Medicaid Services Manual
Transmittal Letter

September 30, 2025

To: Custodians of Medicaid Services Manual

From: Casey Angres
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

Background And Explanation

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to update Appendix B Section 5.: (A) Abraxane® - Updated prior authorization (PA) Guidelines; Section (B). Anti-PD-1 Monoclonal Antibodies – (5.) Opdivo® – Updated Colorectal Cancer (CRC) and Hepatocellular Carcinoma (HCC); Section (D.) Bevacizumab – (1.)(f.) Updated CRC, (1.)(g.) Appendiceal Adenocarcinoma – Colon Cancer, (1.)(i.) HCC, (1.)(m.) Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer; (1.)(r.) updated Vaginal Cancer; and (2.) Updated Dosage Limits; Section (E.) Darzalex® – (1.)(c.) Updated Multiple Myeloma (MM), and (4.) Updated PA Guidelines; Section (F.) Darzalex Faspro® – (1.)(c.) Updated MM and (2.) Updated Dosage Limits for MM; Section (K.) Kadcyla® – Updated Universal Criteria, (1.)(d.) updated Central Nervous System (CNS) Cancer, (1.)(f.) updated Head and Neck Cancer, (2.)(a.) Removed Quantity Limit (max daily dose), (3.) Updated Renewal Criteria, (4.) Updated PA Guidelines; Section (M.) Long-Acting Granulocyte Colony Stimulating Factors – (1.) Updated Pegfilgrastim; Section (N.) Pemetrexed – (j.) Added Thyroid Carcinoma and (2.) Updated Dosage Limits; Section (O.) Human Epidermal Growth Factor Receptor 2 (HER2) Inhibitors – (1.) Perjeta® – Update Breast Cancer, CNS Cancer, CRC, Appendiceal Adenocarcinoma – Colon Cancer, and Head and Neck Cancer, Dosage limits and Recertification Request; (2.) Trastuzumab – Updated Breast Cancer, Gastric, Esophageal and Esophagogastric Junction Cancers, CRC, Appendiceal Adenocarcinoma – Colon Cancer, Dosage Limits, and Recertification Request; Section (P.) CD20 Monoclonal Antibodies – (1.) Rituxan®, Truxima®, Ruxience™, Riabni™ – Updated Oncology Indications, Immunoglobulin G4-related disease (IgG4-RD), Dosing Limits and Recertification Request; Section (R.) Yervoy® – Updated Dosage Limits; Section (S.) Zynlonta® – Updated Dosage Limits and PA Guidelines; Section (T.) Osteoporosis Agents – (b.) Prolia® and Jubbonti® – added Ospomyv®, Stoboclo®, Denosumab-dssb, and Conexxence®/Denosumab-bnht; (c.) Xgeva® and Wyost® – Updated Dosing Limits. Appendix B was renamed from "Standard Therapeutic Drug Classes" to "Physician Administered Drugs" throughout the chapter.

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 October 6, 2025.

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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications, and Updates
Appendix B Section A	**Abraxane®; paclitaxel albumin bound**	Updated PA Guidelines.
Appendix B Section B	**Anti-PD-1 Monoclonal Antibodies**	Updated coverage for Opdivo® (nivolumab) under CRC and HCC.
Appendix B Section D	**Bevacizumab**	Updated coverage for CRC, Appendiceal Adenocarcinoma – Colon Cancer, HCC, Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer, Vaginal Cancer, and Dosage Limits.
Appendix B Section E	**Darzalex® (daratumumab)**	Updated MM and PA Guidelines.
Appendix B Section F	**Darzalex Faspro® (daratumumab and hyaluronidase-fihj)**	Updated coverage for MM and updated Dosage Limits for MM.
Appendix B Section K	**Kadcyla® (ado-trastuzumab emtansine)**	Updated Universal Criteria, CNS Cancer, Head and Neck Cancer, removed Quantity Limit (max daily dose), updated Renewal Criteria and PA Guidelines.
Appendix B Section M	**Long-Acting Granulocyte Colony Stimulating Factors (LA-gCSF)**	Updated coverage for Pegfilgrastim.
Appendix B Section N	**Pemetrexed**	Added coverage for Thyroid Carcinoma and updated Dosage Limits.
Appendix B Section O	**HER2 Inhibitors**	Under Perjeta® - Updated coverage for Breast Cancer, CNS Cancer, CRC, Appendiceal Adenocarcinoma – Colon Cancer, Head and Neck Cancer, Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma), Dosage Limits and Recertification Requests.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications, and Updates
		Under Trastuzumab – Updated coverage for Breast Cancer, Gastric/Esophageal and Esophagogastric Junction Cancers, CRC, Appendiceal Adenocarcinoma – Colon Cancer, Dosage Limits and Recertification Request.
Appendix B Section P	**CD20 Monoclonal Antibodies**	Under Rituxan®, Truxima®, Ruxience™, Riabni™ (rituximab) – updated coverage for Oncology Indications, IgG4-RD, Dosing Limits, and Recertification Request.
Appendix B Section R	**Yervoy® (ipilimumab)**	Updated Dosage Limit.
Appendix B Section S	**Zynlonta® (loncastuximab tesirine-lpyl)**	Updated Dosage Limits and PA Guidelines.
Appendix B Section T	**Osteoporosis Agents**	Under Prolia® and Jubbonti® added Ospomyv, Stoboclo, Denosumab-dssb and Conexxence/Denosumab-bnht. Under Xgeva® and Wyost® updated Dosing Limits.

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

A. Abraxane®; paclitaxel albumin bound

Therapeutic Class: Taxane Chemotherapy
Last Reviewed by the Drug Utilization Review (DUR) Board: April 17, 2025

Physician Administered Drugs (PAD) are subject to prior authorization (PA) and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Administration (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

a. Used as a single agent; and

b. 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. The recipient has human epidermal growth factor (HER2)-negative hormone receptor positive disease; and

1. The recipient is refractory to endocrine therapy or has visceral crisis; and

2. Used as one of the following:

a. As a single agent

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

b. Used in one of the following treatment settings:

1. First-line therapy if no germline BRCA 1/2 mutation and/or HER2 IHC 0+, 1+, or 2+/ISH negative

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

3. Third-line therapy and beyond; or

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

a. Used in combination with pembrolizumab for programmed death-ligand 1 (PD-L1) positive (PD-L1 combined positive score (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 recipients 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

4. The 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 recipient has experienced hypersensitivity reactions despite premedication or the recipient has contraindications 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 recipients 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 who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive)

b. Recipients who have 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, NRG1 gene fusion, or ERBB2 (HER2); and

2. 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 recipients with PD-L1 ≥50%); or

b. Used as a single agent or in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors; and

1. Used in recipients with tumors that have negative actionable molecular biomarkers (may be KRAS G12C mutation positive); or

2. Used in recipients 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, or ERBB2 (HER2); or

c. Used as subsequent therapy; and

1. Used in one of the following:

a. Recipients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping

b. Recipients who are positive for one of the following molecular mutations and have received prior targeted therapy for those aberrations: EGFR S768I, L861Q, and/or G719X mutation; and

c. Used in combination with carboplatin and pembrolizumab for squamous cell histology or

d. Used in combination with carboplatin and atezolizumab for non-squamous histology or

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

2. Used as a single agent or in combination with carboplatin in recipients with contraindications to PD-1 or PD-L1 inhibitors; and

a. 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

b. 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, RET rearrangement, or ROS1 rearrangement; or

c. Used in recipients 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 for first progression after initial systemic therapy (if not previously used)

d. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

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

1. Used as one of the following:

a. Used a single agent; and

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

2. Recipient has platinum-resistant disease; and

c. The recipient has one of the following:

1. Platinum-resistant disease; and

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

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

c. Used for complete remission and relapse <6 months after completing chemotherapy; or

2. Platinum-sensitive disease; and

a. Used for complete remission and relapse ≥6 months after completing chemotherapy; or

d. Recipient has low-grade serous carcinoma; and

1. Recipient has recurrent disease; and

a. Used as a single agent; or

b. Used in combination with carboplatin in recipients with confirmed taxane hypersensitivity; or

e. 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

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

1. Used ≥6 months after completion of primary therapy; or

2. Used <6 months from completion of primary therapy with a fluoropyrimidine-based regimen; or

c. Used as neoadjuvant therapy; and

1. Recipient has resectable disease; 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 Eastern Cooperative Oncology Group (ECOG) PS 0-1; and

c. Used as first-line therapy.

f. Cutaneous Melanoma

1. Recipient has metastatic or unresectable disease; and

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

3. Recipient is not eligible for any of the recommended immunotherapy or targeted therapy options due to progression on prior therapy, unacceptable toxicity, or comorbidities.

g. Uveal Melanoma

1. Used as a single agent for 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. 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. Recipient has a negative skin test to paclitaxel (if available).

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

1. Used in combination with gemcitabine; and

a. Recipient has unresectable, resected gross residual (R2) or metastatic disease; and

1. Used as a primary treatment; or

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

b. The recipient has resectable locoregionally advanced gallbladder cancer; and

1. Used as neoadjuvant therapy; and

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

b. The recipient has incidental finding on pathologic review (cystic duct node positive); or

c. The recipient has mass on imaging.

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; and

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

b. Used as subsequent therapy if not previously given.

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

4. Disease has progressed on alternate first-line systemic therapy; and

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

b. Used in combination with antiretroviral therapy (ART) for recipients 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 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. Recipient has recurrent or metastatic disease.

n. Vaginal Cancer

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

2. Recipient has recurrent or metastatic disease.

2. Dosing Limits

a. Max Units (per dose and over time) [Health Care Financing Administration (HCFA) Common Procedural Coding System (HCPCS) Unit]:

1. Kaposi Sarcoma

a. 300 billable units per 28 days

2. NSCLC

a. 900 billable units per 21 days

3. Cervical Cancer, Biliary Tract Cancers, Vaginal Cancer, and Ampullary Adenocarcinoma

a. 900 billable units per 28 days

4. Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer, Endometrial Carcinoma

a. 2800 billable units per 84 days

5. Cutaneous and Uveal Melanoma

a. 1200 billable units per 28 days

3. Recertification Request:

Coverage may be renewed based upon the following criteria:

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

b. Duration of authorization has not been exceeded (refer to Section I); and

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

d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count {ANC} <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, unless otherwise specified.

b. Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin or in combination with pembrolizumab and carboplatin: Coverage will be provided for up to a maximum of 12 weeks of therapy (12 doses) and may not be renewed.

c. Non-Small Cell Lung Cancer (NSCLC) in combination with atezolizumab and carboplatin: Coverage will be provided for up to a maximum of 18 weeks of therapy (18 doses) and may not be renewed.

d. Neoadjuvant therapy for Ampullary Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

e. Neoadjuvant therapy for Biliary Tract Cancers (Gallbladder Cancer): Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

f. Neoadjuvant and induction therapy in combination with gemcitabine for Pancreatic Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may not be renewed.

g. Kaposi Sarcoma: Coverage will be provided for up to a maximum of 16 weeks of therapy (12 doses) and may not be renewed,

B. Anti-PD-1 Monoclonal Antibodies

Therapeutic Class: Anti-PD-1 Monoclonal Antibodies
Last Reviewed by the DUR Board: April 17, 2025

Physician Administered Drugs (PADs) 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:

      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 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

            2. Recipient has recurrent 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

            3. Recipient has metastatic disease.

            4. Recipient has primary 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. When used as a first-line therapy for stage IV disease, disease must be M1 or unresectable T4, M0.

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; or

2. Recipient has high-risk disease (i.e., prognostic score ≥7 or International Federation of Gynecology and Obstetrics (FIGO) stage IV disease).

7. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as single-agent therapy; and

b. Recipient has recurrent disease; and

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

8. Extranodal NK/T-Cell Lymphomas

a. Used as a single agent; and

b. Used for relapsed or refractory disease following additional therapy with an alternate asparaginase-based combination chemotherapy regimen not previously used; and

c. Participation in a clinical trial is unavailable

9. Thymic Carcinoma

a. Used in combination with axitinib; and

1. Recipient is unable to tolerate first-line combination regimens; and

a. Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; or

b. Used as postoperative systemic therapy after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; or

c. Used as first-line therapy for recurrent, advanced, or

metastatic disease; or

2. Used as second-line therapy; and

a. Recipient has unresectable or metastatic disease.

b. Dosing Limits

1. 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, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity/hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

d. PA Guidelines:

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

2. Imfinzi® (durvalumab)

a. Coverage is provided in the following conditions:

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

b. Universal Criteria

1. Recipient has not received previous therapy with a programmed death (PD-1/PD-L1)- directed therapy unless otherwise specified; and

2. NSCLC

a. Used as a single agent for consolidation therapy; and

1. Recipient has unresectable stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or

2. Recipient has unresectable stage II disease; and

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

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

c. Recipient does not have EGFR exon 19 deletion or exon 21 L858R mutations; or

b. Used as neoadjuvant therapy; and

1. Recipient has resectable disease (tumors ≥4 cm or node positive); and

2. Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; and

3. Recipient has no known EGFR mutations or ALK rearrangements; or

c. Used adjuvant therapy; and

1. Used as a single agent following previous neoadjuvant durvalumab plus chemotherapy and surgery; and

2. Recipient has no known EGFR mutations of ALK rearrangements; and

3. Recipient has stage IB-IIIB [T3-4, N2] disease; or

d. 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. Recipients with tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 ≥1% to 49%; or

2. Recipients who have tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and PD-L1 <1%; or

3. Recipients who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); 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

2. Used as subsequent therapy; and

a. Used for one of the following:

1. Recipients who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping; or

2. Recipients who are positive for one of the following molecular biomarkers and received prior targeted therapy: EGFR S768I, L861Q, and/ or G719X mutation; 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 SCLC (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; or

b. Recipient has limited stage disease (LS-SCLC); and

1. Used as a single agent therapy; and

2. Used if disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

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 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, R2, or metastatic disease; or

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

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

         b. Recipient has incidental finding on pathologic review (cystic duct node positive); or

         c. Recipient has mass on imaging.

