or

4. Recipient has undergone TLND and/or complete excision of disease limited to nodal recurrence; or

5. Recipient has oligometastatic disease and NED after receiving metastasis-directed therapy (e.g., stereotactic ablative therapy or complete resection) or systemic therapy.

19. Uveal Melanoma

a. Used as a single parent; and

b. Recipient has distant metastatic disease.

20. Merkel Cell Carcinoma (MCC)

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

b. Used as a single agent; and

1. Recipient has recurrent disease and both curative surgery and curative radiation therapy are not feasible; or

2. Recipient has recurrent locally advanced or metastatic disease.

21. Adrenal Gland Tumors

a. Recipient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); and

b. Used with or without mitotane.

22. Non-Small Cell Lung Cancer (NSCLC)

a. Used for stage III disease; and

1. Used as a first-line therapy as a single-agent in recipients who are not candidates for surgical resection or definitive chemoradiation; and

2. Used in recipients with tumors expressing PD-L1 (TPS greater than or equal to one percent) as determined by an FDA-approved or CLIA compliant test and with no EGFR or ALK genomic tumor aberrations; or

b. Used for stage IB (T2a greater than or equal to four centimeters), II, or IIIA disease; and

1. Used as adjuvant therapy as a single agent; and

2. Used following resection and platinum-based chemotherapy; or

c. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; and

1. Used as first-line therapy; and

a. Used for one of the following:

1. PD-L1 expression-positive (TPS greater than or equal to one percent) tumors, as detected by an FDA-approved or CLIA compliant test, that are negative for actionable molecular biomarkers

2. Recipients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression less than one percent

3. Recipients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

b. Used in combination with pemetrexed and either carboplatin or cisplatin for non-squamous cell historlogy; or

c. Used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology; or

d. Used as single agent therapy (for PD-L1 expression-positive tumors only); or

2. Used as subsequent therapy; and

a. Used in recipients with tumors expressing PD-L1 (TPS greater than or equal to one percent) as determined by an FDA-approved or CLIA compliant test; and

1. Used as single agent therapy; or

b. Used for one of the following:

1. Recipients with PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy; EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719x-positive tumors, ALK rearrangement, or ROS1 rearrangement

2. Recipients with PS 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET Exon 14 skipping, or RET rearrangement; and

c. Used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology; or

d. Used in combination with pemetrexed and either carboplatin or cisplatin for non-squamous cell histology; or

3. Used as continuation maintenance therapy in recipients who have achieved tumor response or table disease following initial therapy; and

a. Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for non-squamous cell histology; or

b. Used as a single agent following a first-line pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology; or

c. Used as a single agent following a first-line pembrolizumab monotherapy regimen.

23. Primary Cutaneous Lymphomas

a. Used as a single agent; and

1. Recipient has Mycosis Fungoides/Sezary Syndrome; and

a. Used as primary therapy or as subsequent therapy for relapsed or persistent disease; and

1. Recipient has stage III Mycosis Fungoides or stage IV Sezary Syndrome; or

2. Recipient has generalized cutaneous or extracutaneous lesions with large cell transformation (LCT); or

b. Used as subsequent therapy for disease refractory to multiple previous therapies; or

2. Recipient has primary cutaneous CD30+ T-Cell lymphoproliferative disorders; and

a. Used for relapsed or refractory disease; and

b. Used for primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional node (N1) (excludes systemic ALCL).

24. Small Cell Lung Cancer (SCLC)

a. Used as subsequent therapy as a single agent; and

1. Disease has relapsed following a complete or partial response or stable disease with primary treatment (excluding use in recipients who progressed on maintenance atezolizumab or durvalumab at time of relapse); or

2. Recipient has primary progressive disease.

25. Soft Tissue Sarcoma

a. Used as a single agent; and

1. Recipient has alveolar soft part sarcoma (ASPS); or

2. Recipient has cutaneous angiosarcoma; or

b. Used in combination with axitinib; and

1. Recipient has alveolar soft part sarcoma (ASPS).

26. Cutaneous Squamous Cell Carcinoma (cSCC)

a. Used as a single agent; and

1. Recipient has locally advanced, recurrent, or metastatic disease that is not curable by surgery or radiation; or

2. Recipient has unresectable, inoperable, or incompletely resected regional disease or new regional disease that is not curable by radiation therapy.

