Medicaid Services Manual
Transmittal Letter

July 30, 2024

To: Custodians of Medicaid Services Manual

From: Casey Angres
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

Background And Explanation

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to incorporate recommendations approved on April 18, 2024, by the Drug Utilization Review (DUR) Board. Several sections have been updated to include prior authorization criteria and/or quantity limits for Physician Administered Drugs (PAD), including the addition of Wainua™ in Section WWWW and the addition of Section XXXX for Sickle Cell drugs – Lyfgenia® and Casgevy®. Additionally, updates have been made to reflect the provisions of Senate Bill (SB) 156 passed during the 82nd (2023) Session which revises provisions relating to substance use disorders

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 August 5, 2024

Material Transmitted	Material Superseded
MTL OL Chapter 1200 – Prescribed Drugs	MTL 11/23 Chapter 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Section 1203.1B(1)(i)	**Standard PDL Exception Criteria**	Updates due to Senate Bill (SB) 156 passing during the 82nd (2023) Session that revises provisions relating to substance use disorders.
Appendix A Section OO	**Osteoporosis Agents**	Prolia®; Xgeva® (denosumab) Discussion and adoption of prior authorization criteria and/or quantity limits.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section WWWW	**Wainua™ (Eplontersen)**	Addition of new drug.
Appendix A Section XXXX	**Sickle Cell**	Addition of two new drugs – Lyfgenia® and Casgevy®.
Appendix B Section 5A	**Abraxane®; Paclitaxel Albumin-Bound**	Adoption of prior authorization criteria and/or quantity limits.
Appendix B Section B	**Anti-PD-1 Monoclonal Antibodies**	Bavencio® (avelumab); Libtayo® (cemiplimab-rwlc); Ocrevus® (ocrelizumab); Opdivo® (nivolumab); Imfinzi (durvalumab); Tecentriq® (atezolizumab) Discussion and adoption of prior authorization criteria and/or quantity limits.
Appendix B Section C	**Beovu® (brolucizumab-dbll)**	Adoption of prior authorization criteria and/or quantity limits.
Appendix B Section D	**Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™; Avzivi® (Bevacizumab)**	Adoption of prior authorization criteria and/or quantity limits.
Appendix B Section E	**Darzalex® (daratumumab)**	Adoption of prior authorization criteria and/or quantity limits.
Appendix B Section G	**Elaprase® (idursulfase)**	Adoption of prior authorization criteria and/or quantity limits.
Appendix B Section H	**Anti-Angiogenic Ophthalmic Agents:**	Eylea®; Eylea® HD (Intravitreal); Lucentis®; Byooviz™; Cimerli® (ranibizumab) Discussion and adoption of prior authorization criteria and/or quantity limits.

1203 POLICY

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

1203.1 COVERAGE AND LIMITATIONS

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

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

   a. American Hospital Formulary Service Drug Information;

   b. United States Pharmacopeia;

   c. DRUGDEX Information System; or

   d. Peer-reviewed medical literature.

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

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

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

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

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

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

2. Antirejection medications for organ transplants; and

3. Antihemophilic medications.

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

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

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

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

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

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

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

B. Standard PDL Exception Criteria

Drugs that have a "non-preferred" status are a covered benefit for recipients if they meet the coverage criteria.

1. Coverage and Limitations

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

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

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

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

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

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

   g. Psychotropic, Antidepressant Medication – Continuity of Care;

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

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

   i. The drug is being prescribed for a psychiatric condition and all of the following criteria have been met:

      1. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is supported by medical or scientific evidence; and the prescriber provides supportive clinical documentation demonstrating the approved diagnosis or evidence for use;

      2. The prescriber of the drug is one of the following:

         a. A psychiatrist

b. A physician assistant under the supervision of a psychiatrist;

c. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or

d. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph a., b., or c., if the closest practitioner listed in subparagraph a., b., or c., who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured, and

3. The prescriber believes based on the medical history of the insured, or reasonably expects each preferred drug within the same class to be ineffective at treating the psychiatric condition and the prescriber provides supportive clinical documentation demonstrating the reasoning for use of the drug.

4. For the purposes of this section, "psychiatric condition" means a mental disorder for which criteria are prescribed in the current version of the *Diagnostic and Statistical Manual of Mental Disorders*, published by the American Psychiatric Association

2. Prior Authorization forms are available through the Nevada Medicaid Pharmacy Portal at https://nevadamedicaid.magellanrx.com/home.

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight ~~loss~~ management.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

5. Drug Efficacy Study Implementation (DESI) list "Less than Effective Drugs": In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is identical, related or similar to the DESI

OO. Osteoporosis Agents

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)
Last Reviewed by DUR Board: ~~January 19, 2023~~April 18, 2024

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® (abaloparatide); 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://nevadamedicaid.magellanrx.com/provider/forms.

b. Prolia®; Xgeva® (denosumab)

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

2. Prolia

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

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

b. ~~2.~~ Recipient must not have hypocalcemia; and

c. ~~3.~~ Coverage is provided in the following conditions:

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

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

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

3. Osteoporosis in Men and Women

a. Women only: Recipient must be post-menopausal; 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 ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; or

2. T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; or

3. T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; and

c. Recipient has one of the following:

1. Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with

bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; or

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

4. Glucocorticoid-Induced Osteoporosis

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

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

5. Osteoporosis treatment and prevention in prostate cancer patients

a. Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-1 (or patient 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 recipients

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

c. Xgeva

Universal Criteria

1. Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; and

2. Recipient must not have hypocalcemia; and

Coverage is provided in the following conditions:

Prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors.

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

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

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

3. Giant Cell Tumor of the Bone

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

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

2. Disease is localized, recurrent, or metastatic and

a. Used as a single agent; or

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

4. Hypercalcemia of malignancy

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

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

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

2. Patient has a documented contraindication or intolerance to intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid.

5. Systemic Mastocytosis

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

b. Used as second line therapy; and

1. Recipient is not responding to bisphosphonate therapy; or

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

~~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. Coverage will be provided for 12 months and may be renewed.Prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

3. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.

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 humerus; and~~

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

6. Dosing Limits

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

1. Prolia 60 mg/1 mL single-dose prefilled syringe: 1 syringe every 6 months.

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

a. Load: 4 vials for one 28-day cycle.

b. Maintenance: 1 vial monthly.

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

1. Prolia – All indications:

a. 60 billable units every 6 months.

2. Xgeva – Giant Cell Tumor of Bone & Hypercalcemia of Malignancy.

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

~~1.~~ Maintenance:
120 billable units every 4 weeks.

3. Xgeva – Mone metastases from solid tumors, Multiple Myeloma, & Systemic Mastocytosis.

a. 120 billable units ever 4 weeks.

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

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

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

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

b. Prolia

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

a. Absence of fractures.

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

Osteoporosis in Men and Women only:

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

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

c. Xgeva

1. Disease response as indicated by the following:

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

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

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

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

~~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://nevadamedicaid.magellanrx.com/provider/forms.~~

4. ~~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.~~

~~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 12 months.~~

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

~~3. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.~~

~~5. Glucocorticoid-Induced Osteoporosis~~

~~a. Criteria for Physician Administered Drugs (PAD):~~

~~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.~~

6. ~~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~~

7. ~~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 12 months.~~

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

~~3.~~2. Prior Authorization forms are available at: https://nevadamedicaid.magellanrx.com/provider/forms.

~~d.~~ ~~c.~~ Forteo® (teriparatide)

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

WWWW. Wainua™ (Eplontersen)

Therapeutic Class: Antisense oligonucleotides
Last reviewed by DUR Board: April 18, 2024

Wainua™ (Eplontersen) 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. Initial Requests:

    a. The recipient is ≥ 18 years of age; and

    b. The recipient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy); and

    c. Medication prescribed by or in consultation with cardiologist, geneticist, neurologist, or other specialist with advanced knowledge in treating hereditary transthyretin-mediated amyloidosis; and

    d. The recipient has clinical manifestations of polyneuropathy; and

    e. Medication will NOT be used in combination with inotersen (Tegsedi®), tafamidis (Vyndamax®), tafamidis meglumine (Vyndaqel®), patisiran (Onpattro®), or vutrisiran (Amvuttra®); and

    f. The recipient does NOT have any of the following conditions:

        1. Severe renal impairment or end-stage renal disease; or

        2. Moderate or severe hepatic impairment; or

        3. Prior liver transplant; and

    g. Prescriber will supplement Vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of Vitamin A deficiency (e.g., night blindness, dry eyes) occur.

2. Quantity limit:

    a. One pen (45 mg) monthly.

3. Recertification requests:

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

    b. The recipient has demonstrated a clinical benefit based on improvement in clinical manifestations of polyneuropathy from baseline; and

c. The recipient has not experienced any treatment-restricting adverse effects (e.g., severe ocular symptoms related to Vitamin A deficiency).

4. Prior Authorization Guidelines:

a. Initial approval will be given for 12 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.

XXXX. Sickle Cell

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

Sickle Cell 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. Lyfgenia® (lovotibeglogene autotemcel):

   Initial requests:

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

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

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

   d. The recipient has symptomatic disease despite treatment with hydroxyurea and add-on therapy (e.g., crizanlizumab, voxelotor), unless contraindicated; and

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

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

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

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

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

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

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

      1. Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 or HIV-2), hepatitis B virus (HBV), hepatitis C (HCV); or

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

      3. Advanced liver disease; or

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

5. Any history of severe cerebral vasculopathy; and

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

Renewal requests:

1. Coverage not renewable.

2. Prior Authorization Guidelines:

a. MAX 1 treatment course per lifetime.

2. Casgevy® (exagamglogene autotemcel)

Universal criteria:

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

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

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

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

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

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

1. Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 or HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV); or

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

3. Advanced liver disease.

Renewal request:

a. Max 1 treatment course per lifetime.

3. Sickle cell disease (SCD)

Initial request:

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

b. The recipient experienced ≥ vaso-occlusive events/crises (VOE/VOC) per year for the previous two years; and

c. The recipient has symptomatic disease despite treatment with hydroxyurea and add-on therapy (e.g., crizanlizumab, voxelotor), unless contraindicated; and

d. Prescriber attestation that all necessary preparations prior to Casgevy® administration will be followed per package insert (including scheduled transfusions to target required Hb and HbS levels and discontinuation of disease modifying therapies).

Renewal requests:

a. Coverage not renewable.

4. Transfusion-dependent beta-thalassemia (TDT)

Initial request:

a. The recipient has had genetic testing confirming diagnosis β-thalassemia; and

b. The recipient has transfusion-dependent disease defined as a history of transfusions of ≥ 100 mL/kg/year or ≥ 10 units/year of packed red blood cells (pRBCs) in the previous 2 years; and

c. The recipient does not have severely elevated iron in the heart (i.e., recipients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction of [LVEF], < 45% by echocardiogram); and

d. Prescriber attestation that all necessary preparations prior to Casgevy® administration will be followed per package insert (including scheduled transfusions to target required Hb levels and discontinuation of disease modifying therapies).

