MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

May 30, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES
CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to add new prior authorization criteria for Physician-Administered Drugs (PADs). The proposed changes include addition of new PAD-specific prior authorization criteria for Libtayo® (cemiplimab-rwlc), Ocrevus® (ocrelizumab), Opdivo® (nivolumab), Tecentriq® (atezolizumab) within the Anti-PD-1 Monoclonal Antibodies Section; addition of new PAD-specific prior authorization criteria for Eylea® (aflibercept), Lucentis®; Byooviz™; Cimerli™(ranibizumab), Susvimo® (ranibizumab) within the Anti-Angiogenic Opthalmic Agent Section; addition of new PAD-specific prior authorization criteria for SCIG (immune globulin): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify® within the Immunoglobulins Section; addition of new PAD-specific prior authorization criteria for Pemetrexed within the Antimetabolites Section; addition of new PAD-specific prior authorization criteria for Perjeta® (pertuzumab), Herceptin ®; Ogivri®; Kanjinti™; Trazimera™; Herzuma™; Ontruzant® (Trastuzumab); Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) within the HER2 Inhibitor Section; addition of new PAD-specific prior authorization criteria for Rituxan®, Truxima®, Ruxience™, Riabni™ (Rituximab), Rituxan Hycela® (rituximab and hyaluronidase human) within the CD20 Monoclonal Antibodies Section; addition of new PAD-specific prior authorization criteria for Soliris® (eculizumab), Ultomiris® (ravulizumab-cwyz) within the Selective Immunosuppressants Section; addition of new PAD-specific prior authorization criteria for Yervoy® (ipilimumab) within the Anti-CLTA-4 Monoclonal Antibodies Section.

Throughout the chapter, grammar, punctuation, and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These changes are effective June 5, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix B Section B	**Anti-PD-1 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Libtayo® (cemiplimab-rwlc), Ocrevus® (ocrelizumab), Opdivo® (nivolumab), Tecentriq® (atezolizumab).
Appendix B Section H	**Anti-Angiogenic Opthalmic Agent**	Created new section for PAD prior authorization criteria and quantity limits for Eylea® (aflibercept), Lucentis®; Byooviz™; Cimerli™ (Ranibizumab), Susvimo® (ranibizumab).
Appendix B Section I	**Immunoglobulins**	Created new section for PAD prior authorization criteria and quantity limits for SCIG (immune globulin): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify®.
Appendix B Section N	**Antimetabolites**	Created new section for PAD prior authorization criteria and quantity limits for Pemetrexed. Deleted Section for Libtayo®.and placed it under Anti-PD-1 Monoclonal Antibodies Section.
Appendix B Section O	**HER2 Inhibitors**	Created new section for PAD prior authorization criteria and quantity limits for Perjeta® (pertuzumab), Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (Trastuzumab); Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk).
Appendix B Section P	**CD20 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Rituxan®, Truxima®, Ruxience™, Riabni™ (Rituximab) and Rituxan Hycela® (rituximab and hyaluronidase human).
Appendix B Section Q	**Selective Immunosuppressants**	Created new section for PAD prior authorization criteria and quantity limits for Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz).
Appendix B Section R	**Anti-CLTA-4 Monoclonal Antibodies**	Created new section for PAD prior authorization criteria and quantity limits for Yervoy® (ipilimumab).
Appendix B Section S	**Miscellaneous Antineoplastics**	Created new section for PAD prior authorization criteria and quantity limits for Zynlonta® (loncastuximab tesirine-lpyl).

B. Anti-PD-1 Monoclonal Antibodies

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

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

1. Bavencio® (avelumab)

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

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

2. Universal Criteria

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

3. Merkel Cell Carcinoma (MCC)

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

b. Used as single-agent therapy; and

c. Recipient has metastatic or recurrent disseminated disease.

4. Urothelial Carcinoma (Bladder Cancer)

a. Used as single-agent therapy; and

1. Recipient has one of the following diagnoses:

a. Locally advanced or metastatic urothelial carcinoma

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

c. Metastatic or local bladder cancer recurrence post cystectomy

d. Metastatic upper genitourinary (GU) tract tumors

e. Metastatic urothelial carcinoma of the prostate

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

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

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

b. Used for first-line maintenance treatment; and

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

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

4. Renal Cell Carcinoma (RCC)

a. Used in combination with axitinib; and

b. Used as first-line therapy; and

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

5. Gestational Trophoblastic Neoplasia

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

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

a. Recipient has recurrent or progressive disease; and

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

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

6. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as single-agent therapy; and

b. Recipient has recurrent or metastatic disease; and

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

b. Dosing Limits

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

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

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

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

c. Recertification Request

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

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

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

d. Prior Authorization Guidelines:

1. Initial approval will be given for 6 months.

2. Recertification will be given for 6 months.

2. Imfinzi® (durvalumab)

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

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

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

3. Non-Small Cell Lung Cancer (NSCLC)

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

      1. Used as a single agent; and

         a. Used as consolidation therapy: and

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

         c. Disease has not progressed after definitive chemoradiation; or

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

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

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

4. Small Cell Lung Cancer (SCLC)

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

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

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

5. Hepatobiliary Cancers

   a. Recipient has hepatocellular carcinoma (HCC); and

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

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

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

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

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

a. Recipient has unresectable disease; and

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

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

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

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

1. Used in combination with cisplatin and gemcitabine; and

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

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

b. Dosage Limits

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

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

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

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

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

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

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

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

c. Recertification Request

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

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

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

4. NSCLC (single-agent use)

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

5. Hepatobiliary Cancers

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

6. Continuation Maintenance Therapy for SCLC

a. Refer to Section III for criteria.

d. Prior Authorization Guidelines:

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

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

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

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

3. Libtayo® (cemiplimab-rwlc)

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

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

2. Universal Criteria

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

3. Cutaneous Squamous Cell Carcinoma (cSCC)

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

b. Used as a single agent; and

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

4. Basal Cell Carcinoma

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

b. Used as a single agent; and

1. Recipient has locally advanced disease; or

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

3. Recipient has nodal, regional, or metastatic disease.

5. Non-Small Cell Lung Cancer (NSCLC)

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

1. Used as first-line therapy in combination with platinum-based chemotherapy; and

   a. Recipient has locally advanced disease and is not a candidate for surgical resection or definitive chemoradiation; or

   b. Recipient has metastatic disease; or

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

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

   b. Used as a single agent; and

      1. Used as first-line therapy; or

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

b. Dosage Limits

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

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

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

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

c. Recertification Request

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis,

endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc; and

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

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

4. Ocrevus® (ocrelizumab)

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

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

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

3. Recipient has had baseline serum immunoglobulins assessed; and

4. Universal Criteria

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

b. Recipient does not have an active infection; and

5. Multiple Sclerosis

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

b. Must be used as single agent therapy; and

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

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

a. Recipient is less than 65 years; and

b. Recipient has an expanded disability status scale (EDSS) score of less than or equal to six and a half.

b. Dosage Limits

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

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

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

a. Initial Dose

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

b. Subsequent Dose

1. 600 billable units (300 mg) every six months.

c. Recertification Request

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

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

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

4. Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hypertensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), nine-hole peg test (nine-HPT].

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

5. PPMS

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

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

5. Opdivo® (nivolumab)

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

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

2. Universal Criteria

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

3. Ampullary Adenocarcinoma

a. Recipient's disease is microsattelite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used in combination with ipilimumab; and

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

2. Used as subsequent therapy for disease progression.

4. Anal Carcinoma

a. Recipient has metastatic squamous cell disease; and

b. Used as a single agent for subsequent therapy.

5. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

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

a. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma

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

3. Metastatic or local bladder cancer recurrence post-cystectomy

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

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

5. Metastatic upper genitourinary (GU) tract tumors

6. Metastatic urothelial carcinoma of the prostate; or

2. Used as adjuvant therapy; and

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

b. Recipient underwent radical surgical resection or atriall cystectomy; and

c. Recipient is at high risk for disease recurrence.

6. Bone Cancers

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

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

c. Used in combination with ipilimumab; and

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

e. Recipient has no satisfactory alternative treatment options.

7. Adult Central Nervous System (CNS) Cancers

a. Used in one of the following treatment settings:

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

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

3. Recipient has recurrent limited brain metastases

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

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

c. Used as a single-agent for the treatment of brain metastases in recipients with PD-L1 positive non-small cell lung cancer (NSCLC).