6. Hepatocellular Carcinoma (HCC)

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

      1. Recipient has unresectable disease; or

      2. Recipient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy;

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

      1. Recipient has liver-confined, unresectable disease and is deemed ineligible for transplant; or

      2. Recipient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy.

7. Ampullary Adenocarcinoma

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

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

   c. Used for metastatic pancreatobiliary or mixed type disease.

8. Cervical Cancer

   a. Recipient has small cell NECC; and

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

         a. Used in combination with etoposide and either cisplatin or carboplatin; or

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

9. Esophageal Cancer and Esophagogastric Junction Cancers

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

   b. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or Clinical Laboratory Improvement Act (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 MSI-H or 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.

11. Endometrial Cancer

a. Recipient has dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

1. Used for primary advanced or recurrent disease.

2. Used as adjuvant treatment of stage III-IV endometrioid adenocarcinoma.

12. Urothelial Carcinoma (Bladder Cancer)

a. Recipient has muscle invasive bladder cancer (MIBC); and

b. Recipient has stage II (cT2, N0) or -IIIA (cT3, N0; cT4a, N0; cT1-4a, N1) disease; and

1. Used in combination with cisplatin and gemcitabine as neoadjuvant therapy prior to radical cystectomy; or

2. Used a single agent as adjuvant therapy following radical cystectomy; and

a. Recipient received initial therapy with durvalumab, cisplatin, and gemcitabine.

b. Dosage Limits

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

a. NSCLC, SCLC: 672 billable units (6,720 mg) every 84 days.

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

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

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

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

f. Endometrial Cancer: 112 billable units (1,120 mg) every 21 days x six doses, then 150 billable units (1,500 mg) every 28 days.

g. Bladder Cancer: 150 billable units (1,500 mg) every 21 days x four doses, then 150 billable units (1,500 mg) every 28 days for eight doses.

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. Duration of authorization has not been exceeded (refer to Section I); and

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

4. 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 HCST, etc.; and

5. HCC

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

d. PA Guidelines:

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

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

b. 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.

c. NSCLC (resectable disease): Coverage will be provided for a maximum of 12 weeks of neoadjuvant therapy and 48 weeks of adjuvant therapy.

d. SCLC (limited stage disease): Coverage will be provided for six months and may be renewed up to a maximum of 24 months of therapy.

e. Bladder Cancer: Coverage will be provided for a maximum of 12 weeks of neoadjuvant therapy and 32 weeks of adjuvant therapy.

f. Neoadjuvant treatment of Gallbladder Cancer: Coverage will be provided for a maximum of six months and may not be renewed.

3. Libtayo® (cemiplimab-rwlc)

a. Coverage is provided for the following conditions:

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, unless otherwise specified; and

3. Anal Carcinoma

a. Recipient has metastatic squamous cell carcinoma (SCC); and

b. Used as a single agent as subsequent therapy

4. Cutaneous Squamous Cell Carcinoma (cSCC)

a. Used as a single agent; and

1. Recipient has metastatic, locally advanced, or recurrent disease; and

a. 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.

5. Cervical Cancer

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

   b. Recipient has recurrent or metastatic disease.

6. Basal Cell Carcinoma (BCC)

   a. Used as a single agent; and

      1. Recipient has locally advanced or metastatic disease; or

      2. Recipient has nodal disease and surgery is not feasible.

7. 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; and

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

         a. Used as first-line therapy for one of the following:

            1. Recipients who have tumors that are negative for actionable molecular biomarkers

            2. Recipients who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2)

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

            1. Recipients who are positive for one of the following molecular biomarkers and have received prior targeted therapy: EGFR S768I, L861Q, and/or G719X

            2. Recipients who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping; 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 recipients 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.

8. Small Bowel Adenocarcinoma

a. Used as a single agent treatment; and

b. Recipient has microsatellite instability-high (MSI/H)/mismatch repair deficient (dMMR) disease or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mutations/megabase (mut/Mb)] as determined by an FDA-approved or CLIA-compliant test; and

1. Recipient has advanced or metastatic disease; or

2. Recipient has locally unresectable or medically inoperable disease; and

a. Used as primary treatment.

9. Vaginal Cancer

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

   b. Recipient has recurrent or metastatic therapy; and

10. Vulvar Cancer

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

   b. Recipient has advanced or recurrent/metastatic disease

11. Colon Cancer

   a. Used as single agent treatment; and

   b. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test; and

   c. Used for locally unresectable, medically inoperable, advanced, or metastatic disease.

12. Appendiceal Adenocarcinoma – Colon Cancer

   a. Used as single agent treatment; and

   b. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test; and

   c. Recipient has advanced or metastatic disease.

13. Rectal Cancer

   a. Used as single agent treatment; and

   b. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test; and

   c. Used for advanced or metastatic disease.

b. Dosage Limits

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

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. Duration of authorization has not been exceeded (refer to Section I); and

3. 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 HSCT, etc.; and

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

d. PA Guidelines

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, and BCC can be renewed up to a maximum of 24 months of therapy (35 doses).

3. Treatment for recurrent or metastatic Cervical Cancer, recurrent or metastatic Vaginal Cancer and advanced, recurrent, or metastatic Vulvar 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:

1. Recipient is at least 18 years of age; 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 hepatitis B surface antigen (HBsAg) and anti-HBV tests); and

3. Recipient has had baseline serum immunoglobulins assessed; and

4. Recipient does not have a history of life-threatening administration reactions to ocrelizumab.

5. Universal Criteria

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

b. Recipient does not have an active infection; and

c. Must be used as single agent therapy; and

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

6. Multiple Sclerosis (MS)

a. Recipient must have a confirmed diagnosis of MS as documented by laboratory report (i.e., magnetic resonance imaging (MRI)); 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 <65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of ≤6.5.

b. Dosage Limits

1. 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 (600 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. 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. 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 EDSS, timed 25-foot walk (T25-FW), nine-hole peg test (9-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 relapse, ≥2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

4. PPMS

a. Recipient continues to be ambulatory, defined as an EDSS score of <7.5.

d. PA Guidelines

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

5. Opdivo® (nivolumab)

a. Coverage is provided for the following conditions:

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, unless otherwise specified; and

3. Ampullary Adenocarcinoma

a. Recipient's disease is MSI-H or 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 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. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

b. Used in combination with ipilimumab; and

1. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

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

2. Used as neoadjuvant therapy for resectable locoregionally advanced disease (Note: Only applies to Gallbladder Cancer); and

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

   b. Recipient has incidental finding on pathologic review (cystic duct node positive); or

   c. Recipient has mass on imaging.

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 (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)

            5. Metastatic upper 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; 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, unresectable, 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 (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)

5. Metastatic upper GU tract tumors

6. Metastatic urothelial carcinoma of the prostate.

7. Bone Cancers

a. Recipient has one of the following: Ewing Sarcoma, Chondrosarcoma (excluding Mesenchymal Chondrosarcoma), Osteosarcoma, or Chordoma; and

b. Recipient has TMB-H tumors [≥10 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. 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. Used for 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 (TPS ≥1%) positive NSCLC.

9. Pediatric CNS Cancers

a. Recipient is ≤21 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 <3 years of age and used as a single agent; or

b. Recipient is ≥3 years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide.

10. Cervical Cancer

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

    b. Recipient has recurrent or metastatic disease; and

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

11. Colorectal Cancer (CRC)

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

    b. Recipient's disease is MSI-H/dMMR disease or POLE/POLD1 mutation with ultra/hypermutated phenotype [e.g., tumor mutation burden (TMB) >50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test; and

    c. Used in combination with ipilimumab ~~(if candidate for intensive therapy)~~ or as a single agent; and

        1. Used as primary/initial treatment for ~~locally~~ unresectable or medically inoperable, recurrent, advanced, or metastatic disease; or

        2. Used as subsequent therapy for ~~locally~~ unresectable or medically inoperable~~ disease~~, advanced, or metastatic disease; or

        3. Used as neoadjuvant therapy for advanced or metastatic disease.

12. Appendiceal Adenocarcinoma – Colon Cancer

    a. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test; and

    b. Used in combination with ipilimumab (if candidate for intensive therapy) or as a single agent or; and

    c. Recipient has advanced or metastatic disease.

13. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

    a. Used as first-line therapy; and

1. Recipient has squamous cell carcinoma (SCC); 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. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; or

         b. Used in combination with ipilimumab; and

            1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

b. Used as subsequent therapy; and

1. Recipient has SCC; and

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

      1. Used as a single agent; or

      2. Used in combination with ipilimumab; and

      3. Recipient has MSI-H or dMMR disease as determined by an 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 MSI-H or dMMR disease as determined by an 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 MSI-H or 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 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; or

b. Used as a single agent; and

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

e. Used as induction systemic therapy for relieving dysphagia; and

1. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; and

2. Recipient has squamous cell carcinoma (SCC); and

a. Used in combination with ipilimumab; or

b. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

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 MSI-H or 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 MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

c. Used as neoadjuvant or perioperative therapy; and

1. Recipient has MSI-H or 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 recipients who have received preoperative therapy with nivolumab and ipilimumab; or

15. Gestational Trophoblastic Neoplasia

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

b. Recipient has multiagent chemotherapy-resistant disease; and

1. Recipient has intermediate PSTT or ETT; and

a. Recipient has recurrent or progressive disease; and

2. Recipient has high risk disease (i.e., ≥7 Prognostic score or stage IV disease).

16. 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 PS 0-1; and

b. Used for one of the following:

1. Unresectable locoregional recurrence with prior 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. Recipient has unresectable, recurrent, persistent, or metastatic disease; and

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

b. Used in combination with cetuximab for recipients with 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. Hepatocellular Carcinoma (HCC)

   a. Used as first-line therapy; and

      1. Used in combination with ipilimumab; and

      2. Recipient has unresectable or metastatic disease;

   b. Used as subsequent therapy; and

   c. Used in combination with ipilimumab; and

      1. Recipient was previously treated with sorafenib; or

      2. Recipient had disease progression on or after systemic therapy and has not been treated with anti-CTLA~~5~~4-based combinations; or

   d. Used as a single agent for disease progression on or after systemic therapy.

18. Adult Classical Hodgkin Lymphoma (cHL)

   a. Used as a single agent; and

      1. Recipient has relapsed or progressive disease after autologous HSCT and brentuximab vedotin; or

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

      3. Used as palliative subsequent therapy; and

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 17, 2025

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

1. Coverage is provided in the following conditions:

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

   b. Universal Criteria

      1. Recipient has no recent history of hemoptysis (i.e., the presence of ≥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., 5-fluorouracil/5-FU or capecitabine) based regimen for intestinal type disease; and

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

         b. Used for disease progression.

   d. Adult CNS Cancers

      1. Used as single-agent symptomatic mass effect to radiation necrosis, brain edema; and

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

            1. Circumscribe Glioma

            2. Primary CNS Lymphoma

            3. Meningiomas

            4. Brain or Spine metastases

            5. Primary Spinal Cord Tumor

            6. Medulloblastoma

7. Glioblastoma/Gliosarcoma

8. H3-mutated high-grade glioma/High-grade astrocytoma with piloid features (HGPA/Pleomorphic xanthoastrocytoma (PXA) World Health Organization (WHO) Grade 3

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

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

11. 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

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

e. Used in combination with temozolomide and irinotecan for Medulloblastoma (recurrent disease only); or

f. Used as a single agent for surgically inaccessible Meningioma when radiation is not possible; or

3. Used as single agent for Neurofibromatosis type 2 vestibular schwannomas with hearing loss.

e. Cervical Cancer

1. Recipient has adenocarcinoma, adenosquamous, or SCC; and

a. Recipient has recurrent, or metastatic disease; 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 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; or

3. Used in combination with atezolizumab, paclitaxel, and cisplatin or carboplatin; or

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

b. Recipient has small cell NECC; and

1. Used in combination with paclitaxel and topotecan; and

a. Used as first-line therapy; or

b. Used as subsequent therapy (if not previously used as first-line); or

2. Used as a single agent as subsequent therapy.

f. Colorectal Cancer (CRC)

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

~~a. Used in combination with intravenous (IV) fluorouracil-based chemotherapy as first- or second-line treatment for metastatic disease; or~~

~~b.~~a. Used in combination with a fluoropyrimidine (e.g., 5-fluorouracil/5-FU or capecitabine) 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 dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] and~~

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

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

1. Recipient received previous FOLFOX or CapeOX within the past 12 months; and

a. Recipient has pMMR/MSS disease; or

b. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); and

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

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

1. Recipient has pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and

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

e. 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

f.d. Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease; and

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

2. Recipient has pMMR/MSS disease; or

3. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); and

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

g.e. 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 pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); 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 has dMMR/MSI disease

Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed recipients. If deficient mismatch repair (dMMR)/microsatellite instability-high (MSI-H) or polymerase epsilon (POLE)/delta (POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the recipient is a candidate.