Renewal requests:

a. Coverage not renewable.

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

A. Abraxane®; Paclitaxel Albumin Bound~~(paclitaxel protein-bound particles)~~

Therapeutic Class: Taxane Chemotherapy
Last Reviewed by the DUR Board: ~~N/A~~ April 18, 2024

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

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

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

b. Breast Cancer

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

1. Used as a single agent; and

b. ~~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. Disease is HER2-negative hormone receptor positive disease; and

1. Used as one of the following:

a. ~~Used~~ As a single agent

b. ~~or i~~In combination with carboplatin in recipient with high tumor burden, rapidly progressing disease, ~~and~~ or visceral crisis; and

b. ~~Disease is HER2-negative; and~~Used in one of the following treatment settings:

1. First-line therapy if no germline BRCA 1/2 mutation

2. Second-line therapy if not a candidate for fam-trastuzumab-deruxtecan-nxki

3. Third-line therapy and beyond; or

3. Patient has triple negative breast cancer (TNBC); and

a. Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease; or

b. Used as a single agent; and

1. Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; or

2. Used as subsequent therapy; or

c. Used in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, or visceral crisis; and

1. Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; or

2. Used as subsequent therapy; or

~~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~~

4. Recipient has HER2-positive disease; and

a. Used as fourth-line therapy and beyond in combination with trastuzumab; or

5. May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication.

~~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 one of the following:

         a. Recipients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 <1%

         b. Recipients with a PS 0-2 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression positive (≥1%)

         c. Recipients with a PS 0-1 who have tumors are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); and

      2. ~~1.~~ Used in combination with carboplatin and pembrolizumab ~~(~~for squamous cell histology~~)~~ or

      3. Used in combination with carboplatin and atezolizumab ~~(~~for non-squamous histology~~)~~; and

      4. Used in combination with tremelimumab-actl, durvalumab, and carboplatin (excluding use in patients with PD-L1 ≥50%); or

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

a. Used in recipients with tumors that have negative actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1≥%; ~~and~~or

b. Used in patients with tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 <1%; or

c. Used in patients with tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); or

~~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 in one of the following:

a. Patients with a 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

b. Patients with a PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; 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~~

c. ~~b.~~ Used in combination with carboplatin and pembrolizumab ~~(~~for squamous cell histology~~)~~ or

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

e. Used in combination with tremelimumab-actl, durvalumab, and carboplatin; or

~~2.~~ Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS 0-2); and

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

d. Used in recipients with tumors that are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; or

e. Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; or

4. Used as a single agent; and

a. Used for first progression after initial systemic therapy (if not previously used) in recipients with a PS 0-2; or

b. Used in recipients with a PS 2 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

c. Used in recipients with a PS 2 who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; or

d. Used in recipients with a PS 2 and PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy.

~~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, Fallopian Tube, and Primary Peritoneal Cancer ~~(Epithelial Ovarian/Fallopian Tube/Primary Peritoneal)~~

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

   a. Recipient has recurrent or persistent disease; and

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

~~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~~

   c. ~~a.~~ Used a single agent; and

      1. Recipient has platinum-resistant disease; and

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

   d. Recipient has one of the following:

      1. ~~Recipient has p~~Platinum-~~sensitive~~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 complete remission and relapse <6 months after completing chemotherapy; or ~~Used for relapse disease less than six months after complete remission from prior chemotherapy; or~~

2. Platinum-sensitive disease; and~~Recipient has platinum-sensitive disease; and~~

a. Used for complete remission and relapse ≥6 months after completing chemotherapy; or~~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. Patient has recurrent platinum-sensitive or platinum-resistant disease; and

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

2. ~~b.~~ Used in combination with carboplatin ~~for platinum-sensitive disease with~~ in recipients 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 fluoropyrimidine-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 local recurrencet disease in the pancreatic operative bed or recurrent 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; or 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

c. 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. Patient has metastatic or unresectable disease; and

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

3. a. Used as subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g.,

dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.).~~; 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 or unresectable disease.

~~h.~~ Endometrial Carcinoma (Uterine Neoplasms)

1. Used as a single agent therapy; and

2. Used as subsequent therapy for recurrent disease; and

3. ~~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

4. Patient has a negative skin test to paclitaxel (if available).

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.~~ Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)~~Hepatobiliary Adenocarcinoma (Intrahepatic /Extrahepatic Cholangiocarcinoma, Gallbladder)~~

1. Used in combination with gemcitabine for unresectable, resected gross residual (R2) 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 initial therapy after previous FOLFOX/CAPOX in the adjuvant setting within past 12 months or contraindication; or

   b. Used as subsequent therapy; or

   c. ~~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 in recipients intolerant to paclitaxel; 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

   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.

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

b. Used in combination with antiretroviral therapy (ART) for patients with HIV

~~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., equivocal or indeterminate 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.

~~m.~~ Cervical Cancer

1. Used as a single agent as subsequent therapy; and

a. Recipient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); or

b. Patient has recurrent or metastatic disease.

2. Dosing Limits

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

1. Abraxane®/Paclitaxel albumin-bound 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. Breast Cancer, Small Bowel Adenocarcinoma, Endometrial Cancer, Fallopian Tube & Primary Peritoneal Cancer, NSCLC, & Ovarian Cancer~~All other indications~~

1. 900 billable units per 21 days

c. Cutaneous & Uveal Melanoma, Pancreatic Adenocarcinoma, Cervical Cancer, Biliary Tract Cancers, & Ampullary Adenocarcinoma

1. 900 billable units per 28 days

3. Recertification Request:

Coverage may 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. 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~~)~~] hepatic impairment, etc.

4. PA Guidelines:

a. Coverage is provided for six months and may be renewed.~~Initial approval will be given for six months.~~

b. ~~Recertification will be given for six months.~~

B. Anti-PD-1 Monoclonal Antibodies

Therapeutic Class: Anti-PD-1 Monoclonal Antibodies
Last Reviewed by the DUR Board: ~~N/A~~April 18, 2024

Anti-PD-1 Monoclonal Antibodies are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Bavencio® (avelumab)

a. Coverage is provided in the following conditions~~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, retifanlimab, toripalimab, 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

1. Recipient has primary locally advanced disease; and

a. Both curative surgery and curative radiation therapy are not feasible; or

b. Recipient has had disease progression on neoadjuvant nivolumab therapy; or

2. ~~c.~~ Recipient has metastatic ~~or recurrent disseminated~~ disease.

3. Recipient has recurrent locally advanced or recurrent regional disease; and

a. Both curative surgery and curative radiation therapy are not feasible.

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 treated with curative intent

c. Metastatic or local bladder cancer recurrence post cystectomy treated with curative intent

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.

5. 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.

6. 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~~or

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~~ 7 or FIGO stage IV disease).

7. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as single-agent therapy; and

b. Recipient has recurrent ~~or metastatic~~ disease; and

c. Used as subsequent therapy ~~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 four ~~-~~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. PA Guidelines:

1. Coverage will be provided for 6 months and may be renewed.~~Initial approval will be given for 6 months.~~

2. ~~Recertification will be given for 6 months.~~

2. Imfinzi® (durvalumab)

a. Coverage is provided in the following conditions~~Approval will be given if the following criteria are met and documented~~:

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

b. Universal Criteria

1. ~~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, retifanlimab, toripalimab, etc.) unless otherwise specified; and

2. ~~3.~~ Non-Small Cell Lung Cancer (NSCLC)

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

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

2. ~~1.~~ Used as a single agent as consolidation therapy; and

3. Disease has not progressed after definitive concurrent or sequential chemoradiation; or

a. ~~Used as consolidation therapy: and~~

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

c. ~~Disease has not progressed after definitive chemoradiation; or~~

b. 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; and

1. Used as first-line therapy; and

a. Used for one of the following:

1. Patients with tumors that are negative for actionable molecular biomarkers and PD-L1 ≥ 1% to 49%

2. Patients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 < 1%

3. Patients with PS of 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

b. ~~2.~~ Used in combination with tremelimumab ~~actl~~ albumin-bound paclitaxel and carboplatin; or ~~and platinum-based chemotherapy; and~~

c. Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

d. Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; or

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

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

2. Used as subsequent therapy; and

a. Used for one of the following:

1. Recipient with PS of 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement

2. Recipient with PS of 0-1 who are positive for one of the following molecular biomarkers and received prior targeted therapy: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK

rearrangement, or ROS1 rearrangement; and

b. Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; or

c. Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

d. Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; or

3. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy; and

a. Used as a single agent following a first-line regimen with durvalumab and tremelimumab plus chemotherapy; or

b. Used in combination with pemetrexed following a first-line regimen with durvalumab, tremelimumab, pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology.

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. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

a. Used in combination with cisplatin and gemcitabine; and

1. Used as primary treatment for unresectable, resected gross residual (R2), locally advanced, or metastatic disease; or

2. Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant therapy; or

3. Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; or

4. Used as neoadjuvant therapy for resectable locally advanced disease (**NOTE: Only applies to Gallbladder Cancer); and

a. Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; or

b. Recipient has incidental finding on pathologic review; or

c. Recipient has mass on imaging.

6. ~~Hepatobiliary Cancers~~Hepatocellular Carcinoma

a. ~~Recipient has hepatocellular carcinoma (HCC); and~~

a. ~~1.~~ Used a first-line therapy ~~as a single agent~~ in combination with tremelimumab; and

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

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

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

b. ~~2.~~ Used as first-line therapy ~~in combination with tremelimumab-actl~~ as a single agent; and

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

2. ~~b.~~ Recipient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or~~Recipient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); and~~

3. Recipient has metastatic disease or extensive liver tumor burden.

~~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.~~

7. Ampullary Adenocarcinoma

a. Used as first-line therapy in combination with gemcitabine and cisplatin; and

b. Recipient has good performance status (e.g., ECOG 0-1, with good biliary drainage and adequate nutritional intake); and

c. Recipient has pancreatobiliary or mixed type disease; and

1. Recipient has unresectable localized disease; or

2. Recipient has stage IV resected ampullary cancer; or

3. Recipient has metastatic disease at initial presentation.

8. Cervical Cancer

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

b. Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; and

c. Used in combination with etoposide and either cisplatin or carboplatin.

9. Esophageal Cancer and Esophagogastric Junction Cancers

a. Used as neoadjuvant therapy in combination with tremelimumab; and

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

c. Recipient has adenocarcinoma; and

d. Used as primary treatment for recipients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease.

10. Gastric Cancer

a. Used as neoadjuvant therapy in combination with tremelimumab; and

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

c. Recipient has adenocarcinoma; and

d. Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in recipients who are medically fit for surgery.

