Partnership Medi-Cal
Effective: January 1st, 2026

P & T: October 9th, 2025

Approved New & Revised PA Criteria:

Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per Partnership HealthPlan of California Policy #MPRP4033.

1. Requirements for lifileucel (Amtagvi™)
2. Requirements for afamitresgene autoleucel (Tecelra™)
3. Requirements for zenocutuzumab-zbco (Bizengri™)
4. Requirements for telisotuzumab vedotin-tllv (Emrelis™)
5. Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy
6. Requirements for Methoxy polyethylene glycol-epoetin beta (Mircera™)
7. Requirements for Non-Preferred Pegfilgrastim Products (Stimufend™, Fylnetra™, & Udenyca/Udenyca Onbody™)
8. Requirements for Eculizumab (Soliris™ & Biosimilars)
9. Requirements for Ravulizumab (Ultomiris™)
10. Requirements for Romiplostim injection (Nplate™)
11. Requirements for lecanemab-irmb IV (Leqembi™)
12. Requirements for Donanemab (Kisunla™)
13. Requirements for ocrelizumab (Ocrevus™), ocrelizumab & hyaluronidase-ocsq (Ocrevus Zunovo™) and ublituximab-xiiy (Briumvi™)
14. Requirements for Remestemcel-L-rknd (Ryoncil™)
15. Requirements for Spesolimab-sbzo IV injection (Spevigo™)
16. Requirements for Spesolimab-sbzo SC injection (Spevigo™)

Requirements for lifileucel (Amtagvi™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Unresectable or metastatic melanoma in adults previously treated with a PD-1 blocking antibody, and, if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.
Exclusion Criteria	• Uncontrolled brain metastases • Active significant systemic infection • Prior treatment with lifileucel (Amtagvi™) • Prior organ allograft or prior cell transfer • Left ventricular ejection fraction (LVEF) < 45% or New York Heart Association (NYHA) functional classification > Class 1 • Forced expiratory volume in one second (FEV1) of ≤ 60% • Treatment for melanoma of uveal or ocular origin • Patients on systemic steroids for any reason • Eastern Cooperative Oncology Group (ECOG) > 1 • Evidence of liver or kidney dysfunction • Hemorrhage (grade 2 or higher) within 14 days prior to therapy with lifileucel (Amtagvi™)
Required Medical Information	Documentation of ALL of the following must be submitted: 1. Histologically confirmed diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV). 2. Clinic notes documenting history and course of melanoma, including current stage of disease, radiologic disease progression, and current line of therapy 3. Member must have at least one resectable lesion (or aggregate of lesions resected) of ≥ 1.5 cm in diameter post-resection to generate TIL (tumor-infiltrating lymphocyte). 4. Projected start date of treatment including tumor tissue procurement (TTP) procedure. 5. Disease has progressed on treatment with a programmed death receptor-1 (PD-1) blocking antibody. Examples of PD-1 blocking antibodies include pembrolizumab (Keytruda™), nivolumab (Opdivo™). Disease progression is defined by worsening signs of cancer, such as increase in the measurable size of tumors or the appearance of new tumors on imaging tests. 6. BRAF V600 mutation status: If positive for BRAF V600E mutation, documentation should be submitted to show disease has progressed (as defined above) on treatment with a BRAF inhibitor with or without a MEK inhibitor. Examples of BRAF inhibitors include encorafenib (Braktovi™), dabrafenib (Tafinlar™), vemurafenib (Zelboraf™). Examples of MEK inhibitors include binimetinib (Mektovi™), cobimetinib (Cotellic™), trametinib (Mekinist™). 7. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and an estimated life expectancy of ≥3 months. 8. Documentation that member does not have active infection, and screenings for chronic viral infection have been or will be performed (including but not limited to: Hepatitis B, Hepatitis C, and HIV). 9. Member's current cardiac, pulmonary, liver, and renal function (all organ function must be adequate). Labs should include documentation of the