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 pMMR/MSS disease; or

2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); 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-fluorouracil/ 5-FU or capecitabine) or irinotecan-based regimen; or~~following previous oxaliplatin-irinotecan- and/or fluoropyrimidine-based therapy; and~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); and~~

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

b. Used in combination with trifluridine and tipiracil 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 pMMR/MSS disease; or~~

~~b. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb); and~~

~~1. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.~~

Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed recipients. If deficient mismatch repair (dMMR)/microsatellite instability-high (MSI-H) or polymerase epsilon (POLE)/delta (POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the recipient is a candidate.

h. Endometrial Carcinoma (Uterine Neoplasms)

1. Used as a single agent; and

a. As subsequent therapy for recurrent disease that has progressed on prior cytotoxic chemotherapy; or

b. Used in combination with carboplatin and paclitaxel and continued as single agent maintenance; or

1. Used for recurrent disease (excluding first-line use for isolated metastases); or

2. Used as primary or adjuvant therapy (stage III-IV with measurable disease only).

i. Hepatocellular Carcinoma (HCC)

1. Used in combination with atezolizumab; and

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

b. Used as subsequent therapy for progression on or after systemic therapy~~Used as adjuvant therapy following resection or ablation~~; and

1. Recipient has not received previous treatment with bevacizumab or a checkpoint inhibitor.~~Recipient is at a high-risk of recurrence (defined as size >5cm, >3 tumors, macrovascular invasion or microvessel invasion on histology or grade ¾ histology.~~

j. Peritoneal Mesothelioma (PeM)

1. Used as adjuvant therapy following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); and

a. Used in combination with pemetrexed and either cisplatin or carboplatin; and

2. Used as first-line therapy; and

a. Used in combination with pemetrexed and either cisplatin or carboplatin; and

1. Recipient has one or more of the following:

a. Medically inoperable disease

b. Complete cytoreduction is not achievable

c. Presence of any high-risk features

d. Disease has progressed following CRS plus 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; 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

k. Pleural Mesothelioma (PM)

1. Used in combination with pemetrexed and either cisplatin or carboplatin; and

a. Used as induction therapy prior to surgical exploration; and

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

2. Used as first-line therapy; or

3. Used as subsequent therapy; and

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

b. 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 in combination with carboplatin and paclitaxel; or

3. Used for one of the following:

   a. Tumor is negative for actionable molecular biomarkers (may be KRAS G12C mutation positive; or

   b. Tumor is positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or ERBB2 (HER2), NRG gene fusion; and

4. 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

2. Used for subsequent therapy; and

a. Used in combination with atezolizumab, carboplatin, and paclitaxel (excluding use in recipients who have received prior PD-1 or PD-L1 inhibitor therapy); and

1. Used for one of the following:

   a. EGFR S7G8I, L861Q, and/or G719X mutation positive tumors and recipient received prior targeted therapy for those aberrations

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

b. Recipient has contraindications to PD-1 or PD-L1 inhibitors; and

1. Used in combination with one of the following:

   a. Carboplatin and paclitaxel

b. Pemetrexed and either carboplatin or cisplatin; and

2. 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, RET 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 positive tumors

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

3. Used as continuation maintenance therapy in recipients who achieved a tumor response or stable disease after first-line systemic therapy; and

a. Used as a single agent (bevacizumab must have been included in the first-line regimen); or

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

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

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

a. Recipient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; and

b. 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 platinum-resistant recurrent low grade serous carcinoma; and

1. Used in combination with oral cyclophosphamide and pembrolizumab; or

2. Used in combination with one of the following: oral cyclophosphamide, gemcitabine, liposomal doxorubicin, paclitaxel, topotecan, or mirvetuximab soravtansine (in folate receptor-alpha expressing tumors [≥25% positive tumor cells]); or

b. ~~a.~~ Recipient has persistent or recurrent disease; and

1. 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 with carboplatin and either gemcitabine, paclitaxel, or 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, 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 [≥25% positive tumor cells]); 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~~ carcinoma 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

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

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

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

4. Used as continued treatment for stable disease following neoadjuvant therapy (endometrioid and serous histology only); and

a. Used in combination with carboplatin and paclitaxel or docetaxel;

b. Used in combination with oxaliplatin and docetaxel; or

b. Used as neoadjuvant therapy (does not apply to low malignant potential or other non-invasive cancers such as ovarian borderline epithelial tumors~~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 (excludes use in grade 1 endometrioid carcinoma and low-grade serous carcinoma); and

2. 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~~excludes use in grade 1 endometrioid carcinoma and low grade serous carcinoma); or

b. Used following interval debulking surgery (IDS) in recipients 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 IDS in recipients 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.

n. Pediatric Central Nervous System (CNS) Cancers

1. Recipient has recurrent or progressive disease; and

a. Recipient has diffuse high-grade glioma (excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant); and

1. Recipient is ≥21 years of age; and

2. Used as a single agent for palliation; or

2. Recipient has medulloblastoma; and

a. Recipient is ≥3 years of age and ≤21 years of age; and

b. Used as part of the temozolomide, irinotecan, bevacizumab (TEMR) regimen; or

c. Used as part of thalidomide, celecoxib, fenofibrate, etoposide, cyclophosphamide, bevacizumab (MEMMAT) regimen.

o. Renal Cell Carcinoma (RCC)

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

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

a. Used in combination with everolimus; or

b. Used in combination with erlotinib for advanced papillary disease including hereditary leiomyomatosis and RCC (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.

a. Used as initial therapy if pMMR/MSS disease; or

b. Used as subsequent therapy if not previously given.

q. Soft Tissue Sarcoma (STS)

1. Used as a single agent for angiosarcoma; or

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

r. Vaginal Cancer

1. Recipient has recurrent or metastatic disease; and

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

1. Used as first-line therapy; or

2. Used as subsequent therapy (if not previously used as first-line); or

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

1. Tumor expressed PD-L1 (Combined Positive Score [CPS] ≥1) as determined by an FDA-approved or CLIA-compliant test; and

a. Used as first-line; or

b. Used as subsequent therapy (if not previously used as first-line); or

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

1. ~~Used as subsequent therapy.~~

s. Vulvar Cancer

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

2. Used for one of the following:
a. First-line therapy

b. Subsequent therapy (if not previously used); and

3. Used in combination with one of the following:

a. Paclitaxel and cisplatin or carboplatin

b. Pembrolizumab, paclitaxel, and either cisplatin or carboplatin.

2. Dosage Limits

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

~~1. Oncology Indications :~~

1. Small Bowel Adenocarcinoma (SBA)/Ampullary Adenocarcinoma: ~~1.~~ 180 billable units per 42 days.

~~1. 180 billable units per 42 days.~~

~~a.~~2. NSCLC, Cervical Cancer, Vaginal Cancer, HCC, Vulvar Cancer, Endometrial Carcinoma, and Mesotheliomas: ~~1.~~ 170 billable units per 21 days.

~~1. 170 billable units per 21 days.~~

~~b.~~3. CRC and Appendiceal Adenocarcinoma, CNS Cancer, RCC, and all other indications: ~~1.~~ 360 billable units per 42 days.

~~1. 360 billable units per 42 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. Duration of authorization has not been exceeded (refer to Section I); and

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

d. 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 and VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, proteinuria,

E. Darzalex® (daratumumab)

Therapeutic Class: Antineoplastic
Last Reviewed by the DUR Board: April 17, 2025

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

1. Coverage is provided in the following conditions:

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

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies; and

   c. Multiple Myeloma (MM)

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

         a. Lenalidomide and dexamethasone; or

         b. Bortezomib, melphalan, and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipient who are eligible for 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. Carfilzomib and pomalidomide

e. Cyclophosphamide and bortezomib; or

f. Selinexor; or

g. Venetoclax (for recipients with t(11;14) only); or

5. Used in combination with pomalidomide and dexamethasone after therapy 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 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 recipients; or

8. Used for the management of polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS) syndrome; and

a. Used as induction therapy for transplant eligible recipients; and

b. Used in combination with lenalidomide and dexamethasone.

d. Systemic Light Chain Amyloidosis

1. Used for newly diagnosed disease or as a repeat of initial therapy if relapse free for several years; and

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

b. Used as a single agent; and

1. Recipient has stage IIIb disease with no significant neuropathy; or

2. Used for relapsed or refractory disease; and

a. Used in combination with lenalidomide and dexamethasone; or

b. Used as a single agent.

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

1. Multiple Myeloma (MM):

a. 180 billable units every seven days for 12 doses, every 14 days for eight doses, every 21 days for 16 doses, then every 28 days.

2. Systemic Light Chain Amyloidosis:

a. 180 billable units every seven days for eight doses, every 14 days for eight doses, then every 28 days.

3. Pediatric ALL:

a. 180 billable units every seven days for eight doses.

3. Recertification Request

Coverage can 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. Duration of authorization has not been exceeded; and

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

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

4. PA Guidelines:

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

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

b. Use for newly diagnosed MM 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 or refractory/progressive MM 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 MM in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.

e. Use as maintenance therapy for MM in combination with lenalidomide may be renewed for up to a maximum of two years.

f. Use for pediatric acute lymphoblastic leukemia (ALL) may not be renewed.

g. Use for newly diagnosed or repeat of initial therapy is relapse-free for several years systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone may be renewed for up to a maximum of two years.

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

Therapeutic Class: Antineoplastic – CD38 Specific Recombinant Monoclonal Antibody Agent
Last Reviewed by the DUR Board: April 17, 2025

PADs 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~~Coverage is provided in the following conditions:

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

   b. Universal Criteria

      1. Therapy will not be used in combination with other anti-CD38 therapies; and

   c. Multiple Myeloma (MM)

      1. Used in the treatment of newly diagnosed disease in recipients who are ineligible for ASCT in combination with one of the following regimens:

         a. Lenalidomide and dexamethasone; or

         b. Bortezomib, melphalan, and prednisone; or

         c. Cyclophosphamide, bortezomib, and dexamethasone; or

      2. Used in the treatment of newly diagnosed disease in recipients who are eligible for ASCT in combination with one of the following regiments:

         a. Bortezomib, lenalidomide, and dexamethasone; or

         b. VTd; or

         c. Carfilzomib, lenalidomide, and dexamethasone; or

         d. Cyclophosphamide, bortezomib, and dexamethasone; or

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

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

         b. Cyclophosphamide, bortezomib, and dexamethasone; or

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

   a. Lenalidomide; or

   b. Bortezomib; or

   c. Carfilzomib; or

   d. Carfilzomib and pomalidomide; or

   e. Cyclophosphamide and bortezomib; or

   f. Selinexor; or

   g. Venetoclax (for recipients with t(11:14) only); or

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

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 recipients; or

8. Used for the management of polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS) syndrome; and

a. Used as induction therapy for transplant eligible recipients; and

b. Used in combination with lenalidomide and dexamethasone.

d. Systemic Light Chain Amyloidosis

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

1. Used for newly diagnosed disease or as a repeat of initial therapy if relapse-free for several years; and

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

b. Used as single agent; and

1. Recipient has stage IIIb disease with no significant neuropathy; or

2. Used for relapsed or refractory disease; and

a. Used in combination with lenalidomide and dexamethasone; or

b. Used as a single agent.

2. Dosage Limits

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

1. Multiple Myeloma (MM)

~~1.~~a. 180 billable units every seven days for 12 doses, every 14 days for eight doses, every 21 days for 16 doses, then every 28 days.

2. Systemic Light-Chain Amyloidosis

a. 180 billable units every seven days for eight doses, every 14 days for eight doses, then every 28 days.