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:

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

2. 150 billable units (1,500 mg) every 21 days x 5 doses, then 150 billable units (1,500 mg) every 28 days

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

c. Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: 150 billable units (1,500 mg) every 28 days for 3 doses

d. ~~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

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

f. Cervical Cancer: 150 billable units (1,500 mg) every 21 days x 4 doses, then 150 billable units (1,500 mg) every 28 days

c. Recertification Request

Coverage may be renewed based upon the following criteria:

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~~single agent use as consolidation therapy)

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

5. Continuation Maintenance Therapy for NSCLC

   a. Refer to Section III for criteria.

6. ~~Hepatobiliary Cancers~~Hepatocellular Carcinoma

   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-case basis.

7. ~~6.~~ Continuation Maintenance Therapy for SCLC

   a. Refer to Section III for criteria.

8. Esophageal Cancer and Esophagogastric Junction Cancers

a. Coverage may not be renewed

9. Gastric Cancer

a. Coverage may not be renewed

d. PA Guidelines:

1. Coverage will be provided for six months and may be renewed (unless otherwise specified).~~Initial approval for Non-Small Cell Lung Cancer (single agent use) will be given for six months.~~

a. Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: Coverage will be provided for three doses

b. Non-Small Cell Lung Cancer (NSCLC) (single agent use as consolidation therapy): Coverage will be provided for six months and may be renewed up to a maximum of 12 months of therapy.

~~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-actl] 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-actl] and platinum-based chemotherapy, Small Cell Lung Cancer and Hepatobiliary Cancers will be for six months.~~

~~3.~~ Libtayo® (cemiplimab-rwlc)

a. Coverage is provided for the following conditions:~~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., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, toripalimab, etc.), unless otherwise specified; ~~and~~

3. Cutaneous Squamous Cell Carcinoma (cSCC)

a. Used as a single agent; and

1. ~~disease~~ Recipient has metastatic ~~disease~~, locally advanced~~, disease, unresectable disease, inoperable or incompletely resected regional disease, new regional disease, or local or regional recurrence~~ or recurrent disease; and

b. ~~Used as a single agent; and~~

a. ~~c.~~ Recipient is not a candidate for curative surgery or curative radiation therapy; or~~.~~

2. ~~Used as neoadjuvant therapy; and~~

a. Recipient has borderline resectable disease, unresectable disease, or surgery may carry a high morbidity; or

b. Used for one of the following:

1. Tumor has very rapid growth

2. In-transit metastasis

3. Lymphovascular invasion

4. Surgery alone may not be curative or may result in significant functional limitation; and

c. Recipient has very high-risk disease; or

d. Recipient has locally advanced disease.

4. Cervical Cancer

a. Used as a single agent as subsequent therapy; and

b. Recipient has recurrent or metastatic disease.

5. Basal Cell Carcinoma

a. ~~Recipient has previously been treated with a hedgehog pathway inhibitor (HHI) (e.g., vismodegib, sonidegib, etc.)~~

a. ~~b.~~ Used as a single agent; and

1. Recipient has locally advanced or metastatic disease; or

2. ~~Recipient has local recurrence and is not a candidate for curative surgery or curative radiation therapy; or~~

2. ~~3.~~ Recipient has nodal disease and surgery is not feasible.~~, regional, or metastatic disease.~~

6. Non-Small Cell Lung Cancer (NSCLC)

a. Recipient has 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~~Recipient has tumors that are negative for actionable molecular biomarkers~~; and

~~1.~~ Used in combination with platinum-based chemotherapy (e.g., paclitaxel and either carboplatin or cisplatin or pemetrexed and either carboplatin or cisplatin)~~Used as first-line therapy in combination with platinum-based chemotherapy~~; and

a. Used as first-line therapy for one of the following: ~~Recipient has locally advanced disease and is not a candidate for surgical resection or definitive chemoradiation; or~~

1. Recipients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 expression<1%

2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)

3. PD-L1 expression-positive (PD-L1 ≥1%) tumors that are negative for actionable molecular biomarkers; or

b. Used as subsequent therapy for one of the following:

1. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement

2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers:

BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; or

~~2.~~ Used in combination with pemetrexed; and

a. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease after first-line therapy with cemiplimab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; or

~~3.~~ Used as a single agent; and

a. Recipient has tumors that are negative for actionable molecular biomarkers and high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA-approved or CLIA compliant test; and

1. Used as first-line therapy; or

2. Used as continuation maintenance therapy in patients who achieved a tumor response or stable disease after first-line therapy with cemiplimab as monotherapy or as part of combination therapy; or

b. Recipient has tumors with PD-L1 expression <1% or ≥1%-49%; and

1. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy with cemiplimab combination therapy.

6. Vulvar Cancer

a. Used as a single agent as subsequent therapy; and

b. Patient has advanced or recurrent/metastatic disease

~~b. Recipient has metastatic disease; or~~

2. ~~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. Recipient has tumors with high PD-L1 expression (Tumor Proportion Score [TPS] greater than or equal to 50%) as determined by an FDA-approved or CLIA compliant test; and~~

~~b. Used as a single agent; and~~

~~1. Used as first line therapy; or~~

~~2. Used as continuation maintenance therapy in recipients who achieved a tumor response or stable disease after first-line therapy with cemiplimab-rwlc.~~

b. Dosage Limits

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

a. Libtayo 350 mg/~~seven~~7 mL single-dose vial: one vial per 21 days.

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

a. 350 billable units (350 mg) every 21 days.

c. Recertification Request

Coverage may be renewed based on the following criteria:

~~1.~~ 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

~~2.~~ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; and

~~3.~~ Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; and

a. Non-Small Cell Lung Cancer (continuation maintenance therapy):

1. Refer to Section III for criteria

b. Cutaneous Squamous Cell Carcinoma (cSCC) (neoadjuvant therapy):

1. Coverage may not be renewed

c. Cutaneous Squamous Cell Carcinoma (cSCC) (metastatic, locally advanced, or recurrent disease

1. Patient has not exceeded a maximum of 24 months of therapy

d. Cervical Cancer

1. Patient has not exceeded a maximum of 96 weeks of therapy

e. Basal Cell Carcinoma

1. Patient has not exceeded a maximum of 24 months of therapy

f. Vulvar Cancer

1. Patient has not exceeded a maximum of 24 months of therapy

d. PA Guidelines

~~1. Initial approval will be given for six months.~~

~~2. Recertification will be given for six months.~~

Coverage will be provided for six months and may be renewed, unless otherwise specified.

1. Neoadjuvant therapy in cSCC can be authorized up to a maximum of four doses and cannot be renewed.

2. Treatment for metastatic, locally advanced, or recurrent cSCC, Vulvar Cancer and Basal Cell Carcinoma (BCC) can be renewed up to a maximum of 24 months of therapy (35 doses).

3. Treatment for recurrent or metastatic Cervical Cancer can be authorized up to a maximum of 96 weeks of therapy (32 doses)

4. Ocrevus® (ocrelizumab)

a. Coverage is provided in the following conditions:~~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. 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

3. Recipient has had baseline serum immunoglobulins assessed; and

4. 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

b. Must be used as single agent therapy; and

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

5. 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 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 six and a half~~≤6.5.

b. Dosage Limits

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

~~a.~~ Ocrevus 300mg single-dose vial: two vials in first two weeks, then two vials per six months.

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

~~a.~~ Initial Dose

1. 300 billable units (300 mg) on day one and day 15.

~~b.~~ Subsequent Doses

1. 600 billable units (~~36~~00 mg) every six months.

c. Recertification Request

Coverage can be renewed based on the following criteria:

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

~~2. Recipient has not received a dose of ocrelizumab within the past five months; and~~

2. ~~3.~~ 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

3. ~~4.~~ 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), nine-hole peg test (nine-HPT].

a. Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 ~~greater than or equal to one~~ relapse, , ≥ 2 ~~greater than or equal to two~~ unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

4. ~~5.~~ PPMS

a. Recipient continues to be ambulatory, defined as an EDSS score of ~~less than seven and a half~~<7.5.

d. PA Guidelines

1. Coverage will be provided for six months and may be renewed.~~Initial approval will be given for six months.~~

2. ~~Recertification will be given for six months.~~

5. Opdivo® (nivolumab)

a. Coverage is provided for the following conditions~~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., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, toripalimab, etc.), unless otherwise specified; and

3. Ampullary Adenocarcinoma

~~a.~~ Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA approved or CLIA-compliant test; and

~~b.~~ Used in combination with ipilimumab; and

1. Used as first-line therapy for unresectable or metastatic intestinal type disease; or

2. Used as subsequent therapy for disease progression.

4. Anal Carcinoma

~~a.~~ Recipient has metastatic squamous cell disease; and

~~b.~~ Used as a single agent for subsequent therapy.

5. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)

~~a.~~ Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test; and

~~b.~~ Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; and

~~c.~~ Used in combination with ipilimumab; and

~~d.~~ Disease is refractory to standard therapies or there are no standard treatment options available.

6. Urothelial Carcinoma (Bladder Cancer)

~~a.~~ Used as a single agent; and

1. Used for disease that progressed during or following platinum-containing chemotherapy or as a second-line treatment after chemotherapy other than a platinum; and

a. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma

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

3. Metastatic or local bladder cancer recurrence post-cystectomy

4. Recurrent or metastatic primary carcinoma of the urethra; and

a. Recipient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes

5. Metastatic upper genitourinary (GU) tract tumors

6. Metastatic urothelial carcinoma of the prostate; or

2. Used as adjuvant therapy; and

a. Recipient has urothelial carcinoma of the bladder, bulbar urethra, prostate with stromal invasion, ureter, or renal pelvis; and

b. Recipient underwent radical surgical resection ~~or atrial cystectomy~~; and

c. Recipient is at high risk for disease recurrence~~.~~; or

~~b.~~ Used in combination with cisplatin and gemcitabine followed by nivolumab maintenance therapy; and

1. Used as first-line systemic therapy in cisplatin eligible recipient; and

a. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma

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

3. Metastatic or local bladder cancer recurrence post-cystectomy

4. Recurrent or metastatic primary carcinoma of the urethra; and

a. Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes

5. Metastatic upper genitourinary (GU) tract tumors

6. Metastatic urothelial carcinoma of the prostate.

7. ~~6.~~ Bone Cancers

a. Recipient has one of the following: Ewing sarcoma, chondrosarcoma (excluding mesenchymal chondrosarcoma), osteosarcoma, or chordoma; and

b. Recipient has tumor mutation burden-high (TMB-H) tumors [[≥~~greater than or equal to~~ 10~~-~~mutations/megabase (mut/Mb)] as determined by an FDA-approved or CLIA-compliant test; and

c. Used in combination with ipilimumab; and

d. Recipient has unresectable or metastatic disease that progressed following prior treatment; and

e. Recipient has no satisfactory alternative treatment options.