Requirements for lifileucel (Amtagvi™)

	following (from clinical trial inclusion criteria): a. Absolute neutrophil count (ANC) ≥ 1000/mm^3 b. Hemoglobin ≥ 9g/dL c. Platelets ≥ 100,000/mm^3 d. ALT/AST < 5 times the upper limit of normal e. Total bilirubin ≤ 2 mg/dL (members with Gilbert's syndrome must have total bilirubin ≤ 3 mg/dL) f. Estimated GFR > 40 mL/min 10. Echocardiogram to confirm left ventricular ejection fraction ≥ 45%. 11. If the member has known or suspected lung disease, pulmonary function testing that shows forced expiratory volume in one second (FEV1) of > 60%. 12. Member does not have uncontrolled brain metastases. 13. Member does not have hemorrhage (grade 2 or higher) within 14 days prior to therapy. 14. Member will receive lymphodepleting chemotherapy (cyclophosphamide, mesna, fludarabine) prior to infusion of lifileucel (Amtagvi™) 15. Member is deemed eligible for and will receive IL-2 (aldesleukin-Proleukin™) therapy following administration of Amtagvi™ according to package label requirement. • For all requests: Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case

Age Restriction	18 years and older
Prescriber Restriction	Oncologist, to be administered at an Amtagvi™ Authorized Treatment Center (ATC) only.
Coverage Duration	A 3-month treatment window on the authorization but limited to 1 dose per lifetime.
Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3590	Amtagvi™ (lifileucel)	Amtagvi™ is provided as a single dose for infusion containing a suspension of tumor-derived T cells. The dose is supplied in 1 to 4 patient specific IV infusion bag(s) in individual protective metal cassettes. Each dose contains 7.5 x 10^9 to 7^2 x 10^9 viable cells.

Requirements for afamitresgene autoleucel (Tecelra™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Treatment of unresectable or metastatic synovial sarcoma (SyS) in adults who have received prior chemotherapy, are HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive (in blood samples) and whose tumor expresses the melanoma-associated antigen A4 (MAGE-A4) antigen as determined by an approved or cleared companion diagnostic device.
Exclusion Criteria	• Heterozygous or homozygous for HLA-A*02:05P • Eastern Cooperative Oncology Group (ECOG) > 1 • Prior treatment with Tecelra™ or CAR-T therapy • Prior allogeneic hematopoietic stem cell transplant (HSCT) • Active or clinically significant infections and/or inflammatory disorders
Required Medical Information	Documentation of ALL of the following must be submitted: 1. Histologically confirmed diagnosis of unresectable or stage IV synovial sarcoma. 2. Clinic notes documenting history and course of disease, including response to previous therapies to confirm member's disease has progressed following ≥ 1 prior systemic chemotherapy. 3. Results of HLA-A*02 testing to confirm member has at least one of the following inclusion alleles: HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P and does NOT have the exclusion allele (Member is NOT heterozygous or homozygous for HLA-A*02:05P). 4. Results of MAGE-A4 testing to confirm tumor expression. 5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. 6. Screening for Epstein-Barr Virus, Cytomegalovirus, Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus, and any other infectious agents if clinically indicated. 7. Member's current cardiac, pulmonary, liver, and renal function (all organ function must be adequate). 8. Documentation that member will be monitored during and for at least 7 days following administration of Tecelra™ at the healthcare facility, with continued monitoring for least four weeks for signs and symptoms of Cytokine Release Syndrome (CRS) and immune effector cell-associated neurotoxicity syndromes (ICANS). 9. Documentation that member's blood counts will be monitor prior to and for several weeks following administration of Tecelra™ for prolonged severe cytopenia. • Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both approvals and denials not meeting medical necessity.
Age Restriction	18 years and older
Prescriber Restriction	Oncologist, to be administered at Tecelra™ Authorized Treatment Center (ATC) only

Requirements for afamitresgene autoleucel (Tecelra™)

Coverage Duration	A 3-month treatment window on the authorization but limited to 1 dose per lifetime.

Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose (Tecelra™)	FDA-approved recommended dose is 2.68×10^9 to 10×10^9 MAGE-A4 TCR-positive T cells

Requirements for zenocutuzumab-zbco (Bizengri™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Treatment of advanced, unresectable or metastatic non–small cell lung cancer (NSCLC) harboring a neuregulin 1 (*NRG1*) gene fusion in adults with disease progression on or after prior systemic therapy. • Treatment of advanced, unresectable or metastatic pancreatic adenocarcinoma (PDAC) harboring an *NRG1* gene fusion in adults with disease progression on or after prior systemic therapy.
Exclusion Criteria	• NYHA class III or IV congestive HF, LVEF <50%, or a history of significant cardiac disease • Eastern Cooperative Oncology Group (ECOG) > 2
Required Medical Information	Documentation of the following must be submitted: 1. Member has advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) or pancreatic adenocarcinoma (PDAC). 2. Tumor has the presence of *NRG1* gene fusion as determined by FDA-approved or CLIA-compliant test. 3. Member has disease progression on or after prior systemic therapy. 4. Bizengri™ is being requested to use as monotherapy. 5. Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2. 6. LVEF is within normal limits and will be assessed at regular intervals during treatment. 7. Bizengri™ will be administered in a setting with emergency resuscitation equipment and staff who are trained to monitor for infusion-related reactions (IRR) and to administer emergency medications. 8. Member will be monitored for new or worsening pulmonary symptoms indicative of interstitial lung disease (ILD)/pneumonitis. 9. Females of reproductive age have a negative pregnancy test prior to starting therapy and will use effective contraception during treatment and for at least 2 months following the last dose of Bizengri™. • For all requests: Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case
Age Restriction	18 years and older
Prescriber Restriction	Oncologist
Coverage Duration	Initial approval for 3 months to ensure clinical efficacy. Continued approval for up to 6 months per request with documented positive response to treatment as defined by stabilization of disease or decrease in tumor size or spread.
Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for zenocutuzumab-zbco (Bizengri™)

Medical Billing:
Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J9382	Injection, zenocutuzumab-zbco, 1 mg (Bizengri™)	750 mg once every 2 weeks (dose is the same for either indication)

Requirements for telisotuzumab vedotin-tllv (Emrelis™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Treatment of locally advanced or metastatic, nonsquamous non–small cell lung cancer (NSCLC) in adults with high c-MET protein overexpression (≥50% of tumor cells with strong [3+] staining), as determined by an approved test, who have received a prior systemic therapy.
Exclusion Criteria	• Eastern Cooperative Oncology Group Performance Status (ECOG PS) >2
Required Medical Information	Documentation of all of the following must be submitted: 1. Histologically confirmed locally advanced or metastatic NSCLC that is epidermal growth factor receptor (EGFR) wild type. 2. The tumor has high c-Met protein overexpression, defined as ≥50% of tumor cells with strong (3+) membrane staining, confirmed by an FDA-approved test. 3. Member has had at least one prior systemic therapy in the advanced or metastatic setting. 4. Eastern Cooperative Oncology Group (ECOG) performance status of ≤2. 5. Emrelis™ is being requested to use as monotherapy. 6. Member will be monitored for signs and symptoms of interstitial lung disease (ILD)/pneumonitis throughout treatment with Emrelis™. • For all requests: Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case
Age Restriction	18 and older
Prescriber Restriction	Oncologist
Coverage Duration	Initial approval for 3 months to ensure clinical efficacy. Continued approval for up to 6 months per request with documented positive response to treatment as defined by stabilization of disease or decrease in tumor size or spread.
Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
C9306	Injection, telisotuzumab vedotin-tllv (Emrelis™)	Emrelis™ dosing is weight-based and should be calculated using 1.9 mg/kg every 2 weeks. Maximum dose: 190 mg in patients weighing ≥100 kg.