3. Recertification Request

Coverage can be renewed based upon the following criteria:

K. Kadcyla® (ado-trastuzumab emtansine)

Therapeutic Class: Antineoplastic-Antibody Drug Conjugates (ADCs)
Last Reviewed by DUR Board: April 18, 2024

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

1. Coverage is provided in the following conditions:

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

   b. Universal Criteria

      1. Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

      2. Used as a single agent; and

      3. Therapy will not be substituted with or for any trastuzumab-based formulation ~~(i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.)~~; and

   c. Breast Cancer

      1. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

         a. Used as adjuvant therapy; and

            1. Recipient has locally advanced or node positive disease; and

               a. Used for residual disease following completion of planned chemotherapy and mastectomy or breast-conserving surgery (BCS); or

               b. Used in recipients not considering pre-operative systemic therapy; or

            2. Recipient has inflammatory breast cancer; and

               a. Used in recipients who had a response to preoperative systemic therapy, followed by surgery, and needs to complete planned chemotherapy; or

b. Recipient has residual disease following preoperative therapy; or

3. Recipient has early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based therapy; or

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

1. Used as second-line therapy and beyond; or

c. Recipient has metastatic disease that recurred during or within six months of completing adjuvant therapy; and

1. Recipient previously received trastuzumab and a taxane, separately or in combination.

d. Central Nervous System (CNS) Cancer

1. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Used for the treatment of brain metastases in recipients with breast cancer; and

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

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

c. ~~Recipient has~~Used for recurrent limited brain metastases; or

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

e. NSCLC

1. Recipient has ERBB2 (HER2) mutation positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Used as subsequent therapy; and

3. Recipient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of

disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy.

f. Head and Neck Cancer

1. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

2. Recipient has salivary gland tumors; and

3. ~~Used for~~Recipient has recurrent disease with one of the following:

a. ~~Recurrent disease with d~~Distant metastases

b. Unresectable locoregional recurrence with prior RT

c. Unresectable second primary with prior RT.

2. Dosing Limits

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

~~1. Kadcyla® 100 mg single-dose vial: one vial every 21 days.~~

~~2. Kadcyla® 160 mg single-dose vial: three vials every 21 days.~~

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

1. 480 billable units every 21 days.

3. Renewal Criteria:

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 (PS), etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

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

d. ~~c.~~ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: left ventricular dysfunction, hepatotoxicity, pulmonary toxicity (i.e., interstitial lung disease, pneumonitis), thrombocytopenia, neurotoxicity, infusion-related and hypersensitivity reactions, hemorrhage, extravasation at infusion site, etc.; and

e. ~~d.~~ LVEF obtained within the previous three months as follows:

1. Metastatic or Recurrent Breast Cancer: LVEF is >45% or LVEF is 40% to ≤45% and absolute decrease is <10% from baseline; or

2. All other indications: LVEF is ≥50% or LVEF is 45% to <50% and absolute decrease is <10% from baseline~~; and~~.

~~e. Breast Cancer (adjuvant treatment)~~

~~1. Recipient has not exceeded a maximum of 14 cycles of therapy (42 weeks total). (May be given up for up to 17 cycles in recipients who did not receive preoperative therapy).~~

4. PA Guidelines

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

b. Adjuvant treatment in breast cancer is limited to 14 cycles (42 weeks total). (May be given for up to 17 cycles in recipients who did not receive preoperative therapy).

M. Long-Acting Granulocyte Colony Stimulating Factors (LA-gCSF):
Neulasta®; Fulphila®; Udenyca®; Ziextenzo®; Nyvepria™; Fylnetra®; Stimufend®; Rolvedon®; Ryzneuta®; Pegfilgrastim-fpgk

Therapeutic Drug Class: Colony Stimulating Factors
Last Reviewed by DUR Board: July 19, 2024

PADs 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. Pegfilgrastim

a. Coverage is provided in the following conditions:

1. Recipient is at least 18 years of age (Rolvedon® and Ryzneuta® only); and

2. Prophylactic use in recipients with solid tumors or non-myeloid malignancy

a. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of >20%; or

b. Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20% and one or more recipient-related risk factors; or

c. ~~b.~~ Recipient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% and ~~one~~ two or more recipient-related risk factors.

3. Recipient who experience a neutropenic complication from a prior cycle of the same chemotherapy

4. Recipients acutely exposed to myelosuppressive doses from radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

5. Bone marrow transplantation (BMT) failure or engraftment delay (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend®/Pegfilgrastim-fpgk only)

6. Peripheral blood progenitor cell (PBPC) mobilization and transplant (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend®/Pegfilgrastim-fpgk only)

7. Wilms Tumor (nephroblastoma) (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria™, Fylnetra®, and Stimufend®/Pegfilgrastim-fpgk only)

a. Recipient has favorable histology disease; and

N. Pemetrexed
Alimta®; Pemfexy™; Pemetrexed

Therapeutic Drug Class: Antimetabolites
Last Reviewed by DUR Board: April 17, 2025

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

1. Coverage is provided in the following conditions:

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

   b. Central Nervous System (CNS) Cancers

      1. Used as single agent: and

         a. Recipient has Primary CNS Lymphoma; and

            1. Used as induction therapy in recipients unsuitable for or intolerant to high-dose methotrexate (MTX); or

            2. Used for relapsed or refractory disease.

         b. Recipient has leptomeningeal metastases from EGFR mutation-positive NSCLC; and

            1. Used as primary treatment in recipient with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed); or

            2. Used as maintenance treatment in recipients with negative CSF cytology or in clinically stable recipients with persistently positive CSF cytology

   c. Cervical Cancer

      1. Used as subsequent therapy for recurrent or metastatic disease; and

      2. Recipient has SCC, adenocarcinoma, or adenosquamous carcinoma; and

      3. Used as a single agent.

   d. Peritoneal Mesothelioma (PeM)

1. Used as adjuvant therapy following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); and

   a. Recipient has surgical/pathologic high-risk features; and

   b. Recipient has surgical/pathologic high-risk features, and no neoadjuvant therapy was given; and

   c. Used as a single agent or in combination with platinum chemotherapy with or without either bevacizumab or pembrolizumab; or

2. Used as first-line therapy; and

   a. Recipient has biphasic/sarcomatoid histology or bicavitary disease; or

   b. Recipient has one or more of the following; and

      1. Medically inoperable

      2. Complete cytoreduction is not achievable

      3. Presence of any high-risk features

      4. Disease has progressed after prior CRS plus HIPEC and no previous adjuvant systemic therapy was given; and

   c. Used as a single agent or in combination with platinum chemotherapy with or without either bevacizumab or pembrolizumab;

3. Used as subsequent therapy; and

   a. Used as a single agent or in combination with platinum chemotherapy with or without bevacizumab,

      1. Immunotherapy (i.e., nivolumab/ipilimumab) was administered as first-line treatment; or

      2. Used as rechallenge if pemetrexed was administered first-line with good response.

e. Pleural Mesothelioma (PM)

1. Used as induction therapy prior to surgical exploration; and

a. Recipient has clinical stage I disease and epithelioid histology; and

b. Used as a single agent or in combination with platinum chemotherapy, with or without either bevacizumab or pembrolizumab; or

2. Used as first-line therapy; and

a. Used as a single agent or in combination with platinum chemotherapy, with or without either bevacizumab or pembrolizumab; or

3. Used as subsequent therapy; and

a. Used as a single agent or in combination with platinum chemotherapy, with or without bevacizumab; and

1. Immunotherapy (i.e., nivolumab/ipilimumab) was administered as first-line treatment; or

2. Used as rechallenge if pemetrexed was administered first-line with a good response.

f. Non-Squamous Non-Small Cell Lung Cancer (NS-NSCLC)

1. Used in combination with carboplatin or cisplatin-containing regimen; or

2. Used in combination with bevacizumab, pembrolizumab, cemiplimab, or durvalumab for continuation maintenance therapy if previously used first-line and recipient achieved a tumor response or stable disease following initial therapy; or

3. Used as a single agent; and

a. 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 for tumors that are negative for actionable molecular biomarkers; or

2. Used as first-line therapy for EGFR exon 20 mutation, BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon-14 skipping mutation, NRG-1 gene fusion, or ERBB2 (HER2) mutation positive tumors; or

3. Used as subsequent therapy; or

4. Used continuation or switch maintenance therapy in recipients who have achieved tumor response or stable disease following initial therapy.

g. Thymomas/Thymic Carcinoma

1. Used as a single agent; and

a. Recipient is unable to tolerate first-line combination regimens; and

1. Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; or

2. Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection

3. Used as first-line therapy for recurrent, advanced, or metastatic disease; or

b. Used as second-line therapy; and

1. Recipient has unresectable or metastatic disease.

h. Ovarian Fallopian Tube, and Primary Peritoneal Cancer

1. Used as single agent; and

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

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

b. Recipient has recurrent Low-Grade Serous Carcinoma.

i. Vaginal Cancer

1. Used as a single agent; and

2. Used as subsequent therapy for recurrent or metastatic disease.

j. Thyroid Carcinoma

1. Used in combination with carboplatin; and

a. Recipient has Follicular or Papillary Carcinoma; and

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

2. Recipient has progressive and/or symptomatic disease that is refractory to radioactive iodine (RAI) therapy; or

b. Recipient has Oncocytic Carcinoma; and

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

2. Recipient has progressive and/or symptomatic disease that is refractory to radioactive iodine (RAI) therapy; or

c. Recipient has Anaplastic Carcinoma; and

1. Used as second-line therapy for stage IVC (metastatic) disease.

2. Dosage Limits

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

1. Pemfexy™ (500 mg MDV):

a. Primary CNS Lymphoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer: 225 billable units every 21 days

b. Leptomeningeal Metastases from NSCLC: five billable units on days one and five of a seven day cycle, then five billable units every 21 days

c. Thymomas/Thymic Carcinoma, Non-Squamous NSCLC, and Mesotheliomas: 125 billable units every 21 days for six cycles.

2. Pemetrexed (all other manufacturers) (100 mg, 500 mg, 750 mg, 850 mg, and 1000 mg SDV):

a. Primary CNS Lymphoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer: 230 billable units every 21 days

b. Leptomeningeal Metastases from NSCLC: 10 billable units on days one and five of a seven-day cycle, then 10 billable units every 21 days

c. Thymomas/Thymic Carcinoma, Non-Squamous NSCLC, ~~and~~ Mesotheliomas and Thyroid Carcinoma: 130 billable units every 21 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 (PS), etc. identified in Section III; and

b. Duration of authorization has not been exceeded; and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal toxicity (CrCL <45 mL/min), bullous and exfoliative skin toxicity (e.g., SJS/TEN), interstitial pneumonitis, radiation recall, etc.; and

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

4. PA Guidelines

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

1. Thymomas/Thymic Carcinoma: Coverage will be provided for six cycles and may not be renewed

2. Mesothelioma (including PeM, PM, pericardial mesothelioma, and tunica vaginalis testis mesothelioma):

a. In combination with bevacizumab and platinum chemotherapy: Coverage will be provided for six cycles and may not be renewed.

b. In combination with pembrolizumab and platinum chemotherapy: Coverage will be provided for six doses and may not be renewed.

O. HER2 Inhibitors

Therapeutic Drug Class: HER2 Inhibitors
Last Reviewed by DUR Board: January 16, 2025

HER2 Inhibitors 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. Perjeta® (pertuzumab)

   a. Coverage is provided in the following conditions:

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

      2. Universal Criteria

         a. LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

         b. Recipient has HER2-positive disease as determined by an FDA-approved or CLIA-compliant test; and

         c. Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo®); and

      3. Breast Cancer

         a. Used as neoadjuvant or preoperative therapy; and

            1. Recipient has ~~locally advanced~~≥T1c disease, node positive disease, or inflammatory disease; and

            2. Used in combination with trastuzumab and chemotherapy; or

         b. Used as adjuvant therapy; and

            1. Recipient has ~~locally advanced~~≥T1c disease, node positive disease, or inflammatory disease (unless otherwise specified); and

               a. Used in combination with trastuzumab and chemotherapy (pT2-3 and pN0 or pN+ only); or

               b. Used in combination with trastuzumab; or

2. Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; and

a. Recipient has ≥ypT0N0 or pCR disease by axillary staging; and

b. Used in combination with trastuzumab; or

c. Used for recurrent unresectable or metastatic disease or inflammatory breast cancer with no response to preoperative systemic therapy; and

1. Used as first-line therapy in combination with trastuzumab and either paclitaxel or docetaxel; or

2. Used as subsequent therapy in combination with trastuzumab with or without cytotoxic therapy; and

a. Recipient was previously treated with trastuzumab and chemotherapy; and

b. Recipient has not previously received pertuzumab.

4. CNS Cancer

a. Used for the treatment of brain metastases in recipients with breast cancer; and

b. Used in combination with trastuzumab; and

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

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

3. ~~Recipient has~~Used for recurrent limited brain metastases; or

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

5. CRC

a. Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; and

1. Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CAPOX within the past 12 months; ~~and~~or

~~a. Recipient has pMMR/MSS disease; or~~

2. Used as primary treatment for unresectable (or medically inoperable) or metastatic disease if intensive therapy is not recommended; and

a. Recipient has not previously received HER2-targeted therapy; ~~and~~or

~~b. Used in one of the following:~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

3. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or locally unresectable (or medically inoperable) rectal cancer if intensive therapy is not recommended; and

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

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

b. Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; ~~and~~or

~~1. Recipient has dMMR/MSI-H disease; or~~

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

a. Recipient has not previously received HER2-targeted therapy~~; and~~.