27. Extranodal NK/T-Cell Lymphomas

a. Used as a single agent for relapsed or refractory disease; and

b. Disease progressed following additional treatment with an alternative asparaginase-based combination chemotherapy regimen not previously used; and

c. Participation in a clinical trial is unavailable.

28. Thymic Carcinoma

a. Used as a single agent: and

1. Used as first-line therapy for unresectable, locally advanced, or metastatic disease in recipients who are unable to tolerate first-line combination regimens; or

2. Used as postoperative treatment in recipients who are unable to tolerate first-line combination regimens; or

3. Used as second-line therapy for unresectable or metastatic disease.

29. Endometrial Carcinoma (Uterine Neoplasms)

a. Recipient has advanced, recurrent, or metastatic disease that is mismatch repair proficient (pMMR) as determined by an FDA-approved or CLIA-compliant test or not microsatellite instability-high (MSI-H); and

b. Disease has progressed following prior systemic therapy; and

c. Used in combination with Lenvatinib.

30. Vulvar Cancer

a. Used as a single agent; and

b. Recipient has adrenocarcinoma or squamous cell carcinoma; and

c. Recipient has advanced, recurrent, or metastatic disease; and

d. Tumor expresses PD-L1 (CPS greater than or equal to one) as determined by and FDA-approved or CLIA-compliant test; and

e. Used as second-line therapy for disease progression on or after chemotherapy.

31. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Cancer

a. Recipient has at least six months of age; and

b. Used as a single agent; and

c. Recipient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA compliant test; and

d. Pediatric recipients must not have a diagnosis of MSI-H central nervous system cancer; and

e. Recipient has, but is not limited to, one of the following cancers:

1. Colorectal Cancer

a. Used for unresectable or medically inoperable, advanced, or metastatic disease; or

2. Appendiceal Adenocarcinoma – Colon Cancer

a. Used as initial therapy for advanced or metastatic disease; or

b. Used as subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy.

3. Pancreatic Adenocarcinoma

a. Used as subsequent therapy for locally advanced or metastatic disease after progression; or

b. Used for recurrent or metastatic disease after resection; or

c. Used as first-line therapy for metastatic disease; or

d. Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and no disease progression after at least four to six months of first-line therapy in recipients with good performance status (i.e., ECOG PS 0-1).

4. Bone Cancer (Ewing Sarcoma, Chordoma [chondroid or conventional histology], Chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or Osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma])

   a. Used for unresectable or metastatic disease that has progressed following prior treatment; and

   b. Recipient has no satisfactory alternative treatment options.

5. Gastric Cancer (Adenocarcinoma) or Esophageal/Gastrophageal Junction Adenocarcinoma or Squamous Cell Carcinoma

   a. Used as subsequent therapy for recipients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.

6. Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Cancers)

   a. Used for persistent or recurrent disease; and

   b. Recipients is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease).

7. Uterine Neoplasms (Endometrial Carcinoma)

   a. Used as second-line therapy for recurrent or metastatic disease; or

   b. Recipient has advanced disease that has progressed following prior systemic therapy in any setting and is not a candidate for curative surgery or radiation.

8. Penile Cancer

   a. Used as subsequent therapy for unresectable or metastatic disease that has progressed following prior treatment; and

   b. Recipient has no satisfactory alternative treatment options.