8. ~~7.~~ Adult Central Nervous System (CNS) Cancers

a. Used in one of the following treatment settings:
   1. Used as initial treatment in recipients with small asymptomatic brain metastases
   2. Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options
   3. Recipient has recurrent limited brain metastases
   4. Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; and

b. Used as a single-agent or in combination with ipilimumab for the treatment of brain metastases in recipients with BRAF non-specific melanoma; or

c. Used as a single-agent for the treatment of brain metastases in recipients with PD-L1 (Tumor Proportion Score [TPS] ≥1%) positive non-small cell lung cancer (NSCLC).

9. ~~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.

10. ~~9.~~ Cervical Cancer

a. Used as subsequent therapy as a single agent; and

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

c. Tumor expressed PD-L1 (e.g., CPS ~~≥~~1~~greater than or equal to one~~) as determined by an FDA-approved or CLIA-compliant test.

11. ~~10.~~ Colorectal Cancer

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

b. Recipient's disease is microsatellite instability-high (MSI-H)/ ~~or~~ mismatch repair deficient (dMMR) disease or polymerase epsilon/delta (POLE/POLD1) mutation as determined by and FDA-approved or CLIA-compliant test; and

c. Used as a single agent or in combination with ipilimumab; and

1. Used as subsequent therapy and~~for advanced or metastatic disease that progressed following treatment with one of the following:~~

a. Recipient has metastatic, unresectable, or medically inoperable disease; or ~~Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy~~

~~b. Non-intensive therapy in recipients with an improvement in functional status; or~~

2. Used as primary or initial treatment; and

a. Used for isolated pelvic/anastomotic recurrence of rectal cancer; or~~Used as neoadjuvant therapy for clinical T4b colon cancer; or~~

b. Recipient has T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; or

c. Recipient has metastatic, unresectable, or medically inoperable disease; or

3. ~~b.~~ Used as neoadjuvant therapy; and ~~for resectable liver and/or lung metastases; or~~

a. Recipient has clinical T4b colon cancer (for dMMR/MSI-H disease only); or

b. Recipient has resectable liver and/or lung metastases; or

c. Recipient has T3, N Any; T1-2. N1-2; T4, N Any locally unresectable, or medically inoperable rectal cancer (single agent therapy for dMMR/MSI-H disease only).

~~c. Used if resection is contraindicated following neoadjuvant therapy for advanced, locally unresectable, or medically inoperable rectal cancer; or~~

~~d. Used for unresectable (or medically inoperable) or metastatic disease.~~

12. ~~11.~~ Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient~~s' disease is~~ has microsatellite instability-high (MSI-H)/ ~~or~~ mismatch repair deficient (dMMR) disease or polymerase epsilon/delta (POLE/POLD1) mutation as determined by and FDA-approved or CLIA-compliant test; and

b. Used as a single agent or in combination with ipilimumab; and

c. Recipient has advanced or metastatic disease.

1. Used as ~~subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin-irinotecan- and/or fluoropyrimidine-based therapy~~ primary or initial treatment; or

2. Used as subsequent treatment; or~~Used as initial therapy for advanced or metastatic disease.~~

13. ~~12.~~ Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

a. Used as first-line therapy; and

1. Recipient has ~~esophageal~~ squamous cell carcinoma ~~(ESCC)~~; and

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

1. Used in combination with ipilimumab; or

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

b. Recipient has adenocarcinoma; and

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

a. ~~2.~~ Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Used in combination with ipilimumab; and

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

b. Used as subsequent therapy; and

1. Recipient has ~~esophageal~~ squamous cell carcinoma ~~(ESCC)~~; and

a. 2. ~~Recipi~~ent is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; and

1. ~~3.~~ Used as a single agent; or

2. Used in combination with ipilimumab; and

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

2. Recipient has adenocarcinoma; and

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

b. Used in combination with ipilimumab; and

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

c. Used as adjuvant treatment of completely resected disease; and

1. Used as a single agent in recipient with residual disease following neoadjuvant chemoradiotherapy (CRT).

d. Used as neoadjuvant or perioperative therapy; and

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

2. Recipient has adenocarcinoma; and

a. Used in combination with ipilimumab; and

1. Used as primary treatment for patients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; or

b. Used as a single agent; and

1. Used as postoperative management following R0 resection in patients who have received preoperative therapy with nivolumab and ipilimumab.

14. Gastric Cancer

a. Used as first-line therapy; and

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

a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

b. Used in combination with ipilimumab; and

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

b. Used as subsequent therapy; and

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

2. Used in combination with ipilimumab; and

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

c. Used as neoadjuvant or perioperative therapy; and

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

a. Used in combination with ipilimumab; and

1. Used as primary treatment prior to surgery for potentially resectable locoregional disease (cT2 or higher, any N) in recipient who are medically fit for surgery; or

b. Used as a single agent; and

1. Used as postoperative management following R0 resection in patients who have received preoperative therapy with nivolumab and ipilimumab.

15. ~~13.~~ Gestational Trophoblastic Neoplasia

a. Used as 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 has previously treated with a platinum-based regimen; or~~

2. Recipient has high risk disease (i.e., ≥7 ~~greater than or equal to seven~~ Prognostic score or stage IV disease).

~~14. Gastric Cancer~~

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

~~1. Used as first-line therapy in combination with fluoropyrimidine and platinum-containing chemotherapy.~~

16. ~~15.~~ 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 for oligometastatic or metastatic disease; or

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

1. Recipient has nasopharyngeal cancer; and

a. Used in combination with cisplatin and gemcitabine for recipients with performance status 0-1; and

b. 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. Used as a single agent; and

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

2. ~~c.~~ Disease has progressed on or after platinum-containing chemotherapy.

b. Used in combination with cetuximab for recipients with performance status (PS) 0-1; and

1. Used for one of the following:

a. Metastatic disease at initial presentation

b. Recurrent/persistent disease with distant metastases

c. Unresectable locoregional recurrence with prior RT

d. Unresectable second primary with prior RT

e. Unresectable persistent disease with prior RT.

17. ~~16.~~ Hepatocellular Carcinoma (HCC)

a. Used for one of the following:

1. Recipient was previously treated with sorafenib (for use in combination with ipilimumab only)

2. Recipient has unresectable disease and is not a transplant candidate

3. Recipient has liver-confined disease that is inoperable by performance status. comorbidity, or with minimal or uncertain extrahepatic disease

4. Recipient has metastatic disease or extensive liver tumor burden; and

b. Used in combination with ipilimumab; and

1. Recipient has Child-Pugh Class A hepatic impairment; and

2. Used as subsequent therapy for progressive disease; or

c. Used as a single agent; and

1. Patient has Child-Pugh Class B hepatic impairment

~~a. Used in combination with ipilimumab; and~~

~~b. Used as subsequent therapy for progressive disease; and~~

~~c. Recipient has Child-Pugh Class A hepatic impairment; and~~

~~1. Recipient was previously treated with sorafenib; or~~

~~2. Recipient has unresectable disease and is not a transplant candidate; or~~

~~3. Recipient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or~~

~~4. Recipient has metastatic disease or extensive liver tumor burden.~~

18. ~~17.~~ Adult Classical Hodgkin Lymphoma (cHL)

a. Used as a single agent; and

1. Recipient has relapsed or progressive disease after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; or

2. Used for disease that is refractory to at least three prior lines of therapy including autologous (HSCT); or

3. Used as palliative therapy in recipient >~~greater than~~ 60 years of age or with poor performance status or with substantial comorbidities; and

a. Recipient has relapsed or refractory disease ~~progressive disease after autologous HSCT~~; or

~~b. Recipient has relapsed or refractory disease and is transplant ineligible based on comorbidities or failure or second-line chemotherapy; or~~

~~c. Recipient is post-allogeneic stem cell transplant; or~~

b. Used in combination with brentuximab vedotin or ICE (ifosfamide, carboplatin, etoposide) in patients 18 to 60 years of age; and

1. Used as second-line therapy for relapsed or refractory disease; or

2. Used as subsequent therapy (if not previously used) for relapse or refractory disease; and

a. Recipient has a Deauville scale score of 4 or 5 following restaging with FDG-PET/CT.~~relapsed or progressive disease after autologous HSCT; or~~

~~b. Recipient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; or~~

~~c. Recipient is post-allogeneic stem cell transplant.~~

19. ~~18.~~ Pediatric Classical Hodgkin Lymphoma (cHL)

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

b. Recipient has relapsed or refractory disease; and

c. Used in recipients heavily pretreated with platinum or anthracycline-based chemotherapy or if a decrease in cardiac function was observed; and

1. Used as subsequent therapy (if not previously used); and

1. Used as a single agent or in combination with brentuximab vedotin; or

~~a.~~2. Used as re-induction therapy; and

2. ~~Used as a single agent or in combination with brentuximab vedotin; or~~

a. ~~3.~~ Used in combination with brentuximab vedotin; or

b. Used in combination with brentuximab vedotin and radiation therapy (ISRT) in highly favorable recipients who may avoid autologous stem cell rescue (ASCR) (i.e., initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 >1~~greater than one~~ year, absence of extranodal disease or B symptoms at relapse).

20. Kaposi Sarcoma

a. Used in combination with ipilimumab as subsequent therapy; and

b. Recipient has classic disease; and

c. Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and

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

e. Disease has progressed on alternate first-line therapy

21. ~~19.~~ Renal Cell Carcinoma (RCC)

a. Used in combination with ipilimumab; and

1. Recipient has ~~for~~ clear cell histology; and

2. ~~1.~~ Used as first-line therapy in recipients with poor or intermediate risk advanced, relapsed, or stage IV disease; or

3. ~~2.~~ Used as first-line therapy in recipients with favorable risk relapsed or stage IV disease; or

4. ~~3.~~ Used as subsequent therapy in recipients with relapsed or stage IV disease; or

b. Used as a single agent; and

1. Used as subsequent therapy in recipients with advanced, relapsed, or stage IV disease and clear cell histology; or

2. Recipient has relapsed or stage IV disease and non-clear cell histology; or

c. Used in combination with cabozantinib (Cabometyx only); and

1. Recipient has clear cell histology; and

a. Used as first-line therapy for advanced, relapsed, or stage IV disease; or

b. Used as subsequent therapy in recipients with relapsed or stage IV disease; or

2. Recipient has non-clear cell histology; and

a. Recipient has relapsed or stage IV disease.