8. Pediatric Central Nervous System (CNS) Cancers

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

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

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

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

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

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

9. Cervical Cancer

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

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

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

10. Colorectal Cancer

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

b. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

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

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

a. Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy

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

2. Used as primary treatment; and

a. Used as neoadjuvant therapy for clinical T4b colon cancer; or

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

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

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

11. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipients' disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

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

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

2. Used as initial therapy for advanced or metastatic disease.

12. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

a. Used as first-line therapy; and

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

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

1. Used in combination with ipilimumab; or

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

b. Recipient has adenocarcinoma; and

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

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

b. Used as subsequent therapy; and

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

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

3. Used as a single agent; 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).

13. Gestational Trophoblastic Neoplasia

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

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

a. Recipient has recurrent or progressive disease; and

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

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

14. Gastric Cancer

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

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

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

a. Recipient has Cancer of the Nasopharynx; and

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

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

1. Recipient has nasopharyngeal cancer; and

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

b. Used for one of the following:

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

2. Unresectable second primary with prior RT

3. Unresectable persistent disease with prior RT

4. Recurrent/persistent disease with distant metastases; or

2. Recipient has non-nasopharyngeal cancer; and

a. Used as a single agent; and

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

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

16. Hepatocellular Carcinoma (HCC)

a. Used in combination with ipilimumab; and

b. Used as subsequent therapy for progressive disease; and

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

1. Recipient was previously treated with sorafenib; or

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

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

4. Recipient has metastatic disease or extensice liver tumor burden.

17. Adult Classical Hodgkin Lymphoma (cHL)

a. Used as a single agent; and

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

2. Used for disease that is refractory to at least three prior lines of therapy or as palliative therapy in recipient greater than 60 years of age; and

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

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

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

b. Used in combination with brentuximab vedotin or ICE (ifosfamide, carboplatin, etoposide); and

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

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

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

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

18. Pediatric Classical Hodgkin Lymphoma (cHL)

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

b. Recipient has relapsed or refractory disease; and

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

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

a. Used as re-induction therapy; and

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

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

19. Renal Cell Carcinoma (RCC)

a. Used in combination with ipilimumab for clear cell histology; and

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

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

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

b. Used as a single agent; and

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

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

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

1. Recipient has clear cell histology; and

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

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

2. Recipient has non-clear cell histology; and

a. Recipient has relapsed or stage IV disease.

20. Malignant Peritoneal Mesothelioma (MPeM)

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

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

1. Recipient has unresectable diffuse disease; or

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

21. Malignant Pleural Mesothelioma (MPM)

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

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

1. Recipient has stage IIIB or IV disease; or

2. Recipient has sarcomatoid or biphasic histology; or

3. Disease is medically inoperable or unresectable.

22. Cutaneous Melanoma

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

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

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

1. Used as single agent; and

a. Recipient has stage III disease with clinical satellite/in-transit metastases; or

b. Recipient has local satellite/in-transit recurrence; or

c. Used as subsequent therapy for unresectable or metastatic disease; and

1. Used a re-induction therapy in recipients who experienced disease control (i.e., complete or partial response or stable disease) and no residual toxicity from prior anti-PD-1 immunotherapy, but subsequently have disease

progression/relapse greater than three months after treatment discontinuation; and

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

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

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

b. Used in combination with ipilimumab for recipients who progressed on single agent anti-PD-1 therapy; or

d. Used as adjuvant treatment as a single agent; and

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

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

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

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

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

23. Uveal Melanoma

a. Recipient has distant metastatic disease; and

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

24. Merkel Cell Carcinoma

a. Used as a single agent; and

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

2. Used for primary or recurrent metastatic disseminated disease.

25. Non-Small Cell Lung Cancer

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

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

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

1. Used as first-line therapy; and

a. Used for one of the following:

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

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

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

b. Used in combination with ipilimumab; or

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

histology, or paclitaxel and carboplatin for swuamous cell histology, etc.); or

2. Used as subsequent therapy; and

a. Used as a single agent; or

b. Used for one of the following:

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

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

c. Used in combination with ipilimumab; or

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

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

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

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

26. Small Bowel Adenocarcinoma

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

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

1. Used as initial therapy; or

2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

27. Small Cell Lung Cancer (SCLC)

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

1. Used for relapsed disease in recipients with a complete or partial response or stable disease after primary treatment (excluding use in recipients who progressed on maintenance atezolizumab or durvalumab at time of relapse); or

2. Used for primary progressive disease.

28. Extranodal NK/T-Cell Lymphomas

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

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

c. Participation in a clinical trial is unavailable.

29. Endometrial Carcinoma (Uterine Neoplasms)

a. Used as a single agent; and

b. Used as second-line therapy for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) recurrent or metastatic disease.

30. Vulvar Cancer

a. Used as single agent; and

b. Recipient has adenocarcinoma or squamous cell carcinoma; and

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

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

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

1. Used in combination with brentuximab vedotin; and

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

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

b. Dosage Limits

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

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

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

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

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

c. Recertification Request

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe inf usion-related reactions, complications of allogeneic hematopoietic stem cell

transplantation (HSCT), severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis/hepatotoxicity, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), etc.; and

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

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

a. Bone Cancer; or

b. Cervical Cancer; or

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

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

e. Gatric Cancer; or

f. Malignant Pleural Mesothelioma; or

g. Malignant Peritoneal Mesothelioma; or

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

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

j. Vulvar Cancer.

5. Urothelial Carcinoma (adjuvant therapy)

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

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

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

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

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

8. Classical Hodgkin Lymphoma (in combination with ICE)

a. Recipient has not exceeded a maximum of six weeks of therapy.

9. Cutaneous Melanoma (re-induction therapy)

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

10. Merkel Cell Carcinoma (neoadjuvant therapy)

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

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

    a. Recipient has not exceeded a maximum of three cycles.

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

    a. Refer to Section III for criteria.

d. Prior Authorization Guidelines

1. Use in the treatment of Classical Hodgkin Lymphoma:

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

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

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

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

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

    a. Cutaneous Melanoma

    b. Esophageal and Esophagogastric/Gatroesophageal Junction Cancer

    c. Urothelial Carcinoma.

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

    a. Bone Cancer

    b. Cervical Cancer

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

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

e. Gastric Cancer

f. Malignant Pleural Mesothelioma

g. Malignant Peritoneal Mesothelioma

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

i. Renal Cell Carcinoma (in combination with cabozantinib)

j. Vulvar Cancer

6. Initial approval will be given for six months.

7. Recertification will be given for six months.

6. Tecentriq® (atezolizumab)

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

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

2. Universal Criteria

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

3. Urothelial Carcinoma (Bladder Cancer)

a. Used as a single agent; and

b. Recipient has one of the following diagnoses:

1. Locally advanced or metastatic urothelial carcinoma; or

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

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

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

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

6. Metastatic urothelial carcinoma of the prostate; and

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

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

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

4. Non-Small Cell Lung Cancer (NSCLC)

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; and

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

1. Used as a single agent; or

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

1. Recipients with PS 0-1 who have tumors that are negative for actionable molecular markers and PD-L1 less than one percent

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

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

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

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

2. Used as subsequent therapy; and

a. Used as a single agent; or

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

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

2. Recipients with PS 0-1 who are positive for one of the following molecular mutations and received prior targeted therapy: EGFR exon 19 deletion or L858R tumors, EGFR S7681, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; and

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

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

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

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

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

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

b. Recipient has stage II to IIIA disease; and

1. Used as a single agent; and

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

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

5. Small Cell Lung Cancer (SCLC)

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

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

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

6. Hepatocellular Carcinoma (HCC)

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

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

1. Recipient has unresectable or metastatic disease; or

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

3. Recipient has extensive liver tumor burden.

7. Malignant Peritoneal Mesothelioma (MPeM)

a. Used as subsequent therapy in combination with bevacizumab.

8. Cutaneous Melanoma

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

b. Recipient has unresectable or metastatic disease; and

c. Used as first-line therapy in combination with cobimetinib and vemurafenib.

9. Alveolar Soft Part Sarcoma (ASPS)

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

b. Used as a single agent; and

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

b. Dosage Limits

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

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

b. Tecentriq 850 mg single-use vial: one vial per 14 days.

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

a. MPeM: 120 billable units every 21 days.

b. All other indications: 168 billable units every 28 days.

c. Recertification Request

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

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

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

4. Continuation Maintenance Therapy for NSCLC or SCLC

5. NSCLC (adjuvant treatment)

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

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

3. Neoadjuvant therapy in NSCLC can be authorized up to a maximum of 12 months of therapy.

H. Anti-Angiogenic Opthalmic Agents ~~Eylea® (aflibercept)~~

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

Anti-angiogenic Ophthalmic Agents~~Eylea® (aflibercept)~~ are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Eylea®

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

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

~~b~~2. Universal Criteria

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

~~2~~b. Recipient does not have active intraocular inflammation; and

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

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

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

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

4. ~~d.~~ Macular Edema following Retinal Vein Occlusion (RVO)

5. ~~e.~~ Diabetic Macular Edema (DME)

6. ~~f.~~ Diabetic Retinopathy (DR)

b. ~~2.~~ Dosage Limit

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

~~1.~~ a. 2 mg injection: one vial per eye every 28 days.

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

a. ~~1.~~ Diagnosis

1. ~~a.~~ Neovascular age-related macular degeneration (AMD)

a. ~~1.~~ MU for Initial Dosing

1. ~~a.~~ Four units every 28 days x three doses.

a. ~~2.~~ MU for Maintenance Dosing

1. ~~a.~~ Four units every 28-56 days.

2. ~~b.~~ Macular edema following retinal vein occlusion (RVO)

a. ~~1.~~ MU for Initial Dosing

1. ~~a.~~ Four units every 28 days.

a. ~~2.~~ MU for Maintenance Dosing

1. ~~a.~~ Four units every 28 days.

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

a. ~~1.~~ MU for Initial Dosing

1. ~~a.~~ Four units every 28 days x five doses.