9. Vulvular Cancer

a. Recipient has adenocarcinoma or squamous cell carcinoma; and

b. Used as second-line therapy for advanced, recurrent, or metastatic diseae that progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

10. Testicular Cancer

a. Used as third-line therapy

11. Hepatobiliary Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)

a. Used as primary treatment for unresectable or metastatic disease; or

b. Used for unresectable or metastatic disease that has progressed on or after prior treatment.

12. Vulvar Cancer

a. Recipient has adenocarcinoma or squamous cell carcinoma; and

b. Used as second-line therapy for advanced, recurrent, or metastatic disease.

13. Cervical Cancer

a. Used as subsequent therapy for persistent, recurrent, or metastatic disease.

14. Small Bowel Adenocarcinoma

a. Used for advanced or metastatic disease; and

1. Used as initial therapy; or

2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

15. Ampullary Adenocarcinoma

a. Used as subsequent therapy for disease progression; or

b. Used as first-line therapy for unresectable localized or metastatic disease.

16. Breast Cancer

a. Used for recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

b. Recipient has progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

17. Occult Primary/Cancer of Unknown Primary (CUP)

a. Used in symptomatic recipients with PS one-two or asymptomatic recipients with PS 0 and aggressive disease; and

1. Recipient has squamous cell carcinoma; and

a. Recipient has multiple lung nodules; pleural effusion, or disseminated metastases; or

2. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

a. Recipient has one of the following:

1. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated

2. Lung nodules or breast marker-negative pleural effusion

3. Resectable liver disease

4. Peritoneal mass or ascites with non-ovarian histology

5. Retroperitoneal mass of non-germ cell histology in selected recipients

6. Unresectable liver disease or disseminated metastases.

18. Very Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)

a. Recipient has non-nasopharyngeal cancer; and

b. Recipient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease

19. Prostate Cancer

a. Recipient has castration-resistant metastatic disease; and

b. Recipient will continue androgen deprivation therapy (ADT); and

c. Recipient received prior docetaxel and prior novel hormone therapy (excluding recipients with visceral metastases).

20. Well-Differentiated Grade 3 Neuroendocrine Tumors

a. Recipient has progressed following prior treatment and has no satisfactory alternative treatment options; and

1. Recipient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55%], rapid growth rate, negative SSTR-based PET imaging); or

2. Recipient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [less than 55%], positive SSTR-based PET imaging); or

a. Recipient has locally advanced/metastatic disease with

unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55%], rapid growth rate, negative SSTR-based PET imaging); or

b. Recipient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [less than 55%], positive SSTR-based PET imaging); and

1. Recipient clinically significant tumor burden or evidence of disease progression.

21. Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm)

a. Recipient has locoregional unresectable or metastatic disease; and

b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options.

32. Tumor Mutational Burden-High (TMB-H) Cancer

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

b. Recipient has solid tumors that are tumor mutational burden-high (TMB-H0 [greater than or equal to 10 mutations/megabase 9mut/Mb)] as determined by an FDA-approved or CLIA-compliant test; and

c. Used as a single agent; and

d. Pediatric recipients must not have a diagnosis of TMB-H central nervous system cancer; and

e. Recipient has, but is not limited to, one of the following cancers:

1. Bone Cancer (Ewing Sarcoma, Chordoma [chondroid or conventional histology], Chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or Osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma])

a. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

b. Recipient has no satisfactory alternative treatment options.

2. Breast Cancer

a. Recipient has recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

b. Recipient has progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

3. Cervical Cancer

a. Used as subsequent therapy for unresectable or metastatic disease; and

b. Recipient has progressed following prior treatment; and

c. Recipient has no satisfactory alternative treatment options.

4. Gastric Cancer (Adenocarcinoma) or Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma

a. Used as subsequent therapy for recipients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.

5. Hepatobiliary Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)

a. Used for unresectable or metastatic disease that has progressed on or after prior systemic treatment.