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Per FDA approved indications included in the product labeling. CAR-T immunotherapy products included in this criteria: • Idecabtagene vicleucel (Abecma™) • Obecabtagene autoleucel (Aucatzyl™) • Lisocabtagene maraleucel (Breyanzi™) • Ciltacabtagene autoleucel (Carvykti™) • Tisagenlecleucel (Kymriah™) • Brexucabtagene autoleucel (Tecartus™) • Axicabtagene ciloleucel (Yescarta™)
Exclusion Criteria	• CAR-T will not be approved for use as first-line therapy. • Concurrent or prior treatment with another CAR-T immunotherapy. • Concurrent use with a chemotherapy regimen (excluding the necessary lymphodepleting regimen). • CNS disorders or CNS malignancy/metastasis. • Active infectious disease. • ECOG grade 4 or worse.
Required Medical Information	• Histologically confirmed diagnosis of one of the FDA approved indications for which therapy is being requested. • Clinic notes documenting history and course of illness, including response to previous therapies. • Documentation that member does not have active infection, and the recommended screenings in the package labeling, or in treatment guidelines, have been or will be performed for (including but not limited to): Hepatitis B, Hepatitis C, and HIV. • Documentation that member does not have an autoimmune disease or graft-vs-host disease requiring immunosuppression. • Documentation that member will undergo the recommended lymphodepleting regimen prior to CAR-T treatment (cyclophosphamide + fludarabine or appropriate alternative as recommended by package labeling or treatment guidelines). • Documentation that member is able to remain in the vicinity of the certified healthcare facility for at least 2 weeks post-infusion. • Member's current bone marrow, cardiac, pulmonary, liver, and renal function (all organ function must be adequate). • ECOG (Eastern Cooperative Oncology Group) performance status grade. • Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both approvals and denials not meeting medical necessity.
Age Restriction	See prescriber information per drug specific approval information. For most

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

	indications, CAR-T may be approved for members aged 18 or older. Noted exception for tisagenlecleucel (Kymriah™) when used for the treatment of precursor acute lymphoblastic leukemia which is limited to members aged 25 years and younger on the date of the infusion (date of service), not previously treated with any gene therapy.
Prescriber Restriction	Prescribed by a hematologist or oncologist
Coverage Duration	A 3-month treatment window on the authorization but limited to 1 dose only per lifetime.
Other Requirements & Information	Additional required information per FDA-approved indication, at time of publication. **<u>Multiple myeloma, relapsed or refractory:</u>** FDA-approved CAR-T therapies with this indication**: Abecma™, Carvykti™.** Additional information required with request: • For **Abecma™**: Documentation of treatment failure (either due to intolerable adverse reaction or lack of efficacy) with ≥2 prior lines of therapy, with at least one from each mechanism of action group listed below: a) An anti-CD38 monoclonal antibody: daratumumab (Darzalex™), daratumumab-hyaluronidase (Darzalex Faspro™), or isatuximab (Sarclisa™) b) A proteasome inhibitor: bortezomib (Velcade™), carfilzomib (Kyprolis), or ixazomib (Ninlaro™) c) An immunomodulatory agent: lenalidomide (Revlimid™), thalidomide (Thalomid™, accepted off-label use), or pomalidomide (Pomalyst™) • For **Carvykti™**: Documentation of treatment failure (due to either intolerable adverse reaction or lack of efficacy) with ≥1 prior line of therapy that includes a proteasome inhibitor and an immunomodulatory agent and are refractory to lenalidomide. **<u>Large B-cell lymphoma, relapsed or refractory:</u>** FDA-approved CAR-T therapies with this indication: **Breyanzi™, Kymriah™, Yescarta™.** Additional information required with request: For all: • A confirmed diagnosis of large B-cell lymphoma, including ANY of the following types: ▪ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from follicular lymphoma or transformed follicular lymphoma-TFL) ▪ Primary mediastinal large B-cell lymphoma ▪ High-grade B-cell lymphoma ▪ Limitations of use: Not indicated for treatment of primary CNS lymphoma. For **Breyanzi™** or **Yescarta™**: • Documentation of treatment of large B-cell lymphoma in adults that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy OR, • Member has relapsed or refractory disease after two or more lines of systemic therapy OR, • For **Breyanzi™** only: Member is refractory to first-line chemoimmunotherapy or relapses after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age.

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

For **Kymriah™**:

- Documentation of treatment of relapsed or refractory large B-cell lymphoma in adults after two or more lines of systemic therapy.

Follicular lymphoma, relapsed or refractory:

FDA-approved CAR-T therapies with this indication: **Breyanzi™, Kymriah™, Yescarta™.**

- Documentation of treatment of relapsed or refractory follicular lymphoma in adults after two or more lines of systemic therapy.