~~20. Malignant Peritoneal Mesothelioma (MPeM)~~

~~a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); or~~

~~b. Used in combination with ipilimumab as first-line therapy; and~~

~~1. Recipient has unresectable diffuse disease; or~~

~~2. Recipient has unresectable recurrent benign multicystic or well-differentiated papillary disease.~~

~~21. Malignant Pleural Mesothelioma (MPM)~~

~~a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); or~~

~~b. Used in combination with ipilimumab as first-line therapy; and~~

~~1. Recipient has stage IIIB or IV disease; or~~

~~2. Recipient has sarcomatoid or biphasic histology; or~~

~~3. Disease is medically inoperable or unresectable.~~

~~22.~~ Cutaneous Melanoma

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

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

2. Used as a single agent or in combination with ipilimumab; or

b. Used as initial therapy for limited resectable disease; and

1. Used as 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; and

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

a. ~~1.~~ Used a re-induction therapy in recipients who experienced disease control (i.e., complete or partial response or stable disease) and no residual toxicity from prior anti-PD-1 immunotherapy, but subsequently have disease progression/relapse ~~greater than three~~ >3months after treatment discontinuation; and

1. ~~a.~~ Used as a single agent or in combination with ipilimumab; or

b. ~~2.~~ Used after disease progression, intolerance, and/or projected risk of progression with ~~or maximum clinical benefit from~~ BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); and

1. ~~a.~~ Used as a single agent or in combination with ipilimumab if anti-PD-1 was not previously used; or

2. ~~b.~~ Used in combination with ipilimumab for ~~recipients who~~ disease progressi~~oned~~ on single agent anti-PD-1 therapy; or

d. Used as adjuvant treatment; and

1. Used as a single agent; and

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

b. Recipient has stage IIB, stage IIC, or metastatic disease and has undergone complete resection; or

c. Recipient has stage III disease; and

1. Recipient has undergone complete resection; or

2. Recipient has sentinel node positive disease either during observation without additional nodal surgery and with mandatory radiographic nodal surveillance or after complete lymph node dissection (CLND); or

3. Recipient has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND) or following neoadjuvant therapy; or

4. Recipient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision; or

5. Used following wide excision alone *(stage IIIB/C/D disease only)*; or

6. Used following wide excision with negative sentinel lymph node biopsy; or

7. Used for disease that is sentinel lymph node negative or sentinel lymph node biopsy not performed *(stage IIIB/C/D disease only)*; or

e. Recipient has local satellite/in-transit recurrence and has NED after complete excision; or

f. Recipient has resectable disease limited to nodal recurrence following excision and complete TLND or following neoadjuvant therapy; or

g. Recipient has oligometastatic disease and NED following metastasis-directed therapy (i.e., stereotactic ablative therapy or complete resection) or systemic therapy followed by resection; or

h. Used in combination with ipilimumab; and

1. Recipient has oligometastatic disease and no evidence of disease following metastasis- directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or systemic therapy followed by resection; or

i. Used as neoadjuvant therapy; and

j. Used as a single agent or in combination with ipilimumab; and

1. Recipient has stage III disease; and

a. Used as a primary treatment for clinically positive, resectable nodal disease; or

b. Used for limited resectable disease with clinical satellite/in-transit metastases; or

k. Recipient has limited resectable local satellite/in-transit recurrence; or

l. Recipient has resectable disease limited to nodal recurrence.

1. ~~Recipient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; or~~

~~2. Recipient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; or~~

~~3. Recipient has undergone TLND and/or complete excision of disease limited to nodal recurrence; or~~

~~4. Recipient has undergone complete resection of metastatic disease; or~~

~~5. Recipient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., stereotactic ablative therapy or complete resection) or systemic therapy.~~

~~23.~~ Uveal Melanoma

a. Recipient has distant metastatic or resectable disease; and

b. Used as a single agent or in combination with ipilimumab.

~~24.~~ Merkel Cell Carcinoma

a. Used as neoadjuvant treatment; AND

1. Used as a single agent; and

a. Recipient is a surgical candidate with primary clinical N0 locally advanced disease where curative surgery and curative radiation therapy were originally deemed not feasible; or

b. Recipient has primary clinical N+, M0 regional disease with biopsy positive draining nodal basin; or

b. Used for M1 disseminated disease; and

1. Used as a single agent; or

2. Used in combination with ipilimumab; and

a. Recipient progressed on anti-PD-L1 or anti-PD-1 therapy or anti-PD-L1 or anti-PD-1 therapy is contraindicated.

~~1. Used as neoadjuvant treatment for regional, pathologic N+ disease; or~~

~~2. Used for primary or recurrent metastatic disseminated disease.~~

~~25.~~ Malignant Peritoneal Mesothelioma (MPeM)

a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); or

b. Used in combination with ipilimumab as first-line therapy; and

1. Patient has unicavitary disease with epithelioid histology; and

a. Used as adjuvant treatment for medically operable disease following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); and

1. Patient has surgical or pathologic high-risk features and no neoadjuvant therapy was given; or

b. Patient has medically inoperable disease and/or complete cytoreduction not achieved (including high-risk features); or

c. Patient has disease recurrence after prior CRS + HIPEC if no previous adjuvant systemic therapy was given; or

2. Patient has biphasic/sarcomatoid histology; and

a. Patient has bicavitary disease; or

b. Patient has disease recurrence after prior CRS + HIPEC.

~~26.~~ Malignant Pleural Mesothelioma (MPM)

a. Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); or

b. Used in combination with ipilimumab as first-line therapy; and

1. Patient has clinical stage IIIB or IV disease; or

2. Patient has sarcomatoid or biphasic histology; or

3. Disease is medically inoperable or unresectable; or

4. Patient has clinical stage I-IIIA disease with epithelioid histology and did not receive induction chemotherapy.

~~27.~~ Non-Small Cell Lung Cancer

a. Used as neoadjuvant therapy for resectable (tumors ≥ 4 cm or node positive) disease; and

1. Used in combination with platinum-doublet chemotherapy (e.g., cisplatin/carboplatin in combination with paclitaxel, pemetrexed, or gemcitabine); and

2. Recipient is negative for EGFR or ALK rearrangements; or

b. 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. Recipients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers; and PD-L1 expression <1%

2. Recipients with a PS 0-1 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)

3. PD-L1 expression-positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

b. Used in combination with ipilimumab; or

c. Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); or

c. Used as subsequent therapy; and

1. Used as a single agent; or

2. Used for one of the following:

a. Patients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement

b. Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; and

d. Used in combination with ipilimumab; or

e. Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or

f. Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; or

g. Used as continuation maintenance therapy in combination with ipilimumab; and

1. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.

~~a. Used for resectable (tumors greater than or equal to four cm or node positive) disease; and~~

~~1. Used as neoadjuvant therapy in combination with platinum-doublet chemotherapy (e.g., cisplatin/carboplatin in combination with paclitaxel, pemetrexed, or gemcitabine); or~~

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

2. Recipients with a PS zero 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)

3. PD-L1 expression-positive (PD-L1 greater than or equal to one percent) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular biomarkers; and

b. Used in combination with ipilimumab; or

c. Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); or

2. Used as subsequent therapy; and

a. Used as a single agent; or

b. Used for one of the following:

1. Recipients with a 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, ALK rearrangement, or ROS1 rearrangement

2. Recipients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; and

c. Used in combination with ipilimumab; or

~~d. Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; or~~

~~e. Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; or~~

~~3. Used as continuation maintenance therapy in combination with ipilimumab; and~~

~~a. Recipient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy.~~

~~28.~~ Pediatric Aggressive Mature B-Cell Lymphomas – Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

a. Recipient is ≤ 18 years of age; and

1. Used in combination with brentuximab vedotin; and

a. Used as consolidation/additional therapy if a partial response was achieved after therapy for relapsed or refractory disease; or

2. Used as a single agent for relapsed or refractory disease

2~~9~~6. Small Bowel Adenocarcinoma

a. Recipient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used as a single agent or in combination with ipilimumab.~~; 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.~~

30~~27~~. Small Cell Lung Cancer (SCLC)

a. Used as subsequent systemic therapy as a single agent; and

b. There has been a chemotherapy-free interval of ≤6 months; and

1. Recipient has relapsed disease following a complete or partial response or stable disease after primary treatment; or ~~Used for relapsed disease in recipients with a complete or~~

~~partial response or stable disease after primary treatment (excluding use in recipients who progressed on maintenance atezolizumab or durvalumab at time of relapse); or~~

2. Recipient has ~~Used for~~ primary progressive disease.

31. Soft Tissue Sarcoma

a. Extremity/Body Wall, Head/Neck or Retroperitoneal/Intra-Abdominal

1. Used as a single agent or in combination with ipilimumab; and

2. Used as subsequent therapy; and

a. Recipient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; or

b. Recipient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test; and

1. Patient has no satisfactory alternative treatment options

b. Pleomorphic Rhabdomyosarcoma

1. Used as a single agent or in combination with ipilimumab; and

2. Used as subsequent therapy; and

3. Recipient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test; and

4. Recipient has no satisfactory alternative treatment options.

c. Angiosarcoma

1. Used in combination with ipilimumab.

32~~8~~. Extranodal NK/T-Cell Lymphomas

a. Used as a single agent for relapsed or refractory disease; and

b. Used following additional therapy with an alternative asparaginase-based chemotherapy regimen not previously used; and

c. Participation in a clinical trial is unavailable.

33. ~~29.~~ Endometrial Carcinoma (Uterine Neoplasms)

a. Used as a single agent; and

b. Used as second-line therapy for recurrent disease; 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~~recurrent or metastatic disease~~.

3~~0~~. Vulvar Cancer

a. Used as single agent; and

b. Recipient has adenocarcinoma or squamous cell carcinoma; and

c. Used as subsequent ~~second-line~~ therapy for HPV-related advanced, recurrent, or metastatic disease.

~~31. Pediatric Aggressive Mature B-Cell Lymphomas – Primary Mediastinal Large B-Cell Lymphoma (PMBCL)~~

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

~~1. Used in combination with brentuximab vedotin; and~~

~~a. Used as consolidation/additional therapy if a partial response was achieved after therapy for relapsed or refractory disease; or~~

~~2. Used as a single agent for relapsed or refractory disease.~~

35. Thyroid Carcinoma

a. Used as a single agent; and

b. Used for stage IVC (metastatic) anaplastic carcinoma.

~~b.~~ Dosage Limits

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

a. Opdivo 40mg/four mL single-dose vial: two vials per 14 days

b. Opdivo 100mg/10mL single-dose vial: three vials per 14 days

c. Opdivo 120 mg/12mL single-dose vial: three vials per 14 days

d. Opdivo 240 mg/24mL single-dose vial: four vials per 14 days.