6. Head and Neck Cancers

a. Salivary Gland Tumors

1. Used for recurrent metastatic disease in recipients with a PS zero to three; or

2. Used for unresectable locoregional recurrence or second primary with prior radiation therapy.

b. Cancer of the Nasopharynx

1. Used as subsequent therapy for oligometastatic or metastatic disease.

7. Thyroid Carcinoma

a. Anaplastic Carcinoma

1. Used as first- or second-line therapy for metastatic disease

b. Follicular Carcinoma, Papillary Carcinoma, Hurthle Cell Carcinoma

1. Recipient has progressive and/or symptomatic unresectable locoregional recurrent/persistent or metastatic disease not amenable to radioactive iodine (RAI) therapy.

c. Medullary Carcinoma

1. Recipient has unresectable locoregional or recurrent/persistent metastatic disease that is either symptomatic or progressing.

8. Uterine Neoplasms (Uterine Sarcoma [excluding low-grade endometrial stromal sarcoma], Endometrial Carcinoma)

a. Used as second-line therapy for unresectable or metastatic disease that progressed following prior treatment; and

b. Recipient has no satisfactory alternative treatment options.

9. Testicular Cancer

a. Used as third-line therapy

10. Occult Primary/Cancer of Unknown Primary (CUP)

a. Used in symptomatic recipients with PS one-two or asymptomatic recipients with PS zero and aggressive disease; and

1. Recipient has squamous cell carcinoma; and

a. Recipient has multiple lung nodules, pleural effusion, or disseminated metastases; or

2. Recipient has adenocarcinoma or carcinoma not otherwise specified; and

a. Recipient has one of the following:

b. Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated

c. Lung nodules or breast marker-negative pleural effusion

d. Resectable liver disease

e. Peritoneal mass or ascites with non-ovarian histology

f. Retroperitoneal mass of non-germ cell history in selected recipients

g. Unresectable liver disease or disseminated metastases.

11. Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Cancers)

a. Used for persistent or recurrent disease; and

b. Recipient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease).

12. Penile Cancer

a. Used as subsequent therapy for unresectable or metastatic disease that has progressed on previously approved lines of therapy.

13. Prostate Cancer

a. Used as subsequent therapy for unresectable or metastatic disease that has progressed on previously approved lines of therapy.

14. Well-Differentiated Grade 3 Neuroendocrine Tumors

a. Recipient has progressed following prior treatment and has no satisfactory alternative treatment options; and

1. Recipient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [greater than or equal to 55 percent], rapid growth rate, negative SSTR-based PET imaging); and

2. Recipient clinically significant tumor burden or evidence of disease progression.

15. Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm)

a. Recipient has locoregional unresectable or mestastatic disease; and

b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options.

16. Ampullary Adenocarcinoma

a. Used as subsequent therapy for disease progression; or

b. Used as first-line therapy for unresectable localized or metastatic disease.

17. Pancreatic Adenocarcinoma

a. Used as subsequent therapy for locally advanced or metastatic disease after progression; or

b. Used for recurrent or metastatic disease after resection; or

c. Used as first-line therapy for metastatic disease; or

d. Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and disease no progression after at least four to six months of first-line therapy in recipients with good performance status (i.e., ECOG PS zero to one).

18. Soft Tissue Sarcoma

a. Recipient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), cutaneous angiosarcoma, or undifferentiated sarcoma; and

b. Recipient progressed following prior treatment and has no satisfactory alternative treatment options; and

1. Used as subsequent therapy for advanced or metastatic Extremity/Body Wall, Head/Neck disease; or

2. Used as subsequent therapy for recurrent unresectable or recurrent stage IV Retroperitoneal/Intra-Abdominal disease.

b. Dosage Limits

1. Keytruda 100mg/four mL single use vial: 11 vials per 14-day supply.

c. Recertification Requests:

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

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

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse

reactions/rash, etc.), hepatotoxicity when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; and