Acute lymphoblastic leukemia (ALL), B-cell precursor, relapsed or refractory:

FDA-approved CAR-T therapies with this indication for children and young adults up to 25 years of age: **Kymriah™**.

FDA-approved CAR-T therapies with this indication for adults 18 years and older: **Tecartus™, Aucatzyl™**:

For **Kymriah™**:

- Documentation of treatment of relapsed or refractory B-cell precursor ALL for member up to 25 years of age.
- Member has a confirmed diagnosis of B-cell precursor ALL and the member's condition meets ONE of the additional criteria, as specified below in either item 1 or item 2:
  1. Second or later relapse B-cell precursor ALL after failing at least two lines of adequate treatment (with relapse defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after complete remission with chemotherapy and/or allogeneic cell transplant) OR
  2. Refractory B-cell precursor ALL with refractory defined as failure to obtain complete response with induction therapy (with second or later bone marrow relapse, bone marrow relapse after allogeneic stem cell transplant, or primary refractory or chemorefractory after relapse).
- Members with Ph+ ALL require documentation of failure of 2 tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses is required, unless contraindicated or clinically significant adverse effects are experienced, PHC prior authorization may be required for tyrosine kinase inhibitors.

For **Tecartus™ and Aucatzyl™:**

- Documentation of treatment of relapsed or refractory B-cell precursor ALL for member ≥18 years of age.
- Members with Ph+ ALL require documentation of failure of tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses is required, unless contraindicated or clinically significant adverse effects are experienced, PHC prior authorization may be required for tyrosine kinase inhibitors.

Chronic lymphocytic leukemia (CLL), or small lymphocytic lymphoma, relapsed or refractory:

FDA-approved therapies with this indication: **Breyanzi™**.

- Documentation of treatment of relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after two or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor (Venetoclax-based regimen per NCCN guidelines).

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

	Mantle cell lymphoma, relapsed or refractory: FDA-approved CAR-T therapies with this indication: **Breyanzi™**, **Tecartus™.** • Documentation of treatment of relapsed or refractory mantle cell lymphoma (MCL) in adults after 2 or more lines of systemic therapy, including a Burton tyrosine kinase (BTK) inhibitor. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing
Abecma™	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	300 to 460 x 10^6 CAR-T cells, not to exceed the maximum dose of 460 million cells (may be provided in one or more IV bags)
Aucatzyl™	Q2058	Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion	410 × 106 CD19 chimeric antigen receptor (CAR)–positive viable T cells administered as a split dose infusion on day 1 and day 10 (±2 days).
Breyanzi™	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	50 to 110 x 10^6 CAR-T cells, not to exceed the maximum dose of 110 million CAR-T cells (may be provided in one or more IV bags).
Carvykti™	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.	0.5-1.0 x 10^6 CAR-T cells per kg of body weight, not to exceed the maximum dose of up 100 million CAR-T cells (provided in a single IV bag).
Kymriah™	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose varies per indication with range: 0.1 to 6 x 10^8 CAR-T cells, not to exceed maximum dose of 600 million CAR-T cells (provided in single IV bag).
Tecartus™	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose varies per indication with range: 1 to 2 x 10^6 CAR-T cells, not to exceed maximum dose of 200 million CAR-T cells (provided in single IV bag).
Yescarta™	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	2 x 10^6 CAR-T cells, not to exceed maximum dose of 200 million CAR-T cells (provided in single IV bag).

Requirements for Methoxy polyethylene glycol-epoetin beta (Mircera™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Anemia due to chronic kidney disease in adults. • Anemia due to chronic kidney disease in pediatric patients who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA. *Patients on hemodialysis should use J0887: Injection, epoetin beta, 1 microgram, (for ESRD on dialysis), which does not require a TAR when billed by a dialysis center for members over the age of 3 months*
Exclusion Criteria	• Anemia due to cancer chemotherapy. • Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. • Use for anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.
Required Medical Information	1) Clinic notes and laboratory evidence supporting anemia of CKD, including: current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR). 2) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. 3) Pretreatment hemoglobin less than 10.0 g/dL or maintenance phase hemoglobin less than 11.0 g/dL (based on package insert). 4) Dosing interval should not exceed once every 2 weeks for adults or once every 4 weeks for pediatrics.
Age Restriction	3 months and older.
Prescriber Restriction	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.
Coverage Duration	Up to 6 months
Other Requirements & Information	Renewal will require updated labs (Hgb, HCT, iron studies) Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Methoxy polyethylene glycol-epoetin beta (Mircera™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

For Mircera for ESRD, please use J0887: Injection, epoetin beta, 1 microgram, (for ESRD on dialysis), which does not require a TAR when billed by a dialysis center for members over the age of 3 months.