~~b. Used in one of the following:~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

6. Appendiceal Adenocarcinoma – Colon Cancer

a. Used for RAS and BRAF WT disease in combination with trastuzumab; and

b. Recipient has not previously received HER2-targeted therapy; and

c. Used for one of the following

1. Used as initial therapy for advanced or metastatic disease if intensive therapy is not recommended; or

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

~~d. Used in one of the following:~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

7. Head and Neck Cancer

a. Recipient has salivary gland tumors; and

b. Used in combination with trastuzumab; and

c. ~~Used for~~ Recipient has recurrent disease with one of the following:

1. ~~Recurrent disease with d~~Distant metastases

2. Unresectable locoregional recurrence with prior RT

3. Unresectable second primary with prior RT.

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

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

b. Used in combination with trastuzumab.

b. Dosage Limits

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

~~a. Perjeta® 420 mg/14 mL solution for injection:~~

~~1. Loading Dose: two vials~~

~~2. Maintenance Dose: one vial every 21 days.~~

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

a. Loading Dose: 840 billable units x one dose

b. Maintenance Dose: 420 billable units every 21 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 prerequisite therapy), performance status (PS), etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

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

4. ~~3.~~ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: left ventricular dysfunction, severe infusion-related reactions, hypersensitivity reactions/anaphylaxis, etc.; and

5. ~~4.~~ LVEF obtained within the previous three months as follows:

a. Neoadjuvant and adjuvant treatment of breast cancer: LVEF is ≥50% or LVEF has had an absolute decrease of <10% from baseline

b. All other indications: LVEF is >45% or LVEF is 40% to 45% and absolute decrease is <10% from baseline.

~~5. Breast Cancer (neoadjuvant or adjuvant therapy)~~

~~a. Recipient has not exceeded a maximum of one year or treatment (total of 18 cycles).~~

d. PA Guidelines

1. Coverage is provided for six months and may be renewed (unless otherwise specified).

2. Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of one year of treatment [18 cycles].

2. Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (trastuzumab)

a. Coverage is provided in the following conditions:

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

2. Universal Criteria

a. Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every three months) during treatment; and

b. Recipient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

c. Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for seven months after the last dose; and

d. Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla®) or fam-trastuzumab deruxtecan-nxki (Enhertu®); and

e. Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin®, Hylecta®) or pertuzumab/ trastuzumab and hyaluronidase-zzxf (Phesgo®); and

3. Breast Cancer

a. Used as adjuvant therapy; and

1. Recipient has ≥T1 disease, node positive, or inflammatory disease (unless otherwise specified); and

a. Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with ~~or without~~ pertuzumab (pT2-3 and pN0 or pN+ only; or

b. Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) without pertuzumab

~~b.~~c. Used in combination with pertuzumab; or

~~c.~~d. Used as a single agent; or

2. Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; and

   a. Recipient has ≥ypT0N0 or pathological complete response (pCR) disease by axillary staging; and
   b. Used as a single agent or in combination with pertuzumab; or

b. Used as neoadjuvant or preoperative therapy; and

   1. Recipient has ≥T1c disease, node positive, or inflammatory disease; and

   2. Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; or

c. Used for recurrent unresectable (local or regional) or metastatic disease or inflammatory breast cancer; and

   1. Used as a single agent in recipients who have received one or more prior chemotherapy regimens for metastatic disease; or

   2. Used in combination with one of the following:

      a. Paclitaxel as first-line therapy for metastatic disease; or

      b. Endocrine therapy (e.g., tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib) in recipients with hormone-receptor positive disease; and

         1. Recipient is post-menopausal; or

         2. Recipient is pre-menopausal and is treated with ovarian ablation/suppression; or

         3. Recipient is pre-menopausal and will not receive ovarian ablation/suppression (with tamoxifen only); or

         4. Recipient is a male (sex assigned at birth).

      c. Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy

d. Capecitabine and tucatinib as second-line therapy and beyond

e. Cytotoxic chemotherapy as fourth-line therapy and beyond

f. Lapatinib (without cytotoxic therapy) as fourth-line therapy and beyond

g. Pertuzumab with or without cytotoxic therapy as subsequent therapy in recipients previously treated with chemotherapy and trastuzumab (without pertuzumab).

4. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from breast cancer; and

1. Trastuzumab will be administered intrathecally or intraventricularly; and

a. Used as primary treatment in recipients with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, or reasonable systemic treatment options if needed); or

b. Used as maintenance therapy in recipients with negative CSF cytology or in clinically stable recipient with persistently positive CSF cytology; or

b. Recipient has brain metastases from breast cancer; and

1. Used in combination with one of the following:

a. Pertuzumab

b. Capecitabine and tucatinib in recipients previously treated with at least one HER2-directed regimen; and

2. Used in one of the following treatment settings:

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

b. Recipient has recurrent limited brain metastases; or

c. Recipient has recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; or

d. Recipient has relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options.

5. Gastric, Esophageal, and Esophagogastric Junction Cancers

a. Recipient has adenocarcinoma; and

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

c. Used as first-line therapy; and

d. Used in combination with chemotherapy; or

~~1. Used as induction systemic therapy for relieving dysphagia (applies to Esophageal and Esophagogastric Junction Cancers only); and~~

~~a. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high risk lesions, lymphovascular invasion, ≥3 cm, poorly differentiated), cT1B-cT2, N+ or cT3-cT4a, Any N disease; and~~

~~1. Used in combination with chemotherapy; or~~

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

~~a.~~1. Tumor expressed PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-complaint test

~~2. Recipient has early stage disease with favorable histology (applies to Gastric Cancer only); and~~

~~a. Recipient has completed an endoscopic resection; and~~

~~1. Used in combination with chemotherapy; or~~

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

~~a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-complaint test; or~~

~~3. Recipient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic adenocarcinoma; and~~

~~a. Used as first-line therapy; and~~

~~1. Used in combination with chemotherapy; or~~

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

~~a. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test.~~

6. Endometrial Carcinoma – Uterine Neoplasms

a. Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; and

b. Recipient has uterine serous carcinoma or carcinosarcoma; and

1. Recipient has stage III/IV disease; or

2. Recipient has recurrent disease and has not received prior trastuzumab therapy; and

a. Used as first-line therapy; and

1. Recipient does not have isolated metastases; or

b. Used in subsequent therapy.

7. Colorectal Cancer (CRC)

a. Recipient has RAS and BRAF wild-type (WT) disease; and

b. Used in combination with pertuzumab, lapatinib, or tucatinib; and

1. Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CAPOX within the past 12 months; ~~and~~or

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

2. Used as primary treatment for unresectable (or medically inoperable) or metastatic disease if intensive therapy is not recommended; and

a. Recipient has not previously received HER2-directed therapy; and

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

3. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or unresectable (or medically inoperable) rectal cancer if intensive therapy is not recommended; and

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

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

b. Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; ~~and~~or

~~1. Recipient has dMMR/MSI-H disease; or~~

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

a. Recipient has not previously received HER2-directed therapy.~~; and~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

~~b. Recipient is not eligible for or has progressed on checkpoint inhibitor immunotherapy.~~

8. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient has RAS and BRAF WT disease; and

b. Used in combination with pertuzumab, lapatinib or tucatinib; and

c. Recipient has not previously received HER2-targeted therapy; and

d. Used for one of the following:

1. Used as initially therapy for advanced or metastatic disease if intensive therapy is not recommended; or

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

~~e. Used in one of the following:~~

~~1. Recipient has pMMR/MSS disease; or~~

~~2. Recipient has dMMR/MSI-H disease or POLE/POLD1 mutation; and~~

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

9. Head and Neck Cancers

a. Recipient has salivary gland tumors; and

b. Used as a single agent or in combination with either docetaxel or pertuzumab; and

c. Recipient has recurrent disease with one of the following:

1. Distant metastases

2. Unresectable locoregional recurrence with prior RT

3. Unresectable second primary with prior RT.

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

a. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

b. Used in combination with pertuzumab.

b. Dosage Limits

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

a. Ogivri®, Kanjinti®, Trazimera®, Herzuma®, Ontruzant® (420 mg MDV):

1. Gastric, Esophageal, and Esophagogastric Junction Cancer:

a. Load: 92 billable units x one dose

b. Maintenance: ~~69~~138 billable units every ~~1~~42 days

2. CNS Cancer: ~~276 billable units every 28 days~~

a. Load: 92 billable units x one dose

b. Maintenance: 60 billable units every 21 days

3. Breast Cancer, CRC, ~~and~~ Appendiceal Adenocarcinoma, Head and Neck Cancers, and ~~A~~all other indications: 92 billable units every 21 days

~~a.~~b. Herceptin (150 mg SDV):

1. Gastric, Esophageal, and Esophagogastric Junction Cancer:

a. Load: 90 billable units x one dose

b. Maintenance: ~~75~~ 150 billable units every ~~1~~42 days

2. CNS Cancer: ~~300 billable units every 28 days~~

a. Load: 90 billable units x one dose

b. Maintenance: 225 billable units every 21 days

3. Breast Cancer, CRC, ~~and~~ Appendiceal Adenocarcinoma, and Head and Neck Cancers:

a. 90 billable units every 21 days

b. All other indications: ~~90 billable units every 21 days~~

1. Load: 90 billable units x one dose

2. Maintenance: 75 billable units every 21 days.

~~b.a. Ogivri®, Kanjinti®, Trazimera®, Herzuma®, Ontruzant® (420 mg MDV):~~

~~1. Gastric, Esophageal, and Esophagogastric Junction Cancer:~~

~~a. Load: 92 billable units x one dose~~

~~b.a. Maintenance: 69 billable units every 14 days~~

~~2.1. CNS Cancer: 276 billable units every 28 days~~

~~3.1. Breast Cancer, CRC, and Appendiceal Adenocarcinoma, All other indications: 92 billable units every 21 days~~

c. Recertification Request

1. 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 prerequisites therapy), performance status, etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

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

~~c.~~d. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiomyopathy (e.g., left ventricular cardiac dysfunction, arrhythmias, cardiac failure, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, etc.), severe or febrile neutropenia, severe infusion-related reactions, etc.; and

~~d.~~e. LVEF obtained within the previous three months as follows:

1. LVEF is within the institutional normal limits, and has not had an absolute of ≥16% from pre-treatment baseline; or

2. LVEF is below the institutional lower limits of normal and has not had an absolute decrease of ≥10% from pre-treatment baseline; and

d. PA Guidelines

1. Coverage is provided for six months and may be renewed (unless otherwise specified).

a. Neoadjuvant/preoperative and adjuvant treatment in Breast Cancer may be authorized up to a maximum of 52 weeks of treatment.

P. CD20 Monoclonal Antibodies

Therapeutic Class: Antirheumatic, CD20 Monoclonal Antibodies
Last Reviewed by the DUR Board: April 17, 2025

PADs 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. Rituxan®, Truxima®, Ruxience™, Riabni™ (rituximab)

   a. Coverage is provided in the following conditions:

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

      2. Universal Criteria

         a. Recipient does not have a severe, active infection; and

         b. Recipient has been screened for the presence of HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and recipients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; and

         c. Recipient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; and

      3. Oncology Indications

         a. Recipient~~'s~~ ~~is~~ CD20 antigen expression ~~is~~ positive (excluding use for cGvHD, Hematopoietic Cell Transplantation, and Management of Immunotherapy-Related Toxicity); and

      4. Pediatric Mature B-Cell Acute Leukemia (B-AL)

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

         b. Used in combination with chemotherapy for previously untreated disease

      5. Adult Acute Lymphoblastic Leukemia (ALL)

         a. Recipient has Philadelphia chromosome-positive (Ph+) disease; and

            1. Used in combination with a tyrosine kinase inhibitor (TKI)-based regimen; and

a. Recipient is <65 years of age without significant comorbidities; or

2. Used in combination with methotrexate, vincristine, pegaspargase, dexamethasone (MOpAD) for TKI-refractory disease; or

b. Recipient has Philadelphia chromosome-negative (Ph-) disease; and

1. Used as a component of a multiagent chemotherapy.

6. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from lymphomas; and

b. Recipient has primary CNS lymphoma; and

1. Used for induction therapy; and

a. Used as a single agent or in combination with a methotrexate-containing regimen, temozolomide, or lenalidomide; or

b. Recipient has CSF positive or spinal MRI positive disease; or

2. Used for consolidation (monthly maintenance) therapy; and

a. Used as continuation of induction regimen in recipients with complete response or complete response unconfirmed (CRu) to induction therapy; and

1. Used as a single agent; or

2. Used in combination with dose methotrexate; or

3. Used for relapsed or refractory disease; and

a. Used as a single agent, or in combination with systemic therapy in recipients with prior whole brain radiation therapy; and

1. Recipient has CSF positive or spinal MRI positive disease; or

b. Used as a single agent or in combination with either temozolomide, lenalidomide, or high-dose methotrexate/high-dose methotrexate-containing regimen.

7. Adult Hodgkin Lymphoma

a. Recipient has nodular lymphocyte-predominant disease.

8. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

a. Used in combination with fludarabine and cyclophosphamide (FC); or

b. Recipient has disease without del (17p)/TP53 mutation; and

1. Used as first-line therapy in combination with bendamustine (excluding use in frail recipients); or

2. Used as subsequent therapy in combination with one of the following:

a. Bendamustine (recipients <65 years of age without significant comorbidities; excluding use in frail recipients)

b. Idelalisib

c. Lenalidomide

d. Venetoclax; or

c. Recipient has disease with del(17p)/TP53 mutation; and

1. Used as first-line therapy in combination with high-dose methylprednisolone; or

2. Used as subsequent therapy in combination with one of the following:

a. Alemtuzumab

b. High-dose methylprednisolone

c. Idelalisib

d. Lenalidomide; or

3. Used as initial therapy for histologic (Richter's) transformation to DLBCL; and

a. Used in combination with cyclophosphamide, doxorubicin, and vincristine-based regimens (excluding use with venetoclax) or as a component of oxaliplatin, fludarabine, cytarabine, and rituximab (OFAR).

9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

10. Adult B-Cell Lymphomas including, but not limited to, the following:

a. HIV-Related B-Cell Lymphoma

1. Disease is related to Burkitt lymphoma, DLBCL, HHV8-positive DLBCL (not otherwise specified), or primary effusion lymphoma (PEL), plasmablastic lymphoma

b. Burkitt Lymphoma

1. Used in combination with chemotherapy

~~2.~~c. DLBCL

~~3.~~d. Low-Grade (grade 1-2) or Follicular Lymphoma

~~4.~~e. Extranodal Marginal Zone Lymphoma (EMZL) of the Stomach and Nongastric Sites (Noncutaneous)

~~5.~~f. Nodal and Splenic Marginal Zone Lymphoma

~~6.~~g. High-Grade B-Cell Lymphomas

~~7.~~h. Mantle Cell Lymphoma

~~8.~~i. Histologic Transformation of Indolent Lymphomas to DLBCL

~~9.~~j. Post-Transplant Lymphoproliferative Disorders (PTLD) (B-Cell type)

11. ~~e.~~ Castleman Disease

a. ~~1.~~ Recipient has multicentric disease; or

b. ~~2.~~ Recipient has unicentric unresectable disease; and

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

~~b.~~2. Used as second-line therapy for relapsed, refractory, or progressive disease

~~11.~~12. Primary Cutaneous B-Cell Lymphomas

~~12.~~13. Pediatric Aggressive Mature B-Cell Lymphomas

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

1. Used in combination with chemotherapy for one of the following:

a. Primary Mediastinal Large B-Cell Lymphoma

b. Diffuse Large B-Cell Lymphoma (DLBCL)

c. Burkitt Lymphoma

d. Burkitt-like Lymphoma; or

2. Recipient has Post-Transplant Lymphoproliferative Disorders (PTLD) (B-Cell type).

~~13.~~14. Hairy Cell Leukemia

a. Used as a single agent; and

1. Used for incomplete hematologic recovery or relapsed disease in recipients unable to receive purine analogs (i.e., cladribine or pentostatin); or

b. Used in combination with cladribine; or

c. Used in combination with pentostatin; and

1. Used for incomplete hematologic recovery or relapsed disease; or

d. Used in combination with vemurafenib; and

1. Used as initial therapy or for relapse ≥2 years after initial therapy in recipients with indications for treatment who are not candidates for purine analogs including recipients who are frail and those with active infection; or

2. Used for incomplete hematologic recovery or relapse within two years of full hematologic recovery consistent with complete response following initial treatment with cladribine or pentostatin; or

3. Used for progression after therapy for relapsed or refractory disease; and

e. Used in combination with venetoclax; and

1. Used for progression after therapy for relapsed or refractory disease; and

2. Recipient had disease resistance to BRAF inhibitor therapy

~~14.~~15. Histiocytic Neoplasms – Rosai-Dorfman Disease

a. Used as a single agent for nodal, immune-cytopenia, or immunoglobulin G4 (IgG4) diseases; and

1. Used for symptomatic unresectable unifocal disease; or

2. Used for symptomatic multifocal disease; or

3. Used for relapsed/refractory disease.

~~15.~~16. Pediatric Hodgkin Lymphoma

a. Recipient is ≤18 years of age; and

b. Recipient has nodular lymphocyte-predominant; and

c. Used in combination with cyclophosphamide, vinblastine, prednisone (CVbP); and

d. Used as primary treatment for stage IA or IIA disease (incomplete resection and non-bulky disease).

~~16.~~17. Chronic Graft versus Host Disease (cGvHD)

a. Recipient is post-allogeneic hematopoietic cell transplant (generally three or more months); and

b. Used as additional therapy in combination with systemic corticosteroids; and

c. Recipient has no response (e.g., steroid-refractory disease) to first-line therapy options; and

~~17.~~18. Hematopoietic Cell Transplantation

a. Used as conditioning for allogeneic transplant as part of a non-myeloablative regimen in combination with cyclophosphamide and fludarabine.

~~18.~~19. Management of Immunotherapy-Related Toxicities

a. Recipient has been receiving therapy with an immune checkpoint inhibitor; and

1. Recipient has encephalitis related to immunotherapy; and

a. Recipient is autoimmune-encephalopathy-antibody positive; or

b. Recipient has had limited to no improvement after seven to 14 days on high-dose corticosteroids with or without IVIG; or

2. Recipient has bullous dermatitis related to immunotherapy; and

a. Used as additional therapy for severe (G3) or life-threatening (G4) disease; or

3. Recipient has bullous pemphigoid related to immunotherapy, confirmed by biopsy or serology; and

a. Used as additional therapy for moderate (G2) disease; or

4. Recipient has hemolytic anemia with hemolysis related to immunotherapy; and

a. Used as additional therapy for G3 disease if no response to corticosteroids after 5-7 days; or

b. Used as additional therapy for G4 disease if no response to corticosteroids after 3-5 days; or

5. Recipient has thrombocytopenia related to immunotherapy; and

a. Used as additional therapy for G3 or G4 disease if no response to corticosteroids after 1-2 weeks; or

6. Recipient has stage 3 acute kidney injury/elevated serum creatinine related to immunotherapy; and

   a. Toxicity remains >stage 2 after 4-6 weeks of corticosteroids; or

   b. Creatinine increases during corticosteroid taper (or once-off corticosteroids); or

7. Recipient has moderate or severe steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) related to immunotherapy; and

   a. Used for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids; or

8. Recipient has myasthenia gravis related to immunotherapy; and

   a. Used as additional therapy for severe (G3-4) disease that is refractory to plasmapheresis or IVIG.

~~19.~~20. Non-Oncology Indications

a. Recipient is not on concurrent treatment with another CD20-directed therapy, biologic agent~~s~~ or~~,~~ targeted synthetic therapies~~-~~; and

~~20.~~21. Rheumatoid Arthritis (RA)

a. Physician has assessed baseline disease severity utilizing an objective measure/tool; and

b. Documented moderate to severe active disease; and

c. Used in combination with methotrexate unless the recipient has contraindication or intolerance; and

   1. Recipient tried and failed at least three-month trial with one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.); or

   2. Recipient is already established on biologic or targeted synthetic therapy for the treatment of RA; and

d. Previous failure with one or more TNF antagonists; and

e. Recipient has not had treatment with rituximab in the previous four months.

~~21.~~22. Pemphigus Vulgaris

a. Recipient has a diagnosis of pemphigus vulgaris as determined by the following:

1. Recipient has one or more of the following clinical features:

a. Appearance of lesions, erosions, and/or blisters

b. Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)

c. Characteristic scarring and lesion distribution; and

b. Histopathologic confirmation by skin/mucous membrane biopsy; and

c. Positive direct immunofluorescence (DIF) microscopy result or presence of autoantibodies as detected by indirect immunofluorescence (IIF) or enzyme-linked immunosorbent assay (ELISA); and

d. Recipient has moderate to severe disease as assessed utilizing an objective measure tool (i.e., PDAI, PSS, ABSIS, etc.); and

e. Used in combination with glucocorticoids (e.g., prednisone, prednisolone, etc.); and

f. Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out.

~~22.~~23. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

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

b. Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone, etc.).

~~23.~~24. Thrombocytopenic Purpura

a. Diagnosis includes one of the following:

1. Primary thrombocytopenia or idiopathic (immune) thrombocytopenia purpura (ITP).

2. Evans syndrome; and

b. Recipient has previously failed or has a contraindication or intolerance to therapy with corticosteroids; and

c. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) <30 x 10^9/L (30,000mm (3)); and

~~24.~~25. Thrombotic Thrombocytopenic Purpura (TTP)

a. Recipient has immune-mediated or acquired disease with ADAMTS13-deficiency; and

1. Used in combination with corticosteroids and therapeutic plasma exchange (TPE); or

2. Used as a single agent as prophylactic therapy for recipients in remission.

~~25.~~26. Multiple Sclerosis (MS)

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

b. Recipient has a diagnosis of a relapsing form of MS [i.e., RRMS, active SPMS, or CIS]

~~26.~~27. Autoimmune Hemolytic Anemia (AIHA)

a. Recipient has warm-reactive disease refractory to or dependent on glucocorticoids; or

b. Recipient has cold agglutinin disease with symptomatic anemia, transfusion-dependence and/or disabling circulatory symptoms.

~~27.~~28. Systemic Lupus Erythematosus (SLE)

a. Recipient has a diagnosis of active SLE without active lupus nephritis (LN); and

1. The requested agent is FDA-labeled or compendia supported for SLE; and

b. Both of the following:

1. One of the following:

a. The recipient has one of the following:

1. Has tried and had an inadequate response to hydroxychloroquine; or

2. Recipient has intolerance, or hypersensitivity to hydroxychloroquine; or

b. The recipient has an FDA-labeled contraindication to hydroxychloroquine; and

2. One of the following:

a. The recipient has one of the following:

1. Has tried and had an inadequate response to one corticosteroid or immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); or

2. Has an intolerance or hypersensitivity to one corticosteroid or immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); or

b. Recipient has an FDA-labeled contraindication to all corticosteroids and immunosuppressive agents (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); and

c. Recipient is currently treated with and will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide); and

d. Recipient does not have severe active central nervous system (CNS) lupus; and

e. Recipient will not be using in combination Lupkynis®; and

f. One of the following:

1. The recipient will not be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.); or

2. The recipient will be using the requested agent in combination with another immunomodulatory agent and both of the following:

   a. The prescribing information for the requested agent does not limit the use with another immunomodulatory agent; and

   b. There is support for the use of combination therapy (submitted copies of clinical trials, phase III studies, or guidelines required)

~~28.~~29. Lupus Nephritis (LN)

a. Recipient has a diagnosis of active LN and both of the following:

   1. The requested agent is FDA-labeled or compendia supported for LN; and

   2. The recipient has class III, IV, V lupus nephritis (LN) confirmed via kidney biopsy; and

b. Recipient will be using background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide) in combination; and

c. Recipient does not have severe active central nervous system (CNS) lupus; and

d. One of the following:

   1. The recipient will not be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.); or

   2. The recipient will be using the requested agent in combination with another immunomodulatory agent and both of the following:

      a. The prescribing information for the requested agent does not limit the use with another immunomodulatory agent; and

b. There is support for the use of combination therapy (submitted copies of clinical trials, phase III studies, or guidelines required).

~~29.~~30. Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

a. Recipient has muscle-specific tyrosine kinase (MuSK)-antibody positive disease; and

b. Recipient is refractory to standard first-line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)

~~30.~~31. Complications of Transplanted Solid Organ (kidney, liver, lung, heart, pancreas) in Adult and Pediatric Recipients

a. Used for suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation; or

b. Used for treatment of antibody-mediated rejection of solid organ transplantation.

~~31.~~32. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has confirmed diagnosis based on the following:

1. Recipient is seropositive for aquaporin-4 (AQP-4) IgG antibodies; and

a. Recipient has at least one core clinical characteristic; and

b. Alternative diagnoses have been excluded (e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), MS, sarcoidosis, cancer, chronic infection, etc.); or

2. Recipient is seronegative for AQP-4 IgG antibodies or has unknown AQP-4-IgG status; and

a. Recipient has at least two core clinical characteristics occurring as a result of one or more clinical attacks; and

b. Recipient experienced all of the following:

1. At least one core clinical characteristic must be optic neuritis, acute myelitis with LETM, or area postrema syndrome
2. Fulfillment of additional MRI requirements for each area affected; and

c. Alternative diagnoses have been excluded (e.g., MOGAD, MS, sarcoidosis, cancer, chronic infection, etc.); and

b. Used as a single agent or in combination with immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate, etc.).

~~32.~~33. Antisynthetase Syndrome-Related Interstitial Lung Disease

a. Recipient has antisynthetase antibody positive disease (e.g., anti-Jo-1, -PL-7, -PL-12, -OJ, -EJ, etc.); and

b. Physician has assessed baseline disease severity utilizing an objective measure (i.e., baseline glucocorticoid use, pulmonary function testing [i.e., FVC%, total lung capacity (TLC%), diffusing capacity of the lungs for carbon monoxide (DLCO%)], or chest CT scan); and

c. Recipient has documented severe active disease; and

d. Recipient has recurrent or progressive disease despite treatment with glucocorticoids and/or other immunosuppressive agents (e.g., azathioprine, mycophenolate mofetil, cyclophosphamide, tacrolimus, etc.); and

e. Will be used in combination with glucocorticoids or other immunosuppressive agents (e.g., azathioprine, mycophenolate mofetil, cyclophosphamide, tacrolimus, etc.), unless the recipient has a contraindication or intolerance.