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

CNS Cancer, HCC, Cutaneous Melanoma, Uveal Melanoma, & MCC 120 BU: 21 days

Anal Cancer, Biliary Tract Cancer (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma), Bladder/Urothelial Cancer, Bone Cancer, CRC, Appendiceal Adenocarcinoma, Esophageal Cancer, GEJ Cancer, Gastric, GTN, SCCHN, HCC, cHL, Kaposi Sarcoma, RCC, MPM, MPeM, Cutaneous Melanoma, MCC, NSCLC, SBA, STS, Vulvar Cancer, & Cervical Cancer, Thyroid Carcinoma 240 BU: 14 days

Ampullary Adenocarcinoma, Anal Carcinoma, CNS Cancer, CRC, Appendiceal Adenocarcinoma, Esophageal Cancer, MPM, MPeM, Uveal Melanoma, MCC, Cutaneous Melanoma, PMBCL, SBA, SCLC, & Endometrial Carcinoma (Uterine Neoplasms) 340 BU: 14 days

Ampullary Adenocarcinoma, CRC, Appendiceal Adenocarcinoma, cHL, RCC, & SBA 340 BU: 21 days

Esophageal Cancer, GEJ Cancer, Gastric Cancer, MPM, MPeM, & NSCLC 360 BU: 21 days

Anal Carcinoma, Urothelial (Bladder) Cancer, Bone Cancer, CRC, Appendiceal Adenocarcinoma, Esophageal Cancer, GEJ Cancer, GTN, SCCHN, HCC, cHL, RCC, Cutaneous Melanoma, NSCLC, SBA, STS, & Endometrial Carcinoma (Uterine Neoplasms) 480 BU: 28 days

Uveal Melanoma 1140 BU: 14 days

Extranodal NK/T-Cell Lymphoma 40 BU: 14 days

~~c.~~ Recertification Request

Coverage may be renewed based upon the following criteria:

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis/hepatotoxicity, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), etc.; and

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

4. For the following indications, recipient has not exceeded a maximum of two years of therapy:

   a. Biliary Tract Cancer

   b. ~~a.~~ Bone Cancer; or

   c. ~~b.~~ Cervical Cancer; or

   ~~c. Esophageal Cancer (in combination with fluoropyrimidine- and platinum-containing chemotherapy or ipilimumab); or~~

   ~~d.~~ Esophagogastric/Gastroesophageal Junction Cancer ~~(in combination with fluoropyrimidine-and platinum-containing chemotherapy)~~; or

   ~~e.~~ MSI-H/dMMR Gastric, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer (first-line and subsequent therapy)

   ~~f.~~ ~~e.~~ Gastric Cancer (in combination with fluoropyrimidine- and platinum-containing chemotherapy or ipilimumab)~~; or~~

   ~~g.~~ Kaposi Sarcoma

   ~~h.~~ Renal Cell Carcinoma (in combination with cabozantinib)

   ~~i.~~ Malignant Pleural Mesothelioma (initial therapy in combination with ipilimumab)

   ~~j.~~ Malignant Peritoneal Mesothelioma (initial therapy in combination with ipilimumab)

   ~~k.~~ Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)

~~l.~~ Vulvar Cancer

~~m.~~ Urothelial Carcinoma (first line systemic therapy in combination with gemcitabine and cisplatin, followed by nivolumab maintenance therapy).

~~f. Malignant Pleural Mesothelioma; or~~

~~g. Malignant Peritoneal Mesothelioma; or~~

~~h. Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy); or~~

~~i. Renal Cell Carcinoma (in combination with cabozantinib); or~~

~~j. Vulvar Cancer.~~

5. Urothelial Carcinoma (adjuvant therapy)

   a. Recipient has not exceeded a maximum of one year of therapy.

6. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy)

   a. Recipient has not exceeded a maximum of one year of therapy.

7. MSI-H/dMMR Gastric, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer (neoadjuvant or perioperative therapy)

   a. Recipient has not exceeded a maximum of 12 weeks of pre-operative therapy (six doses), followed by a maximum of 36 weeks (nine doses) of postoperative therapy after surgery

8. ~~7.~~ Classical Hodgkin Lymphoma (in combination with brentuximab vedotin)

   a. Recipient has not exceeded a maximum of ~~twelve (~~12~~)~~ weeks of therapy (four doses).

9. ~~8.~~ Classical Hodgkin Lymphoma (in combination with ICE)

   a. Recipient has not exceeded a maximum of ~~six~~ 12 weeks of therapy (six doses).

10. ~~9.~~ Cutaneous Melanoma (~~re-induction~~ adjuvant therapy as a single agent)

a. Recipient has not exceeded a maximum of one year of therapy~~Refer to Section III for criteria (see Cutaneous Melanoma – Used for retreatment of disease as re-induction)~~.

11. Cutaneous Melanoma (adjuvant therapy in combination with ipilimumab)

a. Patient has not exceeded a maximum of four doses

12. Cutaneous Melanoma (re-induction therapy)

a. Refer to Section III for criteria (see Cutaneous Melanoma – Used for retreatment of disease as re-induction)

13. Cutaneous Melanoma (neoadjuvant therapy as a single agent)

a. Patient has not exceeded a maximum of four doses

14. Cutaneous Melanoma (neoadjuvant therapy in combination with ipilimumab)

a. Patient has not exceeded a maximum of three doses

15. ~~10.~~ Merkel Cell Carcinoma (neoadjuvant therapy)

a. Recipient has not exceeded a maximum of two doses.

16. ~~11.~~ Non-Small Cell Lung Cancer (neoadjuvant therapy in combination with platinum-doublet chemotherapy)

a. Recipient has not exceeded a maximum of three~~-~~ doses~~cycles~~.

17. ~~12.~~ Non-Small Cell Lung Cancer (maintenance therapy)

a. Refer to Section III for criteria.

~~d.~~ PA Guidelines

Coverage will be provided for 6 months and may be renewed (unless otherwise specified)

1. Use in the treatment of Classical Hodgkin Lymphoma:

a. In combination with brentuximab vedotin can be authorized up to a maximum of ~~twelve (~~12~~)~~ weeks of therapy (four doses) and may not be renewed; and

b. In combination with ICE (ifosfamide, carboplatin, etoposide) can be authorized up to a maximum of ~~six~~ 12 weeks of therapy (six doses) and may not be renewed.

2. Neoadjuvant or Perioperative Therapy of MSI-H/dMMR Gastric, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancer can be authorized for a maximum of 12 weeks of pre-operative therapy (six doses), followed by a maximum of 36 weeks (nine doses) of postoperative therapy after surgery

3. ~~2.~~ Neoadjuvant treatment of Merkel Cell Carcinoma can be authorized up to a maximum of two doses and may not be renewed

4. ~~3.~~ Neoadjuvant treatment of NSCLC in combination with platinum-doublet chemotherapy may be authorized for a maximum of three cycles and may not be renewed

5. Neoadjuvant treatment of Cutaneous Melanoma in combination with ipilimumab may be authorized for a maximum of three doses and may not be renewed.

6. Neoadjuvant treatment of Cutaneous Melanoma as a single agent may be authorized for a maximum of four doses and may not be renewed.

7. Adjuvant treatment of Cutaneous Melanoma in combination with ipilimumab may be authorized for a maximum of four doses and may not be renewed.

8. ~~4.~~ Adjuvant treatment of the following indications may be renewed up to a maximum of one year of therapy:

   a. Cutaneous Melanoma (single agent)

   b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

   c. Urothelial Carcinoma.

9. ~~5.~~ The following indications may be renewed up to a maximum of two years of therapy:

   a. Biliary Tract Cancer

   b. Bone Cancer

   c. ~~b.~~ Cervical Cancer

   d. ~~c.~~ Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line therapy~~in combination with fluoropyrimidine- and platinum-containing chemotherapy or ipilimumab~~)

   e. ~~d.~~ MSI-H/dMMR Gastric, Esophageal, and Esophagogastric/ Gastroesophageal Junction Cancer (first-line or subsequent

therapy)~~Esophagogastric/Gastroesophageal Junction Cancer (in combination with fluoropyrimidine and platinum-containing chemotherapy)~~

f. ~~e.~~ Gastric Cancer (in combination with fluoropyrimidine- and platinum-containing chemotherapy OR ipilimumab)

g. Kaposi Sarcoma

h. Renal Cell Carcinoma (in combination with cabozantinib)

i. ~~f.~~ Malignant Pleural Mesothelioma (initial therapy in combination with ipilimumab)

j. ~~g.~~ Malignant Peritoneal Mesothelioma (initial therapy in combination with ipilimumab)

k. ~~h.~~ Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)

~~i. Renal Cell Carcinoma (in combination with cabozantinib)~~

l. ~~j.~~ Vulvar Cancer

m. Urothelial Carcinoma (first line systemic therapy in combination with gemcitabine and cisplatin, followed by nivolumab maintenance therapy).

1. ~~Initial approval will be given for six months.~~

2. ~~Recertification will be given for six months.~~

6. Tecentriq® (atezolizumab)

a. Coverage is provided in the following conditions~~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., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, etc.); and

3. ~~Urothelial Carcinoma (Bladder Cancer)~~

~~a. Used as a single agent; and~~

~~b. Recipient has one of the following diagnoses:~~

~~1. Locally advanced or metastatic urothelial carcinoma; or~~

~~2. Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; or~~

~~3. Recurrent or metastatic primary carcinoma of the urethra (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes); or~~

~~4. Primary carcinoma of the urethra that is stage T3-4 cN1-2 or cN1-2 with palpable inguinal lymph nodes; or~~

~~5. Metastatic upper genitourinary (GU) tract tumors; or~~

~~6. Metastatic urothelial carcinoma of the prostate; and~~

~~c. 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); or~~

~~2. Recipient has a PD-L1 expression of greater than or equal to five percent (PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to five percent of the tumor area) as determined by an FDA-approved or CLIA-compliant test.~~

3. ~~4.~~ Non-Small Cell Lung Cancer (NSCLC)

a. ~~Recipient has~~ 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 as a single agent; and

1. Recipients with performance status (PS) 0-2 who have tumors that are negative for actionable molecular markers (may be KRAS G12C mutation positive) and PD-L1 ≥ 50%

(PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test or CLIA-compliant test; or~~Used for tumors that are negative for actionable molecular markers and PD-L1 greater than or equal to 50% (PD-L1 stained greater than or equal to 50% of tumor cells [TC greater than or equal to 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to ten percent of the tumor area [IC greater than or equal to ten percent]), as determined by an FDA-approved test or CLIA-compliant test; and~~

2. Recipients with PS 3 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) regardless of PD-L1 status; or

3. Patients with PS 3 who have tumors positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, ERBB2 (HER2); or

b. Used in combination with one of the following:

1. Carboplatin, paclitaxel, and bevacizumab

2. Carboplatin and albumin-bound paclitaxel;and

~~1. Used as a single agent; or~~

~~a.~~c. Used for non-squamous disease; and ~~in one of the following:~~

1. Recipients with PS 0-1 who have tumors that are negative for actionable molecular markers (may be KRAS G12C mutation positive) and PD-L1 ~~less than one percent~~<1%; or