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J0888</td><td>Injection, epoetin beta, 1 microgram, (for non esrd use)</td><td>
Starting dose adult CKD patients who are not currently treated with an ESA: 1.2 mcg/kg body weight once every month (SC) OR 0.6 mcg/kg body weight once every two weeks (SC or IV)

Starting dose adult patients currently receiving an ESA:
<table>
<tr><th rowspan="2">Previous Weekly Epoetin alfa Dose (units/week)</th><th rowspan="2">Previous Weekly Darbepoetin alfa Dose (mcg/week)</th><th colspan="2">Mircera Dose</th></tr>
<tr><th>Once Monthly (mcg/month)</th><th>Once Every Two Weeks (mcg/every two weeks)</th></tr>
<tr><td>Less than 8000 units</td><td>Less than 40 mcg</td><td>120 mcg</td><td>60 mcg</td></tr>
<tr><td>8000 units to 16000 units</td><td>40 mcg to 80 mcg</td><td>200 mcg</td><td>100 mcg</td></tr>
<tr><td>More than 16000 units</td><td>More than 80 mcg</td><td>360 mcg</td><td>180 mcg</td></tr>
</table>
Starting doses for pediatric patients whose hemoglobin level has been stabilized by treatment with an ESA:
<table>
<tr><th>Previous Weekly Epoetin Alfa or Epoetin Beta Dose (Units/Week)</th><th>Previous Weekly Darbepoetin Alfa Dose (mcg/week)</th><th>Mircera Dose Once Every 4 Weeks (mcg)</th></tr>
<tr><td>Less than 1300 units</td><td>Less than 6 mcg</td><td>30 mcg</td></tr>
<tr><td>1300 units to less than 2000 units</td><td>6 mcg to less than 9 mcg</td><td>50 mcg</td></tr>
<tr><td>2000 units to less than 2700 units</td><td>9 mcg to less than 12 mcg</td><td>75 mcg</td></tr>
<tr><td>2700 units to less than 3500 units</td><td>12 mcg to less than 15 mcg</td><td>100 mcg</td></tr>
<tr><td>3500 units to less than 4200 units</td><td>15 mcg to less than 19 mcg</td><td>120 mcg</td></tr>
<tr><td>4200 units to less than 5500 units</td><td>19 mcg to less than 24 mcg</td><td>150 mcg</td></tr>
<tr><td>5500 units to less than 7000 units</td><td>24 mcg to less than 31 mcg</td><td>200 mcg</td></tr>
<tr><td>7000 units to less than 9500 units</td><td>31 mcg to less than 42 mcg</td><td>250 mcg</td></tr>
<tr><td>greater than or equal to 9500 units</td><td>greater than or equal to 42 mcg</td><td>360 mcg</td></tr>
</table>
Dose adjustment:
• If Hb does not increase by >1 g/dL after 4 weeks increase dose by 25%; do not increase dose more frequently than every 4 weeks.
• If Hb increases >1 g/dL in any 2-week period or >2 g/dL in any 4-week period: Reduce dose by 25% to 50% or hold therapy depending on Hb level and rate of Hb increase
• If Hb is increasing and approaching the upper target threshold: Reduce dose by 25%; if Hb continues to increase, hold therapy until Hb begins to decrease and reinitiate at 75% of the previous dose
</td></tr>
</table>