~~33.~~34. Idiopathic Membranous Nephropathy

a. Recipient has a documented diagnosis of idiopathic (primary) membranous nephropathy; and

b. Secondary causes of membranous nephropathy have been ruled out [e.g., infections, autoimmune diseases, malignancies, nutritional supplements (e.g., lipoic acid, etc.), NSAIDs, etc.]; and

1. Used as first-line therapy in recipient with any of the following moderate to high risk factors for progressive disease:

   a. Proteinuria >3.5 g/day and no decrease >50% after six months of therapy with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB); or

   b. eGFR <60 mL/min/1.73m2; or

   c. Proteinuria >8 g/d for >6 months; or

   d. Recipient has experienced serious complications of nephrotic syndrome (e.g., acute kidney injury, infection, thromboembolic events, etc.); or

2. Used for initial disease relapse following remission on first-line therapy with rituximab, a calcineurin inhibitor (e.g., tacrolimus, cyclosporine, etc.) or cyclophosphamide in combination with glucocorticoids; or

3. Used for treatment-resistance to first-line therapy with rituximab, a calcineurin inhibitor (e.g., tacrolimus, cyclosporine, etc.) or cyclophosphamide in combination with glucocorticoids; and

   a. Recipient has a stable eGFR; and

   b. Will be used in combination with a calcineurin inhibitor if previously treated with rituximab alone in the first-line setting; or

4. Used for disease recurrence following kidney transplant; and

   1. Recipient has proteinuria >1 g/d.

~~34.~~35. Pediatric Idiopathic Nephrotic Syndrome

a. Recipient is 12 years of age or younger

b. Recipient has symptomatic disease (i.e., nephrotic-range proteinuria and either hypoalbuminemia or edema when albumin level is not available)

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

1. Frequently relapsing nephrotic syndrome (FRNS) with at least four relapses per year or at least two relapses within six months of initial presentation

2. Steroid dependent nephrotic syndrome (SDNS) with two consecutive relapses during steroid tapering or within 14 days of cessation of therapy

3. Steroid resistant nephrotic syndrome (SRNS) with failure to achieve complete remission within a 4-6-week course of daily corticosteroids; and

d. Recipient has failed an adequate trial with at least one other steroid-sparing agent (e.g., cyclophosphamide, calcineurin inhibitor [e.g., tacrolimus, cyclosporine, etc.], mycophenolate mofetil, etc.)

~~35.~~36. IgG4-Related Disease

a. Recipient has a confirmed diagnosis of IgG4-RD (e.g., physically exam findings, imaging results, laboratory tests, pathological findings involved organ/sites, etc.); and

b. Other conditions that mimic IgG4-related disease have been ruled out (e.g., malignancy, infection, other autoimmune disorders, etc.); and

c. Recipient is experiencing (or recently experienced) an IgG4-RD flare that required corticosteroid treatment; and

1. Recipient has disease that is refractory to corticosteroids; or

2. Recipient has a contraindication or intolerance to corticosteroid treatment; and

d. Recipient is at a high-risk of recurrent disease flares based on a history of disease in ≥2 organs/site; and

e. At least one of the following organs are affected:

1. Pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, and/or thyroid gland.

b. Dosage Limits

1. Max units (per dose and over time) [HCPCS Unit]:

a. Oncology Indications

1. CLL/SLL:

a. Initial therapy:
1. 100 billable units x one dose, then 130 billable units every seven days x 11 doses

b. Renewal therapy: 130 billable units every eight weeks.

2. ALL

a. 100 billable units twice weekly.

3. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma

a. Initial therapy: 100 billable units every seven days x 12 doses

b. Renewal therapy: 400 billable units every six months

4. Large B-Cell Lymphoma

a. Initial therapy: 100 billable units every seven days x eight doses in a six-month period

b. Renewal therapy: 4800 billable units every 168 days

5. Central Nervous System (CNS) Cancers

a. Initial therapy: 190 billable units every seven days x eight doses

b. Renewable therapy: 400 billable units every six months

6. Hairy Cell Leukemia

a. 100 billable units every seven days x eight doses, 100 billable units every 14 days x eight doses, then 100 billable units every 28 days x four doses.

7. Histiocytic Neoplasms – Rosai-Dorfman Disease

   a. 780 billable units every six months.

8. Chronic Graft Versus Host Disease (cGvHD)

   a. 100 billable units every seven days.

9. Hematopoietic Cell Transplantation

   a. Initial dose: 100 billable units x one dose before transplant

   b. Subsequent doses: 250 billable units every seven days x three doses after transplant.

10. Immunotherapy-Related Toxicities

   a. Bullous Dermatitis: 100 billable units every 14 days x two doses, then 50 billable units at months 12 and 18

   b. Bullous Pemphigoid, Hemolytic Anemia, Thrombocytopenia: 400 billable units every six months

   c. Acute Kidney Injury: 100 billable units every 14 days x two doses

   d. Myositis, Encephalitis: 100 billable units every seven days x four doses

   e. Myasthenia Gravis: 130 billable units every seven days x four doses

11. All other oncology indications (Castleman Disease, Primary Cutaneous B-Cell Lymphomas, or HL):

   a. Initial therapy: 100 billable units every seven days x eight doses in a six-month period

   b. Renewal therapy: 400 billable units every six months.

b. Non-Oncology Indications

1. Rheumatoid Arthritis (RA):

   a. 200 billable units every 24 weeks.

2. Multiple Sclerosis (MS):

   a. 200 billable units every six months.

3. Pemphigus Vulgaris (PV):

   a. Initiation: 100 billable units every seven days x four doses in a 12-month period

   b. Maintenance: 50 billable units every six months.

4. GPA(WG)/MPA:

   a. Induction: 100 billable units every seven days x four doses

   b. Initial Maintenance: 100 billable units every 14 days x two doses

   c. Subsequent Maintenance: 100 billable units every six months.

5. Thrombocytopenic Purpura or Thrombotic Thrombocytopenic Purpura, Complications of Transplanted Solid Organ, IgG4-related diseases:

   a. 100 billable units every seven days x four doses

6. All other non-oncology indications (AIHA, SLE or LN, Myasthenia Gravis, NMOSD, Antisynthetase Syndrome-Related Interstitial Lung Disease, Idiopathic Membranous Nephropathy, Pediatric Idiopathic Nephrotic Syndrome):

   a. 400 billable units every six -months.

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 prerequisite therapy), performance status (PS), etc. identified in Section III; and

2. Duration of authorization has not been exceeded (refer to Section I); and

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), HPV reactivation, serious infections (bacterial, fungal, or viral), cardiovascular adverse reactions (e.g., ventricular fibrillation, myocardial infarction, cardiogenic shock, cardiac arrhythmias), renal toxicity, bowel obstruction or perforation, etc.; and

4. Oncology Indications

   a. Recipient has not exceeded dosing or duration limits as defined in Section I, II, and V; and

5. Adult Acute Lymphoblastic Leukemia (ALL)

   a. Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, quantitative polymerase chain reaction (QPCR), or fluorescence in situ hybridization (FISH).

6. All Other Oncology Indications

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

7. Non-Oncology Indications

   a. Rheumatoid Arthritis (RA)

      1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of recipient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more of a ≥20% improvement on the American College of Rheumatology-20 (ARC20) criteria or improvement of disease severity on RAPID3 assessment]; and

      2. Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the recipient has:

         a. Shown an initial response to therapy; and

b. Received a minimum of one maintenance dose at the dose and interval specified below; and

c. Responded to therapy with subsequent loss of response

b. Thrombocytopenic Purpura (ITP or Evan's Syndrome)

1. Disease response as indicated by the achievement and maintenance of a platelet count of at least 50 x 10^9/L and at least doubling the baseline platelet count

c. Thrombotic Thrombocytopenic Purpura (TTP)

1. Disease response as indicated by an increase in ADAMTS13 activity with a reduction in thrombotic risk

d. Multiple Sclerosis (MS)

1. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in ARR, development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, T25-FW, 9-HPT]

e. Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)

1. Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; and

2. Decreased frequency in the occurrence of major relapse (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)

f. Pemphigus Vulgaris

1. Recipient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; and

a. Disease response as indicated by one of the following:

1. Complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline

2. Recipient has not developed new lesions and established lesions begin to heal

b. For Relapses only:

1. Recipient previously achieved disease control; and

2. Recipient has the appearance of three or more new lesions a month that do not heal spontaneously within one week, or by the extension of established lesions.

g. Autoimmune Hemolytic Anemia (AIHA)

1. Disease response as indicated by improvement in signs of anemia (e.g., dyspnea, fatigue, etc.); and

2. Recipient has had an improvement in laboratory values (e.g., hemoglobin, hematocrit, etc.), reduced transfusion needs, and/or reduced glucocorticoid use

h. Systemic Lupus Erythematosus (SLE)

1. Recipient has experienced clinical benefit (e.g., disease stability and/or improvement as indicated on objective measures of disease severity)

i. Lupus Nephritis (LN)

1. Recipient has experienced clinical benefit (Note: Coverage may only be renewed in recipients experiencing a disease relapse (e.g., increased serum creatinine, increase in protein urine excretion, decrease in eGFR, etc.))

j. Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

1. Disease response as indicated by a decrease in the daily dose of corticosteroids and/or an improvement in signs and symptoms compared to baseline

k. NMOSD

1. Disease response as indicated by stabilization/improvement in any of the following:

   a. Decrease in acute relapses or improvement of stability

   b. Reduced hospitalizations

   c. Reduction/discontinuation in plasma exchange treatments

   d. Reduction/discontinuation of corticosteroids without relapse.

l. Antisynthetase Syndrome-Related Interstitial Lung Disease

1. Disease response as indicated by stabilization/ improvement in any of the following:

   a. Reduction or stabilization of glucocorticoid use from baseline

   b. Improvement or stabilization of pulmonary function testing (i.e., improvement defined as >10% increase in FVC%, TLC%, or DLCO%; stabilization defined as <10% decrease in FVC%, TLC%, or DLCO%)

   c. Improvement or stabilization of chest CT score (improvement defined as >10% decrease in CT score, stabilization defined as a <10% increase in CT score)

m. Idiopathic Membranous Nephropathy

1. Recipient experienced beneficial disease response with improvement in symptoms and/or other objective measures compared to baseline (e.g., reduction in proteinuria, increase and/or normalization of serum albumin, improvement/stability of serum creatinine and/or eGFR, decrease in anti-PLA2R antibody levels, etc.); or

2. Recipient has resistant disease following first-line therapy with rituximab; and

a. Recipient has stable eGFR; and

b. Will be used in combination with a calcineurin inhibitor if previously treated with rituximab alone in the first-line setting.

n. Pediatric Idiopathic Nephrotic Syndrome

1. Recipient previously achieved beneficial disease response from the prior course of therapy; and

2. Recipient is experiencing signs and symptoms of recurrent active disease necessitating additional doses (e.g., recurrence of nephrotic-range proteinuria with a dipstick >3+ [>300 mg/dL] for three consecutive days or urinary protein creatinine ratio [UPCR] ≥200 mg/mmol [≥2 mg/mg] on a spot urine sample on three consecutive days, with or without reappearance of edema in a child who had previously achieved complete remission).

o. IgG4-Related Disease

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

a. Reduction in corticosteroid requirement for IgG4-RD flare treatment from baseline

b. Reduction in IgG4-RD flares from baseline

c. Stabilization/improvement in symptoms, physical exam findings, imaging results, laboratory tests, and/or pathological findings in IgG4-RD involved organ/sites compared to baseline.

~~2. Recipient meets one of the following:~~

~~a. Ongoing maintenance therapy is required due to recipient having a high risk of relapse~~

~~b. Recipient is experiencing signs and symptoms of relapsed active disease necessitating an additional course of therapy.~~

d. PA Guidelines

R. Yervoy® (ipilimumab)

Therapeutic Class: Anti-CLTA-4 Monoclonal Antibodies
Last Reviewed by the DUR Board: April 17, 2025

PADs 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:

   Coverage is provided in the following conditions

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

   b. Ampullary Adenocarcinoma

      1. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

      2. Used in combination with nivolumab; and

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

         b. Used as subsequent therapy for disease progression.