~~7.~~a. MU for Initial Dosing

1. ~~a.~~ Four units every 28-56 days.

c. ~~3.~~ Recertification Request:

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

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

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

d. ~~4.~~ Prior Authorization Guidelines:

1. ~~a.~~ Initial approval will be given for 12 months.

2. ~~b.~~ Recertification will be given for 12 months.

2. Lucentis®; Byooviz™; Cimerli™ (Ranibizumab)

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

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

2. Universal Criteria

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

b. Therapy will not be used with other ophthalmic VEGF inhibitos (i.e., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab via ocular implant, etc.); and

c. Recipient's best corrected visual activity (BCVA) is measured at baseline and periodically during treatment; and

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

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

2. Diabetic Macular Edema (DME) (Lucentis and Cimerli Only)

3. Diabetic Retinopathy (DR) (Lucentis and Cimerli Only)

4. Macular Edema following Rental Vein Occlusion (RVO)

5. Myopic Choroidal Neovascularization (mCNV).

b. Dosage Limits

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

a. 0.3mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days

b. 0.5mg vial/prefilled syringe for injection: one vial/syringe per eye every 28 days.

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

a. Neovascular Age-related Macular Degeneration (AMD)/Macular Edema following Retinal Vein Occlusion (RVO)/Myopic Choroidal Neovascularization (mCNV)

1. Ten units every 28 days

b. Diabetic Macular Edema (DME)/Diabetic Retinopathy (DR) – (Lucentis and Cimerli Only)

1. Six units every 28 days.

c. Recertification Request

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

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

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

b. Myopic choroidal neovascularization only: continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub/retinal fluid or active leakage).

d. Prior Authorization Guidelines

1. Initial approval will be given for three months for myopic choroidal neovascularization (mCNV).

2. Recertification will be given for three months for myopic choroidal neovascularization (mCNV).

3. Initial approval will be given for 12 months for all other indications

4. Recertification will be given for 12 months for all other indications.

3. Susvimo® (ranibizumab)

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

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

2. Universal Criteria

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

b. Recipient does not have ocular inflammation; and

c. Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pergaptanib, brolucizumab, bevacizumab, ranibizumab, faricimab-svoa, etc.) unless supplemental treatment is necessary (see below); and

d. Recipient has not required removal of a Susvimo implant in the past; and

e. Recipient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis®, Byooviz™, Cimerli ™, etc.); and

f. Recipient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; and

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

a. Recipient has previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab).

b. Dosage and Limits

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

a. Susvimo 100mg/mL solution for injection SDV: one vial per eye every 24 weeks.

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

a. Neovascular Age-related Macular Degeneration

1. 40 billable units (four mg) every 24 weeks.

c. Recertification Request

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, septum dislodgement, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs, etc.; and

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

    b. Supplemental treatment only: Recipient has had an insufficient response during initial or maintenance therapy with Susvimo administered every 24 weeks and requires supplemental treatment with intravitreal ranibizumab.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.

I. Immune Globulins (immunoglobin)

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

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

1. Immune Globulins

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

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

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

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

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

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

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

2. ~~b.~~ Two or more serious sinus infections; or

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

4. ~~d.~~ Two or more pneumonias within one year; or

5. ~~e.~~ Recurrent or deep skin abscesses; or

6. ~~f.~~ Need for intravenous antibiotics to clear infections; or

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

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

1. ~~a.~~ Titers were drawn before challenging with vaccination; and

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

3. ~~c.~~ IgG Subclass Deficiency

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

b. ~~2.~~ Recipient has a history of recurrent infections; and

c. ~~3.~~ Recipient is receiving prophylactic antibiotic therapy.

4. ~~d.~~ Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP)

a. ~~1.~~ For acute disease state:

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

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

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

~~b.~~4. ~~2.~~ Chronic Immune Thrombocytopenia (CIT)

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

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

3. ~~c.~~ Duration of illness greater than six months.

5. ~~e.~~ Chronic Inflammatory Demyelination Polyneuropathy (CIDP)

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

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

c. ~~3.~~ Electrodiagnostic testing indicating demyelination:

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

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

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

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

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

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

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

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

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

f. ~~6.~~ Initial approval will be given for three months.

6. ~~f.~~ Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

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

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

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

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

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

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

7. ~~g.~~ Multifocal Motor Neuropathy

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

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

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

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

e. ~~5.~~ Initial approval will be given for three months.

8. ~~h.~~ HIV infected children: Bacterial control or prevention

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

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

9. ~~i.~~ Myasthenia Gravis

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

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

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

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

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

10. ~~j.~~ Dermatomyositis/Polymyositis

a. ~~1.~~ Recipient has severe active disease; and

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

c. ~~3.~~ Diagnosis has been confirmed by muscle biopsy; and

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

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

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

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

h. ~~8.~~ Initial approval will be given for three months.

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

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

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

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

12. ~~l.~~ Stiff-Person Syndrome

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

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

c. ~~3.~~ Recipient has a documented baseline on physical exam.

13. ~~m.~~ Allogeneic Bone Marrow or Stem Cell Transplant

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

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

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

d. ~~4.~~ Initial approval will be given for three months.

14. ~~n.~~ Kawasaki's Disease

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

15. ~~o.~~ Fetal Alloimmune Thrombocytopenia (FAIT)

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

1. ~~a.~~ Previous FAIT pregnancy; or

2. ~~b.~~ Family history of the disease.

3. ~~c.~~ Screening reveals platelet alloantibodies.

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

16. ~~p.~~ Neonatal Alloimmune Thrombocytopenia (NAIT)

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

17. ~~q.~~ Auto-immune Mucocutaneous Blistering Diseases

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

1. ~~a.~~ Pemphigus Vulgaris

2. ~~b.~~ Pemphigus Foliaceus

3. ~~c.~~ Bullous Pemphigoid

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

5. ~~e.~~ Epidermolysis Bullosa Aquisita

6. ~~f.~~ Pemphigus Gestationis (Herpes gestationis)

7. ~~g.~~ Linear IgA Dermatotis; and

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

c. ~~3.~~ Diagnosis has been confirmed by biopsy; and

d. ~~4.~~ Recipient's disease is progressive; and

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

f. ~~6.~~ Recipient has a documented baseline on physical exam.

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

a. ~~1.~~ Used for prevention of infection; and

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

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

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

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

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

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

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

d. ~~4.~~ Two or more pneumonias within one year; or

e. ~~5.~~ Recurrent or deep skin abscesses; or

f. ~~6.~~ Need for intravenous antibiotics to clear infections; or

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

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

a. ~~1.~~ Titers were drawn before challenging with vaccination; and

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

20. ~~t.~~ Toxic Shock Syndrome

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

21. ~~u.~~ Management of Immune-Checkpoint-Inhibitor Related Toxicity

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

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

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

2. ~~b.~~ Stevens-Johnson Syndrome (SJS)

3. ~~c.~~ Toxic epidermal necrolysis (TEN)

4. ~~d.~~ Severe (G3-4) myasthenia gravis

5. ~~e.~~ Transverse myelitis

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

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

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

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

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

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

22. ~~v.~~ Management of CAR T-Cell-Related Toxicity

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

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

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

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

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

~~23~~. ~~w.~~ Supportive Care after Rethymic transplant

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

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

b. ~~2.~~ Dosage Limits

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

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

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

c. ~~3.~~ Recertification Request:

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

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

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

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

5. ~~e.~~ Primary Immunodeficiency (PID)

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

1. ~~a.~~ Decrease in the frequency of infection.

2. ~~b.~~ Decrease in the severity of infection.

6. ~~f.~~ IgG Subclass Deficiency

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

1. ~~a.~~ Decrease in the frequency of infection

2. ~~b.~~ Decrease in the severity of infection; and

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

7. ~~g.~~ Chronic Immune Thrombocytopenia/ITP

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

8. ~~h.~~ Chronic Inflammatory Demyelinating Polyneuropathy

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

9. ~~i.~~ Guillain-Barre Syndrome (Acute Inflammatory polyneuropathy)

a. ~~1.~~ May not be renewed.

10. ~~j.~~ Multifocal Motor Neuropathy

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

11. ~~k.~~ HIV infected children: Bacterial control or prevention

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

1. ~~a.~~ Decrease in the frequency of infection

2. ~~b.~~ Decrease in the severity of infection; and

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

12. ~~l.~~ Myasthenia Gravis

a. ~~1.~~ May not be renewed.

13. ~~m.~~ Dermatomyositis/Polymyositis

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

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

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

1. ~~a.~~ Decrease in the frequency of infection

2. ~~b.~~ Decrease in the severity of infection; and

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

15. ~~o.~~ Stiff Person Syndrome

a. ~~1.~~ Documented improvement from baseline on physical exam.

16. ~~p.~~ Allogeneic Bone Marrow or Stem Cell Transplant

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

17. ~~q.~~ Kawasaki's Disease

a. ~~1.~~ May not be renewed.

18. ~~r.~~ Fetal Alloimmune Thrombocytopenia (FAIT)

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

19. ~~s.~~ Neonatal Alloimmune Thrombocytopenia

a. ~~1.~~ May not be renewed.