Requirements for Non-Preferred Pegfilgrastim Products (Stimufend™, Fylnetra™, & Udenyca/Udenyca Onbody™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Prevention of chemotherapy-induced neutropenia. • Hematopoietic Subsyndrome of Acute Radiation Syndrome [H-ARS]
Exclusion Criteria	• Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.
Required Medical Information	Clinic notes documenting: • Diagnosis • Specific chemotherapy regimen with dose and frequency • Current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable) • Member specific risk factors for developing neutropenia (if any) For prevention of chemotherapy-induced neutropenia: • Clinical documentation supporting inadequate response to a preferred pegfilgrastim product (Neulasta/Neulasta Onpro, Fulphila, Nyvepria, or Ziextenzo) must be provided. • ALSO, must meet ONE of the following: 1. Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. 2. OR Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. • For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.
Age Restriction	None
Prescriber Restriction	Prescribed by, or in consultation with, an oncologist or hematologist.
Coverage Duration	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Non-Preferred Pegfilgrastim Products (Stimufend™, Fylnetra™, & Udenyca/Udenyca Onbody™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Note: preferred pegfilgrastim products (Neulasta, Neulasta Onpro, Fulphila, Nyvepria and Ziextenzo) do not require a TAR when billed with either D70.1 (agranulocytosis due to chemotherapy) or Z51.11 (encounter for antineoplastic chemotherapy), and the maximum dose is not over the limit of 6 mg (12 units).

Product	HCPCS	Description	Dosing, Units
Udenyca, Udenyca OnBody	Q5111	Injection, pegfilgrastim-cbqv (udenyca), biosimilar, 0.5 mg	6mg (12 HCPCS units) once per cycle of chemotherapy, not more often than 14 days
Stimufend	Q5127	Injection, pegfilgrastim-fpgk (stimufend) biosimilar, 0.5 mg	
Fylnetra	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	

Requirements for Eculizumab (Soliris™ & Biosimilars)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy. 2) Generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor antibody-positive (AChR+). 3) Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive. 4) Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Exclusion Criteria	• Unresolved serious *Neisseria meningitidis* infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Concurrent use with other systemic Complement Inhibitors or Neonatal Fc Receptor Antagonists that are not FDA approved for add-on therapy • NMOSD that is negative for AQP4-IgG
Required Medical Information	1) Requirements for atypical hemolytic uremic syndrome (all of the following, a-e): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Weight (kg, lb) d. Documentation that Shiga toxin has been ruled out e. Trial and failure with ravulizumab (Ultomiris™) 2) Requirements for paroxysmal nocturnal hemoglobinuria (all of the following, a-e): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Weight (kg, lb) d. Documentation of trial and failure or reasons why iptacopan (Fabhalta™) OR pegcetacoplan (Empaveli™) cannot be used e. Trial and failure with ravulizumab (Ultomiris™) 3) Requirement for AChR antibody-related myasthenia gravis (all of the following, a-f): a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies. b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta-blockers, hydroxychloroquine, gabapentin, lithium. d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline. e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following (i-vi):

Requirements for Eculizumab (Soliris™ & Biosimilars)

	i. Pyridostigmine ii. Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose iii. Oral glucocorticoid sparing immunomodulatory, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate iv. Zilucoplan (Zilbrysq™) v. Self-administered efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo-PFS™) (preferred), or if unable to self-administer: Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™) vi. Ravulizumab (Ultomiris™) 4) Requirements for Neuromyelitis optica spectrum disorder (NMOSD) (all of the following a-d): a. At least one of the following: i. Optic neuritis Acute myelitis ii. Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting iii. Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) iv. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions v. Symptomatic cerebral syndrome with NMOSD-typical brain lesions b. Seropositive for AQP4-IgG antibodies c. Documentation of trial and failure or contraindication to Satralizumab (Enspryng™) OR Inebilizumab-cdon (Uplizna™) d. Documentation of trial and failure or contraindication to ravulizumab (Ultomiris)

Age Restriction	aHUS: 2 months of age and older gMG: 6 years and older NMOSD, PNH: 18 years and older
Prescriber Restriction	• PNH: Hematologist • aHUS: Nephrologist, Hematologist • gMG: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Renewal Information	Renewal Requests: • Clinical notes with relevant laboratory markers documenting positive response to therapy • Additional items for gMG: o MG-ADL o MGFA classification Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Eculizumab (Soliris™ & Biosimilars)

Medical Billing:

Use is available only through the restricted Soliris™ REMS program.