4. For the following indications, recipient has not exceeded a maximum of twenty-four months of therapy:

   a. Adrenal Gland Tumors

   b. Anal Carcinoma

   c. Bladder Cancer/Urothelial Carcinoma

   d. Cervical Cancer

   e. Classical Hodgkin Lymphoma (cHL)

   f. CNS Cancer

   g. Cutaneous Melanoma (in combination with ipilimumab only)

   h. Cutaneous Squamous Cell Carcinoma (cSCC)

   i. Endometrial Carcinoma

   j. Esophageal/Gastroesophageal Junction Cancer

   k. Gastric Cancer

   l. Hepatocellular Carcinoma (HCC)

   m. Merkel Cell Carcinoma (MCC)

   n. MSI-H/dMMR Cancer

   o. Non-Small Cell Lung Cancer (NSCLC) (first-line or subsequent therapy)

   p. Primary Cutaneous Lymphomas

   q. Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

   r. Renal Cell Carcinoma (RCC) (first-line or subsequent therapy)

   s. Small Cell Lung Cancer (SCLC)

   t. Squamous Cell Carcinoma of the Head and Neck (SCCHN)

   u. Thymic Carcinoma

v. Tumor Mutational Burden-High (TMB-H) Cancer

w. Triple Negative Breast Cancer (recurrent unresectable or metastatic disease)

x. Uveal Melanoma

y. Vulvar Cancer

z. Cutaneous Melanoma (adjuvant treatment)

1. Recipient has not exceeded a maximum of twelve months of therapy.

aa. NSCLC (adjuvant treatment)

1. Recipient has not exceeded a maximum of twelve months of therapy.

bb. Triple Negative Breast Cancer (neoadjuvant treatment)

1. Recipient has not exceeded a maximum of twenty-four weeks of therapy.

cc. Triple Negative Breast Cancer (adjuvant treatment)

1. Recipient has not exceeded a maximum of twenty-seven weeks of therapy.

dd. Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy)

1. Refer to Section III for criteria.

ee. Continuation Maintenance Therapy for NSCLC

1. Refer to Section III for criteria.

d. Prior Authorization Guidelines:

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

K. Kadcyla® (ado-trastuzumab emtansine)

Therapeutic Class: Antineoplastic-Antibody Drug Conjugates (ADCs)
Last Reviewed by DUR Board: N/A

Kadcyla® (ado-trastuzumab emtansine) are subject to prior authorization 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 of age; and

   b. Universal Criteria

      1. Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

      2. Used as a single agent; and

      3. Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.); and

   c. Breast Cancer

      1. Recipient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved or CLIA-compliant test; and

         a. Used as adjuvant therapy; and

            1. Recipient has locally advanced or node positive disease; and

               a. Used for residual disease following completion of planned chemotherapy and mastectomy or breast-conserving surgery (BCS); or

               b. Used in recipients not considering pre-operative systemic therapy; or

            2. Recipient has inflammatory breast cancer; and

a. Used in recipients who had a response to preoperative systemic therapy, followed by surgery, and needs to complete planned chemotherapy; or

b. Recipient has residual disease following preoperative therapy; or

3. Recipient has early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based therapy; or

b. Recipient has metastatic or recurrent unresectable disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used as second-line therapy and beyond; or

c. Recipient has metastatic disease that recurred during or within six months of completing adjuvant therapy; and

1. Recipient previously received trastuzumab and a taxane, separately or in combination.

d. Central Nervous System (CNS) Cancer

1. Recipient has human epidermal growth factor receptor two (HER2)-positive* disease as determined by an FDA_approved or CLIA-compliant test; and

2. Used for the treatment of brain metastases in recipients with breast cancer; and

a. Used as initial treatment in recipients with small asymptomatic brain metastases; or

b. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or

c. Recipient has recurrent limited brain metastases; or

d. Used for recurrent extensice brain metastases with stable systemic disease or reasonable systemic treatment options.

e. Non-Small Cell Lung Cancer (NSCLC)

1. Recipient has ERBB2 (HER2) mutation positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy.

f. Head and Neck Cancer

1. Recipient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved or CLIA-compliant test; and

2. Recipient has salivary gland tumors; and

3. Used for one of the following:

a. Recurrent disease with distant metastases

b. Unresectable locoregional recurrence with prior radiation therapy (RT)

c. Unresectable second primary with prior RT.