20. ~~t.~~ Auto-Immune Mucocutaneous Blistering Diseases

a. ~~1.~~ Documented improvement from baseline on physical exam.

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

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

1. ~~a.~~ Decrease in the frequency of infection

2. ~~b.~~ Decrease in the severity of infection; and

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

22. ~~v.~~ Toxic Shock Syndrome

a. ~~1.~~ May not be renewed.

23. ~~w.~~ Management of Immune Checkpoint Inhibitor related Toxicity

a. ~~1.~~ May not be renewed.

24. ~~x.~~ Management of CAR T-Cell-Related Toxicity

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

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

25. ~~y.~~ Supportive Care after Rethymic transplant

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

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

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

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

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

d. ~~4.~~ Prior Authorization Guidelines:

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

~~1.~~2. Unless otherwise specified, the initial approval will be given for six months.

~~1.~~3. Recertification will be approved for 12 months.

2. SCIG (immune globulin SQ): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia®, Cuvitru®, Cutaquig®, Xembify®

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

1. Baseline values for BUN and serum creatinine obtained within 30 days of request; and

2. Primary immunodeficiency (PID)/Wiskott-Aldrich Syndrome

a. Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome)

1. Recipient is greater than or equal to two years old [HyQvia only: recipient must be greater than or equal to 18 years old]; and

2. Recipient's IgG level is less than 200 mg/dL or both of the following:

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

1. Four or more ear infections within one year

2. Two or more serious sinus infections within one year

3. Two or more serious months of antibiotics within little effect

4. Two or more pneumonias within one year

5. Recurrent or deep skin abscesses

6. Need for intravenous antibiotics to clear infections

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

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

1. Titers were drawn before challenging with vaccination; and

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

3. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Hizentra Only]

a. Recipient must be greater than or equal to 18 years old; and

b. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, six-MWT, Rankin, Modified Rankin, etc.); and

1. Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); or

2. Used for re-initiation of maintenance therapy after experiencing a relapse and requiring pre-induction therapy with IVIG (see Section IV for criteria).

4. Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia

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

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

a. Four or more ear infections within one year

b. Two or more serious sinus infections within one year

c. Two or more months of antibiotics with little effect

d. Two or more pneumonias within one year

e. Recurrent or deep skin abscesses

f. Need for intravenous antibiotics to clear infections

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

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

a. Titers were drawn before challenging with vaccination; and

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

b. Dosage Limits

1. Quantity Limits

a. Hizentra

1. Dose/week: 46g

2. Dose/28 days: 184g

b. Gamunex-C & Gammaked

1. Dose/week: 24g

2. Dose/28 days: 96g

c. Gammagard Liquid

1. Dose/week: 24g

2. Dose/28 days: 96g

d. HyQvia

1. Dose/week: 17.5g
2. Dose/28 days: 69g

e. Cuvitru

1. Dose/week: 23g
2. Dose/28 days: 92g

f. Cutaquig

1. Dose/week: 24g
2. Dose/28 days: 96g

g. Xembify

1. Dose/weel: 24g
2. Dose/28 days: 96g

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

a. Hizentra

a. Billable units/28 days: 960 (PID)/1840 (CIDP)

b. Gamunex-C & Gammaked

1. Billable units/28 days: 192

c. Gammagard liquid

1. Billable units/28 days: 192

d. HyQvia

1. Billable units/28 days: 690

e. Cuvitru

1. Billable units/28 days: 920

f. Cutaquig

1. Billable units/28 days: 960

g. Xembify

1. Billable units/28 days: 960

c. Recertification Request

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 hypersensitivity/anaphylaxis, thrombosis, aseptic meningitis syndrome, hemolytic anemia, hyperproteinemia, acute lung injury, etc.; and

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

4. Primary immunodeficiency (PID)/Wiskott-Aldrich Syndrome

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

1. Decrease in the frequency of infection

2. Decrease in the severity of infection.

5. Chronic Inflammatory Demyelination Polyneuropathy (CIDP) [Hizentra Only]

a. Renewals will be authorized for recipients that have demonstrated a beneficial clinical response to maintenance therapy, without relapse, based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, six-MWT, Rankin, Modified Rankin, etc.); or

b. Recipient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra; and

1. Recipient improved and stabilized on IVIG treatment; and

2. Recipient was not receiving maximum dosing or Hizentra prior to relapse.

6. Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia

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

1. Decrease in the frequency of infection

2. Decrease in the severity of infection; and

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

d. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification approval will be given for 12 months.

~~N. Libtayo® (cemiplimab-rwlc)~~

~~Therapeutic Drug Class: Colony Stimulating Factors~~
~~Last Reviewed by DUR Board: January 19, 2023~~

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

N. Pemetrexed

Therapeutic Drug Class: Antimetabolites
Last Reviewed by DUR Board: N/A

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

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

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

   b. Primary Central Nervous System (CNS) Lymphoma

      1. Used as single agent: and

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

         b. Used for relapsed or refractory disease.

   c. Malignant Peritoneal Mesothelioma (MPeM)

      1. Used as first-line therapy; and

         a. Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy for unresectable disease; or

         b. Used as a single agent or in combination with cisplatin or carboplatin (if cisplatin ineligible) for diffuse or recurrent disease; or

      2. Used as subsequent therapy; and

         a. Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; or

b. Used as a single agent; and

1. Pemetrexed was not administered first-line; or

2. Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted.

d. Malignant Pleural Mesothelioma (MPM)

1. Used as induction therapy; and

a. Used in combination with cisplatin or carboplatin (if cisplatin ineligible) in recipients with epithelioid histology; or

2. Used as first-line therapy; and

a. Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy; or

b. Used as a single agent; or in combination with cisplatin or carboplatin (if cisplatin ineligible) for resected or recurrent disease; or

c. Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; or

1. Pemetrexed was not administered first-line; or

2. Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted.

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

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

2. Used as single-agent therapy; 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 PD-L1 greater than one percent tumors that have negative actionable molecular biomarkers; or

2. Used as first-line therapy for PD-L1 less than or equal to one percent and tumors that have negative actionable molecular markers or BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon-14 skipping mutation, EGFR exon 20 mutation, KRAS G12C mutation, or RET rearrangement positive tumors; or

3. Used as subsequent therapy for first progression after initial systemic therapy; or

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

f. Thymomas/Thymic Carcinoma

1. Used as a single agent; and

a. Used as first-line therapy or postoperative treatment in recipients who are unable to tolerate first-line combination regimens; or

b. Used as second-line therapy for unresectable or metastatic disease.

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

1. Used as single-agent therapy; and

a. Recipient has recurrent or persistent disease; 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.

2. Dosage Limits

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

1. Alimta 100mg powder for injection in a single-use vial: four vials every 21 days

2. Alimta 500 mg powder for injection in a single-use vial: four vials every 21 days

3. Pemfexy 500 mg solution for injection in a multi-dose vial: four vials every 21 days

4. Pemetrexed disodium 750mg powder for injection: two vials every 21 days

5. Pemetrexed disodium 1000mg powder for injection: two vials every 21 days

6. Pemetrexed disodium 100mg/four mL solution for injection: four vials every 21 days

7. Pemetrexed disodium 500mg/20mL solution for injection: four vials every 21 days

8. Pemetrexed disodium 1000mg/40mL solution for injection: two vials every 21 days.

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

1. CNS Lymphoma and Ovarian Cancer: 230 billable units every 21 days

2. All other indications: 130 billable units every 21 days.

3. Recertification Request

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

b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal toxicity (CrCl less than 45 mL/min), bullous and exfoliative skin toxicity (e.g., Stevens-Johnson Syndrome/Toxic epidermal necrolysis), interstitial pneumonitis, radiation recall, etc.; and

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

d. MPeM and MPM

1. May not be renewed when used in combination with platinum therapy and bevacizumab.

e. Thymomas/Thymic Carcinoma

1. May not be renewed

4. Prior Authorization Guidelines

a. Initial approval will be given for six months

1. Thymomas/Thymic Carcinoma: Coverage will be provided for six 21-day cycles and may not be renewed

2. MPeM and MPM: Coverage will be provided for six 21-day cycles and may not be renewed when used in combination with platinum therapy and bevacizumab

b. Recertification will be approved for six months.

O. HER2 Inhibitors

Therapeutic Drug Class: HER2 Inhibitors
Last Reviewed by DUR Board: N/A

HER2 Inhibitors are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits

1. Perjeta®

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

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

2. Universal Criteria

a. 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. 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, node positive, or inflammatory disease; and

2. Used in combination with trastuzumab and chemotherapy; or

b. Used as adjuvant therapy; and

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

a. Used in combination with trastuzumab and chemotherapy; or

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

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

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

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

2. Recipient has not previously received pertuzumab.

4. Central Nervous System (CNS) Cancer

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

b. Used in combination with high-dose 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 recurrent limited brain metastases; or

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

5. Colorectal Cancer (CRC)

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

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

1. Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting.

6. Appendiceal Adenocarcinoma – Colon Cancer

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

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

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 after at least one prior line of treatment in the advanced or metastatic disease setting.