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

      1. Used in combination with nivolumab; and

      2. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

         a. Used as subsequent treatment for progression on or after systemic treatment for unresectable, R2, or metastatic disease; and

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

      3. Used as neoadjuvant therapy for resectable locoregionally advanced (Note: Only applies to Gallbladder Cancer); and

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

b. Recipient has incidental finding on pathologic review (cystic duct node positive); or

c. Recipient has mass on imaging

d. Bone Cancer

1. Recipient has one of the following: Ewing sarcoma, Chondrosarcoma (excluding mesenchymal chondrosarcoma), Osteosarcoma, or Chordoma; and

2. Recipient has TMB-H tumors [≥10 mut/Mb] as determined by an FDA-approved or CLIA-compliant test; and

3. Used in combination with nivolumab; and

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

5. Recipient has no satisfactory alternative treatment options.

e. Central Nervous System (CNS) Cancer

1. Used for the treatment of brain metastases in recipients with BRAF non-specific melanoma; and

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

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

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

c. Used for recurrent limited brain metastases; or

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

f. Colorectal Cancer (CRC)

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

2. Recipient's disease is MSI-H/ dMMR disease or POLE/POLD1 mutation as determined by an FDA-approved or CLIA-compliant test; and

3. Used in combination with nivolumab; and

a. Used as primary/initial treatment for unresectable or medically inoperable, advanced, or metastatic disease; or

b. Used as subsequent therapy for unresectable or medically inoperable, recurrent, advanced, or metastatic disease; or

c. Used as neoadjuvant therapy for advanced or metastatic disease.

g. Appendiceal Adenocarcinoma – Colon Cancer

1. Recipient has MSI-H/dMMR disease or POLE/POLD1 mutation as determined by an FDA-approved or CLIA-compliant test; and

2. Used in combination with nivolumab (if candidate for intensive therapy); and

3. Used for advanced or metastatic disease; and

a. Used as primary or initial treatment; or

b. Used as subsequent treatment.

h. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

1. Used in combination with nivolumab; and

a. Used as first-line therapy; and

1. Recipient has SCC; and

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

2. Recipient has adenocarcinoma; and

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

b. Recipient has MSI-H or 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. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; or

c. Used as neoadjuvant or perioperative therapy; and

1. Recipient has adenocarcinoma; and

2. Used as primary treatment for recipient 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; and

3. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test.

d. Used as induction systemic therapy for relieving dysphagia; and

1. Recipient has squamous cell carcinoma (SCC); and

2. Recipient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease

i. Gastric Cancer

1. Used in combination with nivolumab; and

2. Recipient has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test; and

a. Used as first-line or subsequent therapy; and

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

b. Used as neoadjuvant or perioperative therapy; and

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

j. Hepatocellular Carcinoma (HCC)

1. Used in combination with nivolumab; and

   a. Used as first-line therapy; and

      1. Recipient has unresectable or metastatic disease; or

2. Used as subsequent therapy; and

   a. Recipient was previously treated with sorafenib; or

   b. Recipient has liver-confined, unresectable disease and is deemed ineligible for a transplant; or

   c. Recipient had disease progression on or after systemic therapy and has not been previously been treated with anti-CTLA4-based combination.

k. Kaposi Sarcoma

1. Used in combination with nivolumab as subsequent therapy; and

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

3. Disease progressed on or did not respond to first-line therapy; and

4. Disease progressed on alternate first-line therapy

l. Renal Cell Carcinoma (RCC)

1. Used in combination with nivolumab for clear cell histology; and

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

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

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

m. Peritoneal Mesothelioma (PeM)

1. Used in combination with nivolumab; and

   a. Used as subsequent therapy (if chemotherapy was administered first-line); or

b. Used as first-line therapy; and

1. Used as adjuvant treatment for medically operable disease, following CRS and HIPEC; and

a. Recipient has surgical or pathologic high-risk features; or

2. Recipient has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features; or

3. Recipient has disease recurrence after prior CRS and HIPEC if no previous adjuvant systemic therapy was given; or

n. Pleural Mesothelioma (PM)

1. Used in combination with nivolumab; and

a. Used as subsequent therapy (if chemotherapy was administered first-line); or

b. Used as first-line therapy; or

c. Used as induction therapy prior to surgical exploration

1. Recipient has clinical stage I disease and epithelioid histology

o. Cutaneous Melanoma

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

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

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

2. Used as subsequent therapy for unresectable or metastatic disease; and

a. Used after disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/ binimetinib, etc.); and

1. Used as a single agent or in combination with nivolumab in recipients at least 12 years of age; or

2. Used in combination with pembrolizumab for disease progression following anti-PD-1 therapy; or

b. Used as re-induction therapy in recipients who experienced disease control (i.e., complete or partial response or stable disease) and no residual toxicity from prior use, but subsequently have disease progression/relapse >3 months after treatment discontinuation; and

1. Used as single agent or in combination with anti-PD-1 therapy; and

2. Recipient has completed initial induction ipilimumab therapy (i.e., completion of four cycles within a 16-week period); or

3. Used as adjuvant therapy; and

a. Used as a single agent; and

1. Recipient has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy; or

2. Recipient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); and

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

b. Recipient has resectable disease limited to nodal recurrence following excision of the recurrence and therapeutic lymph node dissection (TLND); or

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

b. Used in combination with nivolumab; and

1. Recipient has oligometastatic disease and NED following metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy, or T-VEC/intralesional therapy) or following systemic therapy followed by resection

4. Used as neoadjuvant therapy; and

a. Used in combination with nivolumab; and

1. Recipient stage III disease; and

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

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

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

3. Recipient has resectable disease limited to nodal recurrence.

p. Uveal Melanoma

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

2. Recipient has metastatic or unresectable disease.

q. Merkel Cell Carcinoma

1. Used for M1 disseminated disease; and

a. Used as a single agent; and

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

b. Used in combination with nivolumab; or

2. Used for primary N+, M0 regional disease with biopsy positive draining nodal basin if curative surgery and curative RT are not feasible; and

a. Used as a single agent; and

1. Recipient has progressed on anti-PD-L1 or anti-PD-1 therapy or ant-PD-L1 or anti-PD-1 therapy is contraindicated; or

b. Used in combination with nivolumab; or

3. Used for primary N+, M0 regional disease with biopsy positive draining nodal basin if curative surgery and curative RT are not feasible; and

a. Used as a single agent; and

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

b. Used in combination with nivolumab.

r. Non-Small Cell Lung Cancer (NSCLC)

1. 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

a. Used as first-line therapy; and

1. Used for one of the following:

a. Recipients with tumors that are negative for actionable molecular biomarkers (may be KRAS G12C mutation positive); or

b. Recipients who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); and

b. Used in combination with one of the following:

1. Nivolumab

2. Nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); or

c. Used as subsequent therapy; and

1. Used for one of the following:

a. Recipients who are positive for one of the following molecular biomarkers and have received prior

target therapy: EGFR S7681, L861Q, and/or G719X; or

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

2. Used in combination with one of the following:

a. Nivolumab

b. Nivolumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology

c. Nivolumab, paclitaxel and carboplatin for squamous cell histology; or

d. Used as continuation maintenance therapy in combination with nivolumab; and

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

s. Small Bowel Adenocarcinoma (SBA)

1. Used in combination with nivolumab; and

2. Recipient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] as detected by an FDA-approved or CLIA-compliant test; and

a. Recipient has advanced or metastatic disease; or

b. Recipient has locally unresectable or medically inoperable disease; and

1. Used as primary treatment.

t. Soft Tissue Sarcoma (STS)

1. Extremity/Body Wall or Head/Neck

a. Used in combination with nivolumab; and

b. Used as subsequent therapy; and

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

2. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

a. Recipient has no satisfactory alternative treatment options.

2. Retroperitoneal/Intra-Abdominal

a. Used in combination with nivolumab; and

b. Used as one of the following:

1. Alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease; or

2. Palliative subsequent therapy for stage IV disease with disseminated metastases; and

c. Used for one of the following:

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

2. Recipient has TMB-H [≥10 mut/Mb] disease as determined by an FDA-approved or CLIA-compliant test; and

a. Recipient has no satisfactory alternative treatment options.

3. Pleomorphic Rhabdomyosarcoma

a. Used in combination with nivolumab; and

b. Used as subsequent therapy; and

4. Angiosarcoma

a. Used in combination with nivolumab

u. Gestational Trophoblastic Neoplasia

1. Used in combination with nivolumab; and

2. Recipient has multiagent chemotherapy-resistant disease; and

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

1. Recipient has recurrent or progressive disease; or

b. Recipient has high-risk disease (i.e., ≥7 Prognostic score or stage IV disease)

4. Dosage Limits

a. Renal Cell Carcinoma (RCC), Small Bowel Adenocarcinoma (SBA), and Ampullary Adenocarcinoma:

1. 150 billable units – 21 days x four doses

b. Colorectal Cancer (CRC), Appendiceal Adenocarcinoma:

1. 150 billable units – 21 days

c. Pleural Mesothelioma (PM), Peritoneal Mesothelioma (PeM), Soft Tisue Sarcoma (STS), MSI-H/dMMR, Esophageal and Esophagogastric/Gastroesophageal Junction Cancer, Gastric Cancer, Biliary Tract Cancers, Bone Cancer and Kaposi Sarcoma, NSCLC, and Gestational Trophoblastic Neoplasia:

1. 150 billable units – 42 days

d. Merkel Cell Carcinoma:

1. Initial: 350 billable units – 21 days x four doses

2. Maintenance: 150 billable units – 42 days

e. Hepatocellular Carcinoma (HCC):

1. 350 billable units – 21 days x four doses

f. CNS Cancers:

1. Initial: 1150 billable units – 21 days x four doses

2. Maintenance: 1150 billable units – 84 days

g. Cutaneous Melanoma:

1. Initial: 350 billable units – 21 days x four doses

2. Maintenance: 350 billable units – 84 days x four doses

h. Uveal Melanoma:

1. 1150 billable units – 21 days x four doses.

~~4.~~5. 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 (PS), etc. identified in Section III; and

b. Duration of authorization has not been exceeded (refer to Section I); and

c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe immune-mediated adverse reactions (e.g., colitis, hepatitis, dermatitis/rash, pneumonitis, nephritis/renal dysfunction, endocrinopathies, etc.), severe infusion-related reactions, complications of allogeneic HSCT, etc.; and

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

~~5.~~6. PA Guidelines

a. Coverage will be provided for six months and may be renewed (unless otherwise specified).

b. The following indications may be authorized up to a maximum of 12 weeks of therapy (four doses) and may not be renewed (coverage may be extended to 16 weeks if four doses were not administered within the 12-week time frame)

1. Ampullary Adenocarcinoma

2. Colorectal Cancer (CRC)

3. Appendiceal Adenocarcinoma (subsequent therapy)

4. CNS Cancer (combination therapy with nivolumab)

S. Zynlonta® (loncastuximab tesirine-lpyl)

Therapeutic Class: Miscellaneous Antineoplastics
Last Reviewed by the DUR Board: July 18, 2024

~~Miscellaneous Antineoplastics~~PADs 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~~Coverage is provided in the following conditions:

   a. Recipient is at least 18 years old; and

   b. Universal Criteria

      1. Used as single agent therapy; and

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

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

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

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

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

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

   c. B-Cell Lymphoma

      1. DLBCL not otherwise specified, DLBCL arising from low grade lymphoma, or HHV8 positive DLCBCL, not otherwise specified

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

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

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

+

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

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

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

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

3. Monomorphic PTLD

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

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

2. Dosage Limits

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

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

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

1. B-Cell Lymphoma

a. Cycle 1-2

1. ~~230~~ 267 billable units ~~(17.25 mg) per each~~ every 21~~-~~ days ~~cycle~~

b. Subsequent Cycles

1. ~~115~~ 134 billable units ~~(8.63 mg) per each~~ every 21~~-~~ days ~~cycle~~.

3. Recertification Request

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

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

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

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

4. PA Guidelines

a. Initial approval will be given for six months and may be renewed.

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

T. Osteoporosis Agents

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

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

1. Coverage and Limitations

a. Evenity® (romosozumab-aqqg)

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

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

b. One of the following:

1. Both the following:

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

b. One of the following:

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

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

c. Both the following:

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

2. One of the following:

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

b. Both the following:

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

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

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

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

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

1. Forteo® (teriparatide)

2. Tymlos® (abaloparatide); and

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

2. PA Guidelines:

   a. PA approval will be given for 12 months.

b. Prolia® and Jubbonti® (denosumab)

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

2. Prolia®, Jubbonti®, Ospomyv®, Stoboclo®, Denosumab-dssb and Conexxence®/denosumab-bnht

a. Coverage is provided in the following conditions:

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

b. Universal Criteria

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

2. Recipients must not have hypocalcemia; and

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

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

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

3. Osteoporosis in Men and Women

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

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

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

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

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

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

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

d. Recipient has one of the following:

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

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

4. Glucocorticoid-Induced Osteoporosis

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

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

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

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

5. Osteoporosis treatment and prevention in prostate cancer patients

a. Recipient must be receiving androgen deprivation therapy and

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

6. Osteoporosis treatment and prevention in breast cancer recipients

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

c. Xgeva® and Wyost®

1. Coverage is provided in the following conditions:

a. Universal Criteria

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

2. Recipient must not have hypocalcemia; and

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

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

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

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

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

2. Giant Cell Tumor of the Bone

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

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

2. Disease is localized, recurrent, or metastatic and

a. Used as a single agent; or

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

3. Hypercalcemia of Malignancy

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

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

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

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

4. Systemic Mastocytosis

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

b. Used as second-line therapy if the recipient is

1. Not responding to bisphosphonate therapy; or

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

c. PA Guidelines:

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

5. Dosing Limits

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

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

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

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

~~b. Maintenance: 1 vial monthly.~~

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

1. Prolia® – ~~All indications~~Osteoporosis:

a. 60 billable units every six months.

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