2. Patients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression positive tumors (PD-L1 ≥ 1%); or~~Recipients with PD-L1 expression positive tumors (PD-L1 greater than or equal to one percent) that are negative for actionable molecular biomarkers~~

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); or~~and~~

c. ~~Used in combination with carboplatin, paclitaxel, and bevacizumab; or~~

d. ~~Used in combination with carboplatin and albumin-bound paclitaxel; or~~

2. Used as subsequent therapy; and

a. Used as a single agent; ~~or~~and

b. ~~Used for non-squamous disease in one of the following:~~

1. Patients with PS0-2; or~~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~~

2. Patients with PS 3 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement; OR~~Recipients with PS 0-1 who are positive for one of the following molecular mutations and received prior targeted therapy: EGFR exon 19 deletion or L858R tumors, EGFR S7681, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; and~~

3. Patients with PS 3 who are positive for one of the following molecular biomarkers and received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R, EGFR S768I, L861Q and/or G719X, ALK rearrangement, or ROS1 rearrangement; or

b. Used in combination with one of the following:

1. ~~c. Used in combination with~~ cCarboplatin, paclitaxel, and bevacizumab; ~~or~~

2. ~~d. Used in combination with~~ cCarboplatin and albumin-bound paclitaxel; ~~or~~and

c. Used for non-squamous disease; and

1. Patients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR

2. Patients with PS 0-1 who are positive for one of the following molecular biomarkers and received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; OR

3. Used as continuation maintenance therapy in recipients who have achieved a tumor response or stable disease following initial therapy; and

a. Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; or

b. Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; or

c. Used as a single agent following a first-line regimen with single agent atezolizumab; or

4. Used as adjuvant therapy as a single agent; and

a. Tumor expresses PD-L1 ≥1% as determined by an FDA-approved test or CLIA-compliant test; and

b. Used following resection and previous adjuvant chemotherapy; and

1. Patient has stage II to IIIA disease; or

2. Patient has stage IIIB (T3, N2) disease; and

a. Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements.

b. ~~Recipient has stage II to IIIA disease; and~~

1. ~~Used as a single agent; and~~

2. ~~Used as adjuvant treatment following resection and previous adjuvant chemotherapy; and~~

3. ~~Tumor expressed PD-L1 greater than or equal to one percent as determined by an FDA-approved test or CLIA-compliant test~~

5. 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 carboplatin; or

2. Used as single-agent maintenance therapy after initial therapy with atezolizumab, etoposide, and carboplatin.

6. Hepatocellular Carcinoma (HCC)

a. Used as first-line therapy in combination with bevacizumab; and

b. ~~Recipient has Child-Pugh Class A hepatic impairment; and~~

1. Recipient has unresectable or metastatic disease; or

2. Recipient has liver confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or

a. ~~b.~~ Recipient has Child-Pugh Class A hepatic impairment; and

3. Recipient has extensive liver tumor burden.

a. Patient has Child-Pugh Class A or B hepatic impairment

7. Malignant Peritoneal Mesothelioma (MPeM)

a. Used as subsequent therapy in combination with bevacizumab.

8. Cutaneous Melanoma

a. Recipient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; and

b. Used in combination with cobimetinib and vemurafenib; and

c. ~~b.~~ Recipient has unresectable or metastatic disease; and

1. ~~c.~~ Used as first-line therapy; or ~~in combination with cobimetinib and vemurafenib.~~

2. Used as subsequent therapy for disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; OR

3. Used as re-induction therapy in patients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation.

9. Alveolar Soft Part Sarcoma (ASPS)

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

b. Used as a single agent; and

c. ~~Recipient has unresectable or metastatic disease that is not curable by surgery.~~

10. Cervical Cancer

a. Patient has small cell neuroendocrine carcinoma of the cervix (NECC); and

b. Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; and

c. Used in combination with etoposide and either cisplatin or carboplatin

a. Dosage Limits

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

a. Tecentriq 1,200 mg single-use vial: one vial per 21 days.

b. Tecentriq 8~~40~~50 mg single-use vial: one vial per 14 days.

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

a. MPeM and Cervical Cancer: 120 billable units every 21 days.

b. All other indications:

1. 168 billable units every 28 days.

2. 120 billable units every 21 days.

3. 84 billable units every 14 days.

b. Recertification Request

Coverage can be renewed based upon the following criteria:

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

2. 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: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis, including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)] myocarditis, pericarditis, vasculitis, solid organ

transplant rejection etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

4. Cutaneous Melanoma (re-induction therapy)

   a. Refer to Section III for criteria

5. ~~4.~~ Continuation Maintenance Therapy for NSCLC or SCLC

   a. Refer to Section III for criteria

6. ~~5.~~ NSCLC (adjuvant treatment)

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

c. Prior Authorization Guidelines

1. Coverage will be provided for six months and may be renewed (unless otherwise specified). ~~Initial approval will be given for six months.~~

2. ~~Recertification will be given for six months.~~

2. ~~3. Neoa~~Adjuvant therapy in NSCLC can be renewed ~~authorized~~ up to a maximum of 12 months of therapy.

C. Beovu® (brolucizumab-dbll)

Therapeutic Class: Ophthalmic-Macular Degeneration
Last Reviewed by the DUR Board: ~~N/A~~April 18, 2024

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

1. Coverage is provided in the following conditions:~~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)

         a. 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

Coverage can be renewed based upon the following criteria:

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 doses ~~disease~~ and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment week 16:

a. Decrease in BCVA of ≥5 ~~greater than or equal to five~~ letters compared to baseline; or

b. Decrease in BCVA of ≥3 ~~greater than or equal to three~~ letters and central subfield thickness (CST) increase ≥75 microns compared ~~due to neovascular AMD disease activity compared~~ with week 12; or

c. Decrease in BCVA of ≥5 ~~greater than or equal to five~~ letters due to neovascular AMD disease activity ~~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 eight-~~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 ≥ 5 ~~greater than or equal to five~~ letters compared to baseline; and

b. Increase in central subfield thickness compared to baseline.

4. PA Guidelines:

a. Coverage will be provided annually and may be renewed.~~Initial approval be given for 12 months.~~

b. ~~Recertification will be approved for 12 months.~~

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

Therapeutic Class: ANP -Human Vascular Endothelial Growth Factor Inhib Rec-MC Antibody
Last Reviewed by the DUR Board: April 18, 2024~~N/A~~

Avastin®; Mvasi®; Zirabev™; Alymsys®; Vegzelma™; Avzivi®(Bevacizumab) are subject to PA and quantity limitations ~~–~~based on the Application of Standards in Section 1927 of the SSA Act and/or approved by t~~he~~ DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity ~~–––~~limits.

1. Coverage is provided in the following conditions~~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~~5-fluorouracil/ ~~five~~5-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~~

         b. Used 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 as single-agent short-course therapy ~~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. Circumscribe Glioma ~~(WHO Grade 1)~~

2. Primary CNS Lymphoma

3. Meningiomas

4. Brain or Spine metastases

5. Medulloblastoma

6. Glioblastoma/Gliosarcoma/H3-mutated high-grade glioma

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 or progressive 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/H3-mutated high-grade glioma

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

a. 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. Used as a single agent as subsequent therapy; or

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

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

a. Used in combination with paclitaxel and topotecan; or

b. Used as a single agent 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~~5-fluorouracil/5-FU or capecitabine) ~~or irinotecan~~ based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; and~~or~~

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

2. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

b. Used in combination with irinotecan as initial treatment for unresectable metastatic disease; and

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; and

2. Recipient received previous FOLFOX or Cape OX within the past 12 months; or

c. Used in combination irinotecan as subsequent therapy for advanced metastatic disease; and

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

2. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

d. 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

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

1. Recipient progressed through all available regimens (e.g., oxaliplatin-based therapy, irinotecan-based therapy, fluoropyrimidine-based therapy, etc.); and

2. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

3. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

4. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

f. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; and

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

a. Used if resection is contraindicated following total neoadjuvant therapy; and

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

2. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

2. Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

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

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

2. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

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

a. Used in combination with a fluoropyrimidine (e.g., ~~5~~five-fluorouracil/ ~~five~~5-FU or capecitabine) or irinotecan-based regimen following previous oxaliplatin-irinotecan-and/or fluoropyrimidine-based therapy; and~~or~~

1. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

2. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

a. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; or

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

1. Recipient progressed through all available regimens (e.g., oxaliplatin-based therapy, irinotecan-based therapy, therapy without irinotecan or oxaliplatin, etc.); and

a. Recipient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; or

b. Recipient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; and

1. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Recipient has recurrent disease; and

a. Used as a single agent; and

1. Used as subsequent therapy for disease that has progressed on prior cytotoxic chemotherapy; or

2. Used as continuation maintenance therapy following use in combination with carboplatin and paclitaxel; or

b. Used in combination with carboplatin and paclitaxel.

~~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

a. Recipient has unresectable or metastatic disease; or

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

1. ~~2.~~ Recipient has Child-Pugh Class A or B hepatic impairment~~disease~~; or~~and~~

c. ~~a.~~ Recipient has~~-~~ extensive liver tumor burden~~unresectable or metastatic disease~~; and~~or~~

1. ~~b.~~ Recipient has Child-Pugh Class A or B hepatic impairment.~~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 (~~M~~PeM)

1. Used as ~~first-line~~ adjuvant therapy; and

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

b. Recipient has unicavitary disease with epithelioid histology; 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~~ 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 biphasic/sarcomatoid histology or bicavitary disease; or

2. Recipient has unicavitary disease with epithelioid histology; and

a. Recipient is medically inoperable and/or complete cytoreduction is not achievable (including high-risk features); or

b. Patient has recurrent disease after prior cytoreductive surgery (CRS) + hyperthermic intraperitoneal (IP) chemotherapy (HIPEC) and no previous adjuvant systemic therapy was given; OR

3. Used as subsequent therapy; and

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

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

2. Used as a rechallenge if pemetrexed-based treatment was administered first-line with good response; or

4. Used in combination with atezolizumab; and

a. Recipient has not received previous therapy with immune checkpoint inhibitors (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, etc.)

b. ~~Used in combination with atezolizumab.~~

k. ~~Malignant~~ Pleural Mesothelioma (~~M~~PM)

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

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

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

      2. Used as a rechallenge if pemetrexed-based treatment with administered first-line with good response.

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 exon 21 L858R mutations; or

      2. Used for one of the following:

         a. Recipients with a performance status (PS) ≤ 1~~less than or equal to one~~ who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 expression ~~less than one percent~~<1%; or

         b. PD-L1 expression positive ~~tumors~~ (PD-L1 ≥1%~~greater than or equal to one percent~~) that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive); or

c. Recipients with a PS 0-1 ~~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 inhibitors