7. Head and Neck Cancer

a. Recipient has salivary gland tumors; and

b. Used in combination with trastuzumab; and

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

1. Distant metastases; or

2. Unresectable locoregional recurrence with prior radiation therapy (RT); or

3. Unresectable second primary with prior RT.

8. Hepatobiliary Cancers

a. Recipient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; and

b. Used as subsequent treatment for progression on or after systemic treatment for unresectable or metastatic diseae; and

c. 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.

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

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. 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: left ventricular dysfunction, severe infusion-related reactions, hypersensitivity reactions/anaphylaxis, etc; and

4. Left ventricular ejection fraction (LVEF) obtained within the previous three months as follows:

a. Neoadjuvant and adjuvant treatment of breast cancer: LVEF is greater than or equal to 50% OR LVEF has had an absolute decrease of less than 10% from baseline

b. All other indications: LVEF is greater than 45% OR LVEF is 40% to 45% and absolute decrease is less than 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. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months.

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

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

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

2. Universal Criteria

   a. 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 two (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

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

   d. 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 locally advanced, node positive, or inflammatory disease; and

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

         b. Used as a single agent; or

         c. Used in combination with pertuzumab; or

   b. Used as neoadjuvant or preoperative therapy; and

      1. Recipient has locally advanced, 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 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 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 third-line therapy and beyond

f. Lapatinib (without cytotoxic therapy) as third-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

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

b. Used as first-line therapy in combination with chemotherapy with or without pembrolizumab (excluding use in combination with DCF [docetaxel, carboplatin, and fluorouracil]).

6. Endometrial Carcinoma – Uterine Neoplasms

a. Used in combination with carboplatin and paclitaxel; and

b. Recipient has stage III/IV or recurrent uterine serous carcinoma.

7. Colorectal Cancer (CRC)

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

b. Used in combination with pertuzumab or lapatinib; and

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

1. Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease if intensive therapy is not recommended; or

2. Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting.

8. Appendiceal Adenocarcinoma – Colon Cancer

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

b. Used in combination with pertuzumab or lapatinib; and

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

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 after at least one prior line of treatment in the advanced or metastatic disease setting.

9. Head and Neck Cancer

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 radiation therapy (RT)

3. Unresectable second primary with prior RT.

10. Hepatobiliary Cancers

a. Recipient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; and

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

c. Used in combination with pertuzumab.

b. Dosage Limits

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

a. 150 mg single-dose vial: six vials day one, then five vials every 21 days thereafter

b. 420 mg multiple-dose vial: three vials day one, then two vials every 21 days thereafter.

c. Recertification Request

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

2. 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: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, etc.), severe or febrile neutropenia, severe infusion-related reactions, etc.; and

4. Left ventricular ejection fraction (LVEF) obtained within the previous three months as follows:

a. LVEF is within the institutional normal limits, and has not had an absolute of greater than or equal to 16% from pre-treatment baseline; or

b. LVEF is below the institutional lower limits of normal, and has not had an absolute decrease of greater than or equal to ten percent from pre-treatment baseline.

5. Breast Cancer (neoadjuvant and adjuvant therapy)

a. Recipient has not exceeded a maximum of fifty-two (52) weeks of treatment (total 18 cycles).

d. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months

a. Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of 52 weeks of treatment [18 cycles]

3. Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)

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

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

2. Universal Criteria

a. 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 two HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; and

c. Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or famtrastuzumab deruxtecan-nvki (Enhertu); and

d. Therapy will not be used in combination with intravenous chemotherapy agent; and

e. Therapy will not be used in combination with trastuzumab (or any of its biosimilar products [e.g., Ogivri, Kanjiti, Trazimera, Herzuma, Ontruzant]) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); and

3. Breast Cancer

a. Used as adjuvant therapy; and

1. Used as a single agent following anthracycline-based therapy; or

b. Used for metastatic disease; and

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

b. Dosage Limits

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

a. Herceptin Hylecta (600 mg trastuzumab/10,000 units hyaluronidase) single-dose: one vial every 21 days.

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

a. 60 billable units every 21 days.

c. Recertification Request

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. 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: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis), neutropenia, severe administration-related reactions (e.g., hypersensitivity, anaphylaxis), etc.; and

4. Left ventricular ejection fraction (LVEF) within the previous three months as follows:

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

b. LVEF is below the institutional lower limits of normal, and has not had an absolute decrease of greater than or equal to 10% from pre-treatment baseline; and

5. Breast Cancer (adjuvant treatment)

a. Recipient has not exceeded a maximum of 52 weeks of therapy.

d. Prior Authorization Guidelines

1. Initial approval will be given six months.

2. Recertification will be given six months.

a. Adjuvant therapy may be authorized for a total of fifty-two weeks.

P. CD20 Monoclonal Antibodies

Therapeutic Class: Antirheumatic, CD20 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

CD20 Monoclonal Antibodies are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Rituxan®, Truxima®, Ruxience™, Riabni™ (Rituximab)

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

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

2. Universal Criteria

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

b. Recipient has been screened for the presence of hepatitis B (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 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

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-negative (Ph-) disease; and

1. Used for induction/consolidation treatment; and

a. Used in combination with a regimen containing an anthracycline and vincristine; or

2. Used for relapsed/refractory treatment; and

a. Used in combination with MOpAD regimen (methotrexate, vincristine, pegaspargase, dexamethasone).

6. Central Nervous System (CNS) Cancer

a. Recipient has leptomeningeal metastases from lymphomas; and

1. Rituximab will be administered intrathecally; or

b. Recipient has primary CNS lymphoma; and

1. Used as a component of induction therapy in combination with a methotrexate-containing regimen, temozolomide, lenalidomide, or as a single agent; or

2. Used as a component of consolidation therapy in combination with a methotrexate-containing regimen; or

3. Used for relapsed or refractory disease as a single agent, or in combination with either temozolomide, lenalidomide, or high-dose methotrexate.

7. Adult Hodgkin Lymphoma

a. Recipient has nodular lymphocute-predominant disease.

8. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/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 less than 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 one of the following:

a. Alemtuzumab

b. 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

e. Venetoclax; or

3. Used as first-line therapy for histologic (Richter's) transformation to diffuse large B-cell lymphoma; and

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

9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

10. Adult B-Cell Lymphomas

a. AIDS-Related B-Cell Lymphoma

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

b. Burkitt Lymphoma

1. Used in combination with chemotherapy

c. Castleman Disease

1. Recipient has multicentric disease; or

2. Recipient has unicentric disease; and

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

b. Used for unresectable disease or symptomatic disease after incomplete resection

d. Diffuse Large B-Cell Lymphoma

e. Low-Grade (grade 1-2) or Follicular Lymphoma

f. Gastric & Non-Gastric (Noncutaneous) MALT Lymphoma

g. High Grade B-Cell Lymphomas

h. Mantle Cell Lymphoma

i. Nodal & Splenic Marginal Zone Lymphoma

j. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma

k. Post-Transplant Lymphoproliferative Disorder (PTLD) (B-Cell Type).

11. Primary Cutaneous B-Cell Lymphomas

12. Pediatric Aggressive Mature B-Cell Lymphomas (Primary Mediastinal Large B-Cell Lymphoma, Diffuse Large B-Cell Lymphoma, Burkitt Lymphoma, and Burkitt-like Lymphoma)

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

b. Used in combination with chemotherapy.

13. Hairy Cell Leukemia

a. Used as a single agent; and

1. Used for less than complete responses or relapsed disease in recipients unable to receive purine analogs (i.e., cladriine or pentostatin); or

b. Used in combination with cladribine; or

c. Used in combination with pentostatin; and

1. Used for less than complete response or relapsed disease; or

d. Used in combination with vemurafenib; and

1. Used for less than complete response or relapsed disease; or

2. Used for progression after relapsed or refractory therapy.

14. 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. Pediatric Hodgkin Lymphoma

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

b. Recipient has nodular lymphocyte-predominant; and

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

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

16. Chronic Graft-Versus-Host Disease (cGVHD)

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

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

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

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

17. Hematopoietic Cell Transplantation

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

18. Management of Immunotherapy-Related Toxicities

a. Recipient has been receiving therapy with an immune checkpoint inhibitor (e.g., cemiplimab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, ipilumamb, dostarlimab, nivolumab/relatlimab-rmbw, etc.); and

1. Recipient has non-viral 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 pulse-dose methylprednisolone with or without intravenous immunoglobulin (IVIG); or

2. Recipient has bullous dermatitis related to immunotherapy; and

a. Used as additional therapy for moderate (G2), severe (G3) or life-threatening (G4) disease; or

3. Recipient has moderate or severe steroid-refractory myalgias or myositis, or life-threatening steroid-refractory myositis related to immunotherapy; or

4. 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. Non-Oncology Indications

a. Recipient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); and

20. Rheumatoid Arthritis (RA)

a. Documented moderate to severe active disease; and

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

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

d. Previous failure with one or more preferred TNF antagonists at least one of which should be a self-injectable; and

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

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

21. Pemphigus Vulgaris

a. Recipient has a diagnosis of pemphigus vulgaris as determined by one or more of the following clinical features:

1. Appearance of lesions, erosions and/or blisters

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

3. 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. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulmatosis) 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. Thrombocytopenic Purpura

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

b. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30 x 109/L (30,000mm (3)); and

c. Diagnosis includes one of the following:

1. Primary thrombocytopenia or Idiopathic (Immune) thrombocytopenia purpura (ITP).

.