2. Dosing Limits

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

1. Kadcyla 100 mg singe-dose vial: one vial every 21 days.

2. Kadcyla 160 mg single-dose vial: three vials every 21 days.

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

1. 480 billable units every 21 days.

3. Renewal Criteria:

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

b. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity, pulmonary toxicity (i.e., interstitial lung disease, pneumonitis), thrombocytopenia, neurotoxicity, infusion-related and hypersensitivity reactions, hemorrhage, extravasation at infusion site, etc.; and

d. Left ventricular ejection fraction (LVEF) obtained within the previous 3 months as follows:

1. Metastatic or Recurrent Breast Cancer: LVEF is >45% OR LVEF is 40% to ≤45% and absolute decrease is <10% from baseline; or

2. All other indications: LVEF is ≥50% OR LVEF is 45% to <50% and absolute decrease is <10% from baseline; and

e. Breast Cancer (adjuvant treatment)

1. Recipient has not exceeded a maximum of 14 cycles of therapy (42 weeks total).

L. Aranesp® (darbepoetin alfa)

Therapeutic Class: Recombinant Human Erythropoietins
Last Reviewed by DUR Board: January 19, 2023

Aranesp® (darbepoetin alfa) are subject to prior authorization 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 of age (unless otherwise specified); and

   b. Initiation of therapy Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct); and

   c. Universal Criteria

      1. Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); and

      2. Recipient has adequate iron stores as demonstrated by serum ferritin greater than or equal to 100 ng/mL (mcg/L) and transferrin saturation (TSAT) greater than or equal to 20% (measured within the previous three months for renewal); and

      3. Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; and

      4. Recipient does not have uncontrolled hypertension; and

   d. Anemia Due to Myelodysplastic Syndrome (MDS)

      1. Endogenous serum erythropoietin level of less than or equal to 500 mUnits/mL; and

      2. Recipient has lower risk disease (i.e., defined by IPSS-R [Very Low, Low, Intermediate]); and

      3. Recipient has symptomatic anemia.

   e. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

      1. Endogenous serum erythropoietin level of less than 500 mUnits/mL.

   f. Anemia Due to Chemotherapy Treatment

      1. Recipient is receiving concomitant myelosuppressive chemotherapy; and

2. Recipient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); and

3. There are a minimum of two additional months of planned chemotherapy.

g. Anemia Due to Chronic Kidney Disease (Non-Dialysis Recipients)

1. Recipient at least one month of age.

2. Dosage Limits

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

1. Aranesp 10 mcg prefilled syringe: one syringe up to every seven days

2. Aranesp 25 mcg vial or prefilled syringe: one vial or syringe up to every seven days

3. Aranesp 40 mcg vial or prefilled syringe: one vial or syringe up to every seven days

4. Aranesp 60 mcg vial or prefilled syringe: one vial or syringe up to every seven days

5. Aranesp 100 mcg vial or prefilled syringe: one vial or syringe up to every seven days

6. Aranesp 150 mcg prefilled syringe: one syringe up to every seven days

7. Aranesp 200 mcg vial or prefilled syringe: one vial or syringe up to every seven days

8. Aranesp 300 mcg vial or prefilled syringe: one vial or syringe up to every 14 days (MPN may be as frequent as every seven days)