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 exon 21 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 — ≥1%~~greater than or equal to one percent~~) tumors that are negative for actionable molecular biomarkers after ~~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 (bevacizumab must have been included in the first-line regimen); 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~~ progression; 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

a. 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~~

2. ~~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~~ gemcitabine, liposomal doxorubicin, paclitaxel, or topotecan; or

~~3.~~ Used in combination with oral cyclophosphamide and pembrolizumab; or

~~4.~~ Used in combination with mirvetuximab soravtansine-gynx (in folate receptor-alpha expressing tumors); or

~~5.~~ Used in combination with carboplatin and either gemcitabine, paclitaxel, or liposomal doxorubicin; or

3. Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in recipients who have received no prior chemotherapy (mucinous, clear cell, carcinosarcoma, endometrioid, and high-grade serous histology only); or

4. Used in combination with paclitaxel and carboplatin for recurrence in recipients who have received no prior chemotherapy (low-grade serous histology only); or

5. Used as maintenance therapy; and

a. Used for stage II-IV disease following primary therapy including bevacizumab; and

1. Used as a single agent in recipients that are BRCA1/2 wild-type or unknown and homologous recombination (HR)

proficient, HR deficient, or status unknown (grade 2/3 endometrioid and high-grade serous histology only); or

2. Used in combination with olaparib or niraparib (if unable to tolerate olaparib); and

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~~

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

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

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

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

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

b. Used in combination with oxaliplatin and docetaxel; or

b. Used as neoadjuvant therapy (endometrioid and serous histology only); and

1. Used in combination with one of the following:

a. Carboplatin and paclitaxel or docetaxel

b. Oxaliplatin and docetaxel; and

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

c. Used as adjuvant therapy; and

1. Used in combination with oxaliplatin and docetaxel; and

a. Recipient has pathologic stage II-IV disease (mucinous, clear cell, carcinosarcoma, grade 2/3 endometrioid, and high-grade serous histology only); or

b. Used following interval debulking surgery (IDS) in patients with a response or stable disease to neoadjuvant therapy (endometrioid and serous histology only); and

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

2. Used in combination with carboplatin and paclitaxel or docetaxel; and

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

b. Used following interval debulking surgery (IDS) in patients with a response or stable disease to

neoadjuvant therapy (endometrioid and serous histology only); and

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

~~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 (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); 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 relapsed or 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~~for 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-(e.g., 5-fluorouracil/5-FU or capecitabine) 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, recurrent or metastatic, ~~or recurrent~~ disease.

2. Dosage Limits

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

Avastin, Mvasi, Zirabev, Alymsys, Vegzelma, Avzivi:

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/Q5129):

a. CRC & Appendiceal Adenocarcinoma, CNS Cancers, RCC:

1. 120 billable units per 14 days

b. Small Bowel Adenocarcinoma/Ampullary Adenocarcinoma:

1. ~~6~~90 billable units per 14 days

c. ~~b.~~ NSCLC, Cervical Cancer, HCC, Vulvar Cancer, ~~M~~PM, & ~~M~~PeM:

1. 170 billable units per 21 days

d. ~~c.~~ All other indications:

1. 1~~2~~70 billable units per 14 days

3. Recertification Request: ~~¥~~

Coverage may be renewed based upon the following 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: 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~~ combination therapy with atezolizuab):

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. Coverage will be provided for 6 months and may be renewed (unless otherwise specified).~~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~~ April 18, 2024

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. Coverage is provided in the following conditions:~~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. 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. 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 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 (ixazomib may be substituted for carfilzomib; 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

f. Venetoclax (for patients with t(11:14) only); or

5. Used in combination with pomalidomide and dexamethasone after ~~at least two prior~~ therapy~~ies~~ including lenalidomide and a proteasome inhibitor (bortezomib, 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 or in combination with lenalidomide; 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

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

b. Used for newly diagnosed disease; and

1. Recipient has significant neuropathy; or

2. Recipient has stage IIIb disease with no significant neuropathy.

e. Pediatric Acute Lymphoblastic Leukemia (All)

1. Recipient age ≥ 1 and ≤ 30 years; and

2. Recipient has relapsed/refractory T-cell all; and

3. Used in combination with vincristine, pegaspargase/calaspargase, doxorubicin, and prednisone/dexamethasone.

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 one to eight, then every two weeks, ~~w~~Weeks 9-24, then every four weeks-~~w~~Week 25 onwards; or

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

a. Weekly, W~~w~~eeks one to eight, then every two weeks, W~~w~~eeks 9-24, then every four weeks – W~~w~~eek 25 onwards; or

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

~~1.~~ Up to 180 billable units per dose

~~a.~~ Weekly, W~~w~~eeks one to eight, then every two weeks, W~~w~~eeks 9-24, then every four weeks – W~~w~~eek 25 onwards.

c. ~~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 9-24, then every four weeks – week 25 onwards.~~

3. Recertification Request

Coverage can be renewed based upon the following criteria:

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 Ssection 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 or refractory/progressive multiple myeloma ~~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.

5. Use as maintenance therapy for multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of two years.

e. Pediatric Acute Lymphoblastic Leukemia

1. May not be renewed.

4. PA Guidelines:

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

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. Use as maintenance therapy for multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of two years.

f. Use for pediatric acute lymphoblastic leukemia may not be renewed.

g. Initial approval will be given for six months.

h. ~~f.~~ Recertification will be given for six months.

G. Elaprase® (idursulfase)

Therapeutic Class: Lysosomal Enzymes
Last Reviewed by the DUR Board: ~~N/A~~April 18, 2024

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

1. Coverage is provided in the following conditions~~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~~or

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

      Hunter syndrome (Mucopolysaccharidosis II; MPS II)

      1. ~~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~~ 6mg/~~three~~3 mL vial: 10 vials per ~~seven~~7 ~~-~~days.

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

1. ~~2.~~ 60 billable units every ~~seven~~7 -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~~6-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 reduction in 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 reduction in uGAG levels.

4. PA Guidelines:

a. Coverage will be provided for 12 months and may be renewed.~~Initial approval will be given for 12 months.~~

b. ~~Recertification will be given for 12 months.~~

H. Anti-Angiogenic Ophthalmic Agents: Eylea®; Eylea® HD (Intravitreal)

Therapeutic Class: Anti-angiogenic ophthalmic agents
Last Reviewed by the DUR Board: ~~N/A~~April 18, 2024

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

1. Eylea®

a. Coverage is provided in the following conditions~~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 is free of ocular and/or peri-ocular infections; and

b. Recipient does not have active intraocular inflammation; and

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

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

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

~~1.~~1. Neovascular (Wet) Age-Related Macular Degeneration (AMD)

~~4.~~2. Macular Edema following Retinal Vein Occlusion (RVO)

~~5.~~3. Diabetic Macular Edema (DME)

~~6.~~4. Diabetic Retinopathy (DR)

5. Retinopathy of Prematurity (ROP)

f. Recipient is a premature infant with a maximum gestational age at birth of 32 weeks OR a birth weight of >800 to 1500g.

b. Dosage Limit

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

Eylea;

a. 2 mg/0.05 mL injection: one vial/pre-filled syringe per eye every 28 days.

Eylea HD:

a. 8 mg/0.07 mL injection: one vial/kit per eye every 28 days

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

a. Diagnosis

1. Neovascular age-related macular degeneration (AMD)

a. MU for Initial Dosing

1. Four units every 28 days x three doses.

a. MU for Maintenance Dosing

1. Four units every 28-56 days.

~~1~~2. Macular edema following retinal vein occlusion (RVO)

a. MU for Initial Dosing

1. Four units every 28 days.

a. MU for Maintenance Dosing

1. Four units every 28 days.

~~2~~3. Diabetic Macular Edema (DME)/ Diabetic Retinopathy (DR)

a. MU for Initial Dosing

1. Four units every 28 days x five doses.

a. MU for ~~Initial~~ renewal Dosing

1. Four units~~—~~ per pivotal trial~~every 28-56 days~~.

4. Retinopathy of Prematurity (ROP)

a. MU for Initial Dosing

1. Two doses (one dose per eye).

a. MU for Initial Dosing

1. Four units every 28-56 days.

c. Recertification Request:

Coverage can be renewed based upon the following criteria:

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

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

a. Retinopathy of Prematurity (ROP) (Eylea Only)

1. Patient still has the presence of active ROP requiring treatment; and

2. At least 10 days have elapsed since receiving initial treatment

b. All Other Indications

~~3.~~1. 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.

d. PA Guidelines:

1. Coverage will be provided annually and may be renewed, unless otherwise specified~~Initial approval will be given for 12 months~~.

2. Coverage for Retinopathy of Prematurity (ROP) will be provided initially for a total of 2 doses (1 dose per eye) and may be renewed as re-treatment for up to an additional 4 doses (2 doses per eye) (Refer to Section IV for re-treatment criteria)~~Recertification will be given for 12 months~~.

2. Lucentis®; Byooviz™; Cimerli™ (Ranibizumab)

a. Coverage is provided in the following conditions:~~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 is free of ocular and/or peri-ocular infections; and

b. Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab via ocular implant, etc.); and

c. Recipient's best corrected visual acuity~~activity~~ (BCVA) is measured at baseline and periodically during treatment; and

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

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

2. Diabetic Macular Edema (DME) (Lucentis and Cimerli Only)

3. Diabetic Retinopathy (DR) (Lucentis and Cimerli Only)

4. Macular Edema following Rental Vein Occlusion (RVO)

5. Myopic Choroidal Neovascularization (mCNV).

b. Dosage Limits

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

a. 0.3mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days

b. 0.5mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days.

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

a. Neovascular Age-related Macular Degeneration (AMD)/Macular Edema following Retinal Vein Occlusion (RVO)/Myopic Choroidal Neovascularization (mCNV)

1. Ten billable units every 28 days

b. Diabetic Macular Edema (DME)/Diabetic Retinopathy (DR) – (Lucentis and Cimerli Only)

1. Six billable units every 28 days.

c. Recertification Request

Coverage can be renewed based upon the following criteria:

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

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

a. 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; or

b. Myopic choroidal neovascularization only: continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub/retinal fluid or active leakage).

d. PA Guidelines

1. Coverage for myopic choroidal neovascularization (mCNV) will be provided for 3 months and may be renewed.~~Initial approval will be given for three months for myopic choroidal neovascularization (mCNV).~~

2. Coverage for all other indications will be provided annually and may be renewed.~~Recertification will be given for three months for myopic choroidal neovascularization (mCNV).~~

3. ~~Initial approval will be given for 12 months for all other indications~~

4. ~~Recertification will be given for 12 months for all other indications.~~

3. Susvimo® (ranibizumab)

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 is free of ocular and/or peri-ocular infections; and

b. Recipient does not have ocular inflammation; and