24. Thrombotic Thrombocytopenic Purpura (TTP)

a. Recipient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30x109/L (30,000/mm(3)); and

b. 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. 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.

26. Lupus Nephritis

a. Recipient has disease that is non-responsive or refractory to standard first-line therapy (e.g., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, calcineurin inhibitors [e.g., tacrolimus]); and

b. Used as a single agent or add-on therapy in combination with mycophenolate mofetil, mycophenolic acid, cyclophosphamide.

27. 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.)

28. 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.

29. 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., multiple sclerosis, 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. Dissemination in space (greater than or equal to two different core clinical characteristics)

3. Fulfillment of additional MRI requirements, as applicable

c. Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); and

b. Used as a single agent or in combination with immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate, etc.).

b. Dosage Limits

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

a. Rituxan 100mg/10mL injection: 12 vials per 28-day supply

b. Rituxan 500mg/50mL injection: eight vials per 28-day supply

c. Truxima 100mg/10mL injection: 12 vials per 28-day supply

d. Truxima 500mg/50mL injection: eight vials per 28-day supply

e. Ruxience 100mg/10mL injection: 12 vials per 28-day supply

f. Ruxience 500mg/50mL injection: either vials per 28-day supply

g. Riabni 100mg/10mL injection: 12 vials per 28-day supply

h. Riabni 500mg/50mL injection: eight vials per 28-day supply.

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

a. Oncology Indications

1. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Leukemia (SLL):

   a. Initial therapy:

      1. Loading dose: 100 billable units x one dose

      2. Subsequent doses: 130 billable units every 28 days x five doses per six months

   b. Renewal therapy: 130 billable units every eight weeks.

2. All

   a. 100 billable units twice weekly x 18 doses.

3. Hairy Cell Leukemia

   b. 100 billable units weekly x eight doses.

4. Histiocytic Neoplasms – Rosai-Dorfman Disease

   a. 130 billable units weekly x six doses in a six-month period.

5. Pediatric Hodgkin Lymphoma

   a. 100 billable units x three doses.

6. cGVHD

   a. 100 billable units weekly x eight doses.

7. Hematopoietic Cell Transplantation

   a. Initial dose: 100 billable units x one dose before transplant

   b. Subsequent doses: 250 billable units x three doses after transplant.

8. All other oncology indications:

   a. Initial therapy: 100 billable units weekly x eight doses per six months

b. Renewal therapy: 100 billable units x four doses per six months.

b. Non-Oncology Indications

1. Rhematoid Arthritis (RA):

a. 100 billable units every 14 days x two doses in a 16-week period.

2. Pemphigus Vulgaris:

a. Initiation: 100 billable units weekly x four doses in a 12-month period

b. Maintenance: 50 billable units every 16 weeks.

3. GPA(WG)/MPA:

a. Induction: 100 billable units weekly x four doses in a four-month period

b. Initial Maintenance: 50 billable units x two doses in a six-month period

c. Subsequent Maintenance: 50 billable units every six months.

4. All other non-oncology indications:

a. 100 billable units weekly x four doses in a six-month period.

c. Recertification Request

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), hepatitis B virus 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

3. Oncology Indications

   a. Recipient has not exceeded dosing or duration limits as defined in Section I, II, and V; and

4. Adult Acute Lymphoblastic Leukemia (ALL)

   a. Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

5. Hairy Cell Leukemia

   a. Coverage may not be renewed

6. Pediatric B-Cell Acute Leukemia and Aggressive Mature B-Cell Lymphomas (induction or consolidation therapy)

   a. Coverage may not be renewed

7. Pediatric Hodgkin Lymphoma

   a. Coverage may not be renewed

8. Chronic Graft-Versus-Host Disease (cGVHD)

   a. Coverage may not be renewed

9. Hematopoietic Cell Transplantation

   a. Coverage may not be renewed

10. Management of Immunotherapy-Related Toxicities

   a. Coverage for use in the treatment of myalgias/myositis/myasthenia gravis/encephalitis may not be renewed

   b. Coverage for use in bullous dermatitis: Recipient has not exceeded a maximum of 18 months of therapy (four total doses)

11. All Other Oncology Indications

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

12. 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 greater than or equal to 20% improvement on the American College of Rheumatology-20 (ARC20) criteria]; 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 as necessary to reduce the risk for bleeding

c. Thrombotic Thrombocytopenic Purpura (TTP)

1. Disease response as indicated by an increase in ADAMTS13 activity with a reduction in thrombotic risk

d. 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)

e. Pemphigus Vulgaris

1. Recipient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; and

   a. Disease response as indicated by complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline; or

   b. Recipient has not experienced continued development of new lesions and improvement in signs and symptoms of condition compared to baseline; or

      1. For Relapses only: Recipient previously had active 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

f. Autoimmune Hemolytic Anemia (AIHA)

1. Disease response as indicated by improvement in anemia signs and symptoms (e.g., dyspnea, fatigue, etc.) as well as: improvement in laboratory values (Hb/Hct), reduced transfusion needs, and/or reduced glucocorticoid use

g. Lupus Nephritis

1. 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.)

h. 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

i. Complications of transplanted solid organ

1. Coverage may not be renewed

j. NMOSID

1. Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability reduced hospitalizations, reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months (12 months initially for pemphigus vulgaris)

2. Recertification will be given for six months

a. Maintenance therapy for oncology indications (excluding ALL, Hairy Cell Leukemia, Mantle Cell Lymphoma, induction/consolidation of Pediatric B-Cell Acute Leukemia/Aggressive Mature B-Cell Lymphomas, and Pediatric Hodgkin Lymphoma) may be renewed for up to a maximum of two years

1. ALL and Mantle Cell Lymphoma may be renewed until disease progression or intolerable toxicity (ALL may be renewed for up to a total of 18 doses)

2. Hairy Cell Leukemia may not be renewed

3. Induction/Consolidation of Pediatric B-Cell Acute Leukemia and Aggressive Mature B-Cell Lymphomas may not be renewed

4. Pediatric Hodgkin Lymphoma may not be renewed.

b. Management of Immunotherapy-Related Toxicities:

1. Myalgias/Myositis/Myasthenia Gravis/Encephalitis may not be renewed

2. Bullous dermatitis may be renewed for a maximum of 18 months (four total doses)

c. Relapse therapy for Pemphigus Vulgaris must be at least 16 weeks past a prior infusion

d. Chronic Graft-Versus-Host Disease (cGVHD) may not be renewed

e. Hematopoietic Cell Transplantation may not be renewed

f. Lupus Nephritis may be renewed only in recipients experiencing a disease relapse

g. Complications of transplanted solid organ may not be renewed.

2. Rituxan Hycela® (rituximab and hyaluronidase human)

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

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

2. Universal Criteria

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

b. Recipient has been screened for the presence of hepatitis B virus (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 is CD20 antigen expression positive; and

d. Recipient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; and

e. Rituxan Hycela will not be used with intravenous chemotherapy agents; and

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

4. B-Cell Lymphomas

a. Follicular Lymphoma (FL)

b. Diffuse Large B-Cell Lymphomas

c. High Grade B-Cell Lymphomas

d. Castleman Disease

e. Gastric & Non-gastric MALT Lymphoma

f. Mantle Cell Lymphoma

g. Nodal and Splenic Marginal Zone Lymphoma

h. Histologic transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma

i. Post-transplant lymphoproliferative disorder (PTLD)

5. Hairy Cell Leukemia

6. Primary Cutaneous B-Cell Lymphoma

7. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

b. Dosage Limits

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

a. Rituxan Hycela 1,400mg/23,400 Units per 11.7 mL single-dose vial: four vials per 28-day supply

b. Rituxan Hycela 1,600mg/26,800 Units per 13.4 mL single-dose vial: one vial per 28-day supply.

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

a. Follicular Lymphoma (FL):

1. Relapsed-Refractory

a. 1,400 mg/23,400 U (140 billable units) weekly up to seven doses

2. Previously Untreated

a. 1,400 mg/23,400 U (140 billable units) every 21 days x seven doses

b. 1,400 mg/23,400 U (140 billable units) every 21 days x seven doses

3. Non-progressing after first line CVP chemotherapy

a. 1,400 mg/23,400 U (140 billable units) weekly x three doses at six months intervals (up to a maximum of 15 doses).

b. Diffuse Large B-Cell Lymphoma (DLBCL);

1. 1,400 mg/23,400 U (140 billable units) every 14 or 21 days x seven doses

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

1. 1,600 mg/26,800 U (160 billable units) every 28 days x five doses

d. Hairy Cell Leukemia

1. 1,400 mg/23,400 U (140 billable units) weekly up to seven doses

e. Other indications:

1. 1,400 mg/23,400 U (140 billable units) weekly for x seven doses in a six-month period; or

2. 1,400 mg/23,400 U (140 billable units) every eight weeks (maintenance treatment).

c. Recertification Request

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

2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity or other administration reactions (i.e., local cutaneous reactions), tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiac adverse reactions, renal toxicity, bowel obstructions or perforation, etc.; and

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

4. Recipient has not exceeded dosing or duration limits as defined in Sections I, II, and V.

d. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months

3. Maintenance therapy for mantle cell lymphoma may be renewed until disease progression or intolerable toxicity

4. Hairy Cell Leukemia may not be renewed

5. Maintenance therapy for all other indications may be renewed for up to a maximum of two years.

Q. Selective Immunosuppressants

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

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

1. Soliris® (eculizumab)

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

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

2. Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program; and

3. Universal Criteria

a. Recipient must be vaccinated again meningococcal disease at least two weeks prior to initiation of therapy and will continue to revaccinated according to current medical guidelines for vaccine use (if urgent Soliris therapy is indicated in an unvaccinated recipient, administer meningococcal vaccine(s) as soon as possible and provide recipients with two weeks of antibacterial drug prophylaxis); and

b. Recipient does not have an unresolved, serious systemic infection (e.g., Neisseria meningitidis, etc.); and

c. Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, ravulizumab, pegcetacoplan, satralizumab, inebilizumab, etc.).