9. Aranesp 500 mcg prefilled syringe: one syringe up to every 14 days

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

1. MDS (J0881 only): 500 billable units every 14 days

2. MPN (J0881 only): 300 billable units every seven days

3. CKD (Non-Dialysis Recipients):

a. Initial: 100 billable units every 14 days

b. Maintenance: 600 billable units every 28 days

4. Chemotherapy-induced: 600 billable units every 21 days

3. Recertification Requests:

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

b. Previous dose was administered within the past 60 days; and

c. Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; and

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in recipients with cancer, severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), etc; and

e. Anemia Due to Myelodysplastic Syndrome (MDS):

1. Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%

f. Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis:

1. Hemoglobin (Hb) less than 10 g/dL and/or Hematocrit (Hct) less than 30%

g. Anemia Due to Chemotherapy Treatment:

1. Refer to Section III for criteria

h. Anemia Due to Chronic Kidney Disease (Non-Dialysis Recipients):

1. Pediatric recipients: Hemoglobin (Hb) less than 12 g/dL and/or Hematocrit (Hct) less than 36%

2. Adult recipients: Hemoglobin (Hb) less than 11 g/dL and/or Hematocrit (Hct) less than 33%.

4. Prior Authorization Guidelines:

a. Initial approval will be given for 45 days.

b. Recertification will be given for 45 days.

M. Colony Stimulating Factors

Therapeutic Drug Class: Colony Stimulating Factors
Last Reviewed by DUR Board: January 19, 2023

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1. Pegfilgrastim

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

1. Prophylactic use in recipients with solid tumors or non-myeloid malignancy

a. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20%; or

b. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20% and one or more of the following co-morbidities:

1. Age is greater than or equal to 65 years receiving full dose intensity chemotherapy

2. Extensive prior exposure to chemotherapy

3. Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation

4. Persistent neutropenia (ANC less than or equal to 1000/mm(3))

5. Bone marrow involvement by tumor

6. Recipient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)

7. Recent surgery and/or open wounds

8. Poor performance status

9. Renal dysfunction (creatinine clearance less than 50 mL/min)

10. Liver dysfunction (elevated bilirubin greater than 2.0 mg/dL)

11. Chronic immunosuppression in the post-transplant setting, including organ transplant

2. Recipient who experience a neutropenic complication from a prior cycle of the same chemotherapy

3. Recipients acutely exposed to myelosuppressive doses from radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

4. Bone marrow transplantation (BMT) failure or engraftment delay

5. Peripheral blood progenitor cell (PBPC) mobilization and transplant

6. Wilms Tumor (Nephroblastoma)

a. Recipient has favorable histology disease; and

b. Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

b. Dosage Limits

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

a. Neulasta six mg prefilled syringe: one syringe per 14 days

b. Neulasta Onpro kit: one kit per 14 days

c. Fulphila six mg prefilled syringe: one syringe per 14 days

d. Udenyca six mg prefilled syringe: one syringe per 14 days

e. Ziextenzo six mg prefilled syringe: one syringe per 14 days

f. Nyvepria six mg prefilled syringe: one syringe per 14 days

g. Fylnetra six mg prefilled syringe: one syringe per 14 days

h. Stimufend six mg prefilled syringe: one syringe per 14 days

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

a. Acute Radiation Exposure

1. 12 billable units weekly x two doses

2. 12 billable units x two doses

b. All other indications:

1. 12 billable units per 14 days

c. Recertification Requests:

1. Coverage for all other indications can be renewed based upon the following criteria:

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia, etc.

d. Prior Authorization Guidelines:

1. Bone marrow transplantation (BMT) failure or engraftment delay: Coverage will be provided for one dose only and may not be renewed.

2. Peripheral blood progenitor cell (PBPC) mobilization and transplant: Coverage will be provided for one dose only and may not be renewed.

3. Initial approval will be given for four months.

4. Recertification will be given for four months.

N. Libtayo® (cemiplimab-rwlc)

Therapeutic Drug Class: Colony Stimulating Factors
Last Reviewed by DUR Board: January 19, 2023

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