4. Paroxysmal Nocturnal Hemoglobinuria (PNH)

a. Diagnosis must be accompanied by detection of PNH clones of at least 10% by flow cytometry diagnostic testing; and

1. Demonstrate the presence of at least two different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least two different cell lines (e.g., granulocytes, monocytes, erythrocytes); and

b. Recipient has laboratory evidence of significant intravascular hemolysis (i.e., LDH greater than or equal to one and a half x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):

1. Recipient has symptomatic anemia (i.e., hemoglobin less than seven g/dL or hemoglobin less than 10 g/dL, in at least two independent measurements in a recipient with cardiac symptoms

2. Presence of a thrombotic event related to PNH

3. Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency pulmonary insufficiency/hypertension)

4. Recipient is pregnant and potential benefit outweighs potential fetal risk

5. Recipient has disabling fatigue

6. Recipient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; and

c. Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobulin level, packed RBC transfusion requirement, and history of thrombotic events; and

d. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

5. Atypical Hemolytic Uremic Syndrome (aHUS)

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

b. Recipient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); and

c. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (i.e., ADAMTS-13 activity level greater than or equal to ten percent); and

d. Shiga toxin E. coli related hemolytic uremic syndrome (STEC-UHS) has been ruled out; and

e. Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis or known genetic defect in cobalamin C metabolism, etc.); and

f. Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement; and

g. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

6. Generalized Myasthenia Gravis (gMG)

a. Recipient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and

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

c. Recipient has had a thymectomy (Note: Applicable only to recipients with thymomas or non-thymomatous recipients who are 50 years of age or younger); and

d. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); and

e. Recipient has a MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to six; and

f. Recipient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); and

g. Recipient had an inadequate response after a minimum one-year trial with two or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

1. Recipient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; and

h. Recipient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®).

7. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has a confirmed diagnosis based on the following:

1. Recipient was found to be seropositive for aquaporin-four (AQP4) IgG antibodies; and

2. Recipient has at least one core clinical characteristics; and

3. Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); and

b. Recipient has a history of at least two relapses in the last 12 months or three relapses in the 24 months, with at least one relapse in the last 12 months; and

c. Recipient has an Expanded Disability Status Score (EDSS) of less than or equal to seven (i.e., presence of at least limited ambulation with aid); and

d. Recipient is receiving concurrent corticosteroid therapy of 20 mg per day or less and those receiving immunosuppressive therapy (e.g., azathioprine, glucocorticoids, mycophenolate, etc.) are on a stable dose regimen; and

e. Recipient has not received therapy with rituximab or mitoxantrone in the last three months; and

f. Received has not received intravenous immune globulin (IVIG) in the last three weeks; and

g. Recipient had an inadequate response, or has a contraindication or intolerance, to rituximab or inebilizumab, and

h. Recipient will not concomitantly receive therapy with any of the following:

1. IL6-inhibitor (e.g., satralizumab); and

2. Anti-CD20-directed antibody (e.g., rituximab); and

3. Anti-CD19-directed antibody (e.g., inebilizumab).

b. Dosage Limits

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

   a. Loading Doses:

      1. Three vials Days 1, 8, 15 and 22; then four vials Day 29

   b. Maintenance Doses:

      1. Four vials every 14 days.

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

   a. Indication: PNH

      1. Loading Doses: 60 billable units Days one, eight, 15, and 22; then 90 billable units Day 29

      2. Maintenance Dose: 90 billable units every 14 days

   b. Indication: aHUS, gMG, NMOSD

      1. Loading Doses: 90 billable units Day one, eight, 15, and 22; then 120 billable units Day 29

      2. Maintenance Dose: 120 billable units every 14 days.

c. Recertification Request

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: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, thrombotic microangiopathy complications (TMA), etc.; and

3. Paroxysmal Nocturnal Hemoglobinuria (PNH)

   a. Recipient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) or experienced a spontaneous disease remission or received curative allogeneic stem cell transplant; and

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

1. Decrease in serum LDG from pretreatment baseline Stabilization/improvement in hemoglobin level from pretreatment baseline

2. Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

3. Reduction in thromboembolic events.

4. Atypical Hemolytic Uremic Syndrome (aHUS)

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

1. Decrease in serum LDH from pretreatment baseline

2. Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline

3. Increase in platelet count from pretreatment baseline

4. Decrease in plasma exchange/infusion requirement from pretreatment baseline.

5. Generalized Myasthenia Gravis (gMG)

a. Recipient experienced an improvement (i.e., reduction) of at least three-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; or

b. Recipient experienced an improvement of at least five-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score.

6. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Recipient has stabilization and/or improvement of neurologic symptoms as evidenced by a decrease in acute relapses, EDSS, hospitalizations, or plasma exchange treatments.

c. Prior Authorization Guidelines

1. PNH and aHUS: Initial approval will be given for 12 months

2. PNH and aHUS: Recertification will be given for 12 months

3. gMG and NMOSD: Initial approval will be given for six months

4. gMG and NMOSD: Recertification will be given for six months.

2. Ultomiris® (ravulizumab-cwvz)

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

1. Recipient is at least one month of age (unless otherwise specified); and

2. Prescribed is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program; and

3. Universal Criteria

a. Recipients must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (If urgent Ultomiris therapy is indicated in an unvaccinated recipient, administer meningococcal vaccine(s) as soon as possible and provide recipients with two weeks of antibacterial drug prophylaxis); and

b. Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, eculizumab, pegcetacoplan, satralizumab, inebilizumab, etc.); and

4. Paroxysmal Nocturnal Hemoglobinuria (PNH)

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

b. Recipient is complement inhibitor treatment-naïve; and

1. Diagnosis must be accompanied by detection of PNH clones of at least five by flow cytometry diagnostic testing; and

a. Demonstrate the presence of at least two different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least two different cell lines (e.g., granulocytes, monocytes, erythrocytes); and

b. Recipient has laboratory evidence of significant intravascular hemolysis (i.e., LDH greater than or equal to one and a half x ULN) with symptomatic disease and at least one other indication for therapy

from the following (regardless of transfusion dependence):

1. Recipient has symptomatic anemia (i.e., hemoglobin less than seven g/dL or hemoglobin less than 10 g/dL, in at least two independent measurements in a recipient with cardiac symptoms

2. Presence of a thrombotic event related to PNH

3. Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension)

4. Recipient is pregnant and potential benefit outweighs potential fetal risk

5. Recipient has disabling fatigue

6. Recipient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; and

c. Documented baseline values for one or more of the following (necessary for renewal); serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement, history of thrombotic events.

5. Atypical Hemolytic Uremic Syndrome (aHUS)

a. Used as switch therapy; and

1. Recipient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

b. Recipient is complement inhibitor treatment-naïve; and

1. Recipient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); and

2. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level greater than or equal to 10%); and

3. Shiga toxin E. Coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out; and

4. Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis or known genetic defect in cobalamin C metabolism, etc.); and

5. Documented baseline values for one or more of the following (necessary for renewal); serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and dialysis requirement.

6. Generalized Myasthenia Gravis (gMG)

a. Used as switch therapy; and

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

2. Recipient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; or

b. Recipient is complement inhibitor treatment-naïve; and

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

2. Recipient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and

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

4. Recipient has had a thymectomy (note: applicable only to recipients with thymomas or non-thymomatous recipients who are 50 years of age or younger); and

5. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); and

6. Recipient has a MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to six; and

7. Recipient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); and

8. Recipient had an inadequate response after a minimum of one-year trial with two or more immunosuppressive therapies (e.g., corticosteroids, plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); or

a. Recipient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy.

b. Dosage Limits

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

a. Ultomiris 10 mg/mL – 30 mL SDV: 10 vials on day zero followed by 13 vials starting on day 14 and every eight weeks thereafter

b. Ultomiris 100 mg/mL – three mL SDC: 10 vials on day zero followed by 13 vials starting on day 14 and every eight weeks thereafter

c. Ultomiris 100 mg/mL – 11mL SDV: three vials on day zero followed by three vials starting on day 14 and every eight weeks thereafter

d. Ultomiris 245 mg/3.5mL single-dose cartridge on-body delivery system: two on-body delivery systems weekly.

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

a. Ultomiris IV

1. PNH/aHUS/gMG: 300 units on Day zero followed by 360 units on Day 14 and every eight weeks thereafter

b. Ultomiris SQ

1. PNH/aHUS: 49 units weekly.

c. Recertification Request

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: serious meningococcal infections (septicemia and/or meningitis), infusion-related reactions, other serious infections, thrombotic microangiopathy (TMA) complications, etc.; and

3. Paroxysmal Nocturnal Hemoglobinuria (PNH)

a. Recipient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) or experienced a spontaneous disease remission or received curative allogeneic stem cell transplant; and

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

1. Decrease in serum LDH from pretreatment baseline Stabilization/improvement in hemoglobin level from pretreatment baseline

2. Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

3. Reduction in thromboembolic events.

4. Atypical Hemolytic Uremic Syndrome (aHUS)

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

1. Decrease in serum LDH from pretreatment baseline

2. Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline

3. Increase in platelet count from pretreatment baseline

4. Decrease in plasma exchange/infusion requirement from pretreatment baseline.

5. Generalized Myasthenia Gravis (gMG)

a. Recipient experienced an improvement (i.e., reduction) of at least three-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; or

b. Recipient experienced an improvement of at least five-points from baseline in Quantitative Myasthenia Gravis (QMG) total score.

6. Switch therapy from Soliris to Utomiris

d. Prior Authorization Guidelines

1. Initial approval will be given for 12 months

2. Recertification will be given for 12 months.

R. Yervoy® (ipilimumab)

Therapeutic Class: Anti-CLTA-4 Monoclonal Antibodies
Last Reviewed by the DUR Board: N/A

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

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

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

2. Ampullary Adenocarcinoma

a. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Used in combination with nivolumab; and

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

2. Used as subsequent therapy for disease progression.

3. Bone Cancer

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

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

c. Used in combination with nivolumab; and

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

e. Recipient has no satisfactory alternative treatment options.

4. Central Nervous System (CNS) Cancer

a. Used for the treatment of brain metastases in recipients with BRAF non-specific melanoma; and

b. Used in combination with nivolumab or as a single agent; 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. Recipients has recurrent limited brain metastases; or

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

5. Colorectal Cancer (CRC)

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

b. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

c. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

d. Used in combination with nivolumab; and

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

a. Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy; or

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

2. Used as primary treatment; and

a. Used as neoadjuvant therapy for clinical T4b colon cancer; or

b. Used as neoadjuvant therapy of resectable liver and/or lung metastases; or

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

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

6. Appendiceal Adenocarcinoma – Colon Cancer

a. Recipient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and

b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

c. Used in combination with nivolumab; and

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

2. Used as initial therapy for advanced or metastatic disease.

7. Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers

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

b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

c. Used as first-line treatment with combination with nivolumab; and

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

8. Hepatocellular Carcinoma (HCC)

a. Used in combination with nivolumab; and

b. Used as subsequent therapy for progressive disease; and

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

1. Recipient was previously treated with sorafenib; or

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

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

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

9. Renal Cell Carcinoma (RCC)

a. Used in combination with nivolumab for clear cell histology; and

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

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

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

10. Malignant Peritoneal Mesothelioma (MPeM)

a. Used in combination with nivolumab; and

1. Used as subsequent therapy (if not administered first-line); or

2. Used as first-line therapy; and

a. Recipient has unresectable diffuse disease; or

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

11. Malignant Pleural Mesothelioma (MPM)

a. Used in combination with nivolumab; and

1. Used as subsequent therapy (if not administered first-line); or

2. Used as first-line therapy; and

a. Recipient has stage IIIB or IV disease; or

b. Recipient has sarcomatoid or biphasic histology; or

c. Disease is medically inoperable or unresectable.

12. Cutaneous Melanoma

a. Used as first-line therapy for unresectable or metastatic disease in combination with nivolumab; or

b. Used as initial therapy for limit resectable local satellite/in-transit recurrence; and

1. Used as a single agent; and

2. Recipient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); or

c. Used as subsequent therapy for unresectable or metastatic disease; and

1. Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); and

a. Used as a single agent in recipients at least 12 years of age if not previously used alone or in combination with anti-PD-1 therapy; or

b. Used in combination with nivolumab if not previously used or for recipients who progress on single agent anti-PD-1 therapy; or

c. Used in combination with pembrolizumab, if not previously used alone or in combination with anti-PD-1 therapy, for recipients who progress on single agent anti-PD-1 therapy; or

2. 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 greater than three months after treatment discontinuation; and

a. Used as single agent or in combination with anti-PD-1 therapy; and

b. Recipient has completed initial induction ipilimumab therapy (i.e., completion of four cycles within a 16 week period); or

d. Used a single agent for adjuvant therapy; and

1. Recipient has pathologic involvement of regional lymph nodes of more than one 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 no evidence of disease (NED) after complete excision; or

b. Recipient has undergone complete therapeutic lymph node dissection (TLND) and/or complete excision of nodal recurrence; or

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

13. Uveal Melanoma

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

b. Recipient has distant metastatic disease.

14. Non-Small Cell Lung Cancer (NSCLC)

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

1. Used as first-line therapy; and

a. Used for one of the following:

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

2. Recipients with a PS zero to one who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)

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

b. Used in combination with nivolumab; or

c. Used in combination with 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

2. Used as subsequent therapy; and

a. Used for one of the following:

1. Recipients with a PS zero to one who are positive for one of the following molecular mutations and have received prior target therapy: EGFR exon 19 deletion or L858R tumors, EGFR S7681, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement; or

2. Recipients with a PS zero to one 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

b. Used in combination with nivolumab; or

c. Used in combination with nivolumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; or

d. Used in combination with nivolumab, paclitaxel and carboplatin for squamous cell histology; or

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

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

15. Small Bowel Adenocarcinoma (SBA)

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

b. Recipient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and

c. Used in combination with nivolumab; and

1. Used as initial therapy; or

2. Used as subsequent therapy for recipients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy.

B. Dosage Limits

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

   a. Yervoy 200mg/40mL injection:

      1. Five vials per 84 days (initially up to five vials per 21 days x four doses)

   b. Yervoy 50mg/10mL injection:

      1. Three vials per 84 days (initially up to three days per 21 days x four doses).

C. Recertification Request

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

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

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

4. Coverage may not be renewed for the following indications:

   a. Colorectal Cancer (subsequent therapy/disease progression); or

   b. Appendiceal Adenocarcinoma (subsequent therapy/disease progression)

   c. CNS metastases from Melanoma (combination therapy with nivolumab)

   d. Cutaneous Melanoma (first-line or subsequent therapy)

   e. Hepatocellular Carcinoma

   f. Renal Cell Carcinoma

   g. Small Bowel Adenocarcinoma

   h. Ampullary Adenocarcinoma

   i. Uveal Melanoma

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

    a. Bone Cancer

    b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

    c. Peritoneal Mesothelioma

    d. Malignant Pleural Mesothelioma

    e. Non-Small Cell Lung Cancer

6. Cutaneous Melanoma (re-induction therapy)

7. Cutaneous Melanoma (adjuvant treatment – maintenance therapy)

    a. Recipient has not exceeded a maximum of three years of therapy

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

D. Prior Authorization Guidelines

1. Initial approval will be given for six months

2. Recertification will be given for six months

3. The following indications may be authorized up to a maximum of twelve weeks of therapy and may not be renewed (coverage may be extended to 16 weeks if four doses were not administered within the 12-week time frame)

    a. Colorectal Cancer (subsequent therapy/disease progression)

    b. Appendiceal Adenocarcinoma (subsequent therapy/disease progression)

    c. CNS metastases from Melanoma (combination therapy with nivolumab)

    d. Cutaneous Melanoma (first-line or subsequent therapy)

    e. Hepatocellular Carcinoma

    f. Renal Cell Carcinoma

    g. Small Bowel Adenocarcinoma

    h. Ampullary Adenocarcinoma

    i. Uveal Melanoma

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

   a. Bone Cancer

   b. Esophageal and Esophagogastric/Gastroesophageal Junction Cancer

   c. Malignant Peritoneal Mesothelioma

   d. Malignant Pleural Mesothelioma

   e. Non-Small Lung Cancer

5. Cutaneous Melanoma (adjuvant treatment)

   a. Coverage will be provided for six months and may be renewed for up to a maximum of three years of maintenance therapy.

S. Zynlonta® (loncastuximab tesirine-lpyl)

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

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

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

1. Recipient is at least 18 years old; and

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

3. Universal Criteria

a. Used as single agent therapy; and

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

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

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

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

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

g. 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

4. Large B-Cell Lymphoma

a. Recipient has relapsed or refractory disease (includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma); and

b. Recipient has received at least two prior lines of therapy.

B. Dosage Limits

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

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

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

a. Relapsed or Refractory B-Cell Lymphoma

1. Cycle 1-2

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

2. Subsequent Cycles

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

C. Recertification Request

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. 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), myelosuppression, infections, severe cutaneous reactions (e.g., photosensitivity, rash), etc.; and

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

D. Prior Authorization Guidelines

1. Initial approval will be given for six months.

2. Recertification will be given for six months.