Dose limits & billing requirements (approved TAR is required)

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J1299</td><td>Injection, Eculizumab, 2 mg</td><td rowspan="3">aHUS, gMG, NMOSD (≥ 18 yrs):
900 mg IV qwk x 4 doses, then 1,200 mg for the 5th dose on week 5, then 1,200 mg q2wks thereafter.
Pediatric dosing for aHUS (≥ 2 months) & gMG (≥6 years):<table><tr><th>Weight</th><th>Induction dose (qwk)</th><th>Maintenance dose</th></tr><tr><td>≥ 40 kg</td><td>900 mg x 4</td><td>1,200 mg at week 5, then q2wks</td></tr><tr><td>30 -39 kg</td><td>600 mg x 2</td><td>30 -39 kg 600 mg x2 900 mg at week 3, then q2wks</td></tr><tr><td>0 – 29 kg</td><td>600 mg x 2</td><td>600 mg at week 3, then q2wks</td></tr><tr><td>10 – 19 kg</td><td>600 mg x 1</td><td>300 mg at week 2, then q2wks</td></tr><tr><td>5 - 9 kg</td><td>300 mg x 1</td><td>300 mg at week 2 then q3wks</td></tr></table>PNH:
600 mg IV qwk x 4 doses, then 900 mg for the 5th dose on week 5, then 900 mg q2wks thereafter.</td></tr>
<tr><td>Q5152</td><td>Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg</td></tr>
<tr><td>Q5151</td><td>Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg</td></tr>
</table>

Requirements for Ravulizumab (Ultomiris™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome to inhibit complement mediated thrombotic microangiopathy. 2) Paroxysmal nocturnal hemoglobinuria. 3) Generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor antibody-positive (AChR+) 4) Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive.
Exclusion Criteria	• Unresolved serious *Neisseria meningitidis* infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Concurrent use with other systemic Complement Inhibitors or Neonatal Fc Receptor Antagonists that are not FDA approved for add-on therapy • NMOSD that is negative for AQP4-IgG
Required Medical Information	1) Requirements for atypical hemolytic uremic syndrome (all of the following, a-d): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor c. Weight (kg, lb) d. Documentation that Shiga toxin has been ruled out 2) Requirements for paroxysmal nocturnal hemoglobinuria (all of the following, a-d): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor c. Weight (kg, lb) d. Documentation of trial and failure or reasons why iptacopan (Fabhalta™) OR pegcetacoplan (Empaveli™) cannot be used 3) Requirement for AChR antibody-related myasthenia gravis (all of the following, a-f): a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline

Requirements for Ravulizumab (Ultomiris™)

	e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following (i-v): i. Pyridostigmine ii. Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose iii. Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate iv. Zilucoplan (Zilbrysq™) v. Self-administered efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo-PFS™) (preferred), or if unable to self-administer: Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™) 4) Requirements for Neuromyelitis optica spectrum disorder (NMOSD) (all of the following, a-c): a. At least one of the following: i. Optic neuritis Acute myelitis ii. Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting iii. Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) iv. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions v. Symptomatic cerebral syndrome with NMOSD-typical brain lesions b. Seropositive for AQP4-IgG antibodies c. Documentation of trial and failure or contraindication to Satralizumab (Enspryng™) OR Inebilizumab-cdon (Uplizna™)
Age Restriction	aHUS and PNH: ≥ 1 months MG, NMOSD: ≥ 18 years
Prescriber Restriction	• aHUS: Nephrologist, Hematologist • PNH: Hematologist • MG: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Information	Renewal Requests: • Clinical notes with relevant laboratory markers documenting positive response to therapy • Additional items for gMG: ○ MG-ADL

Requirements for Ravulizumab (Ultomiris™)

	○ MGFA classification Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:
Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1303	Injection, Ravulizumab, 10mg	aHUS and PNH ≥ 1 month:

Weight	Loading dose	Maintenance dose IV (start 14 days after loading dose)	Maintenance Interval
5 kg – 9 kg	600 mg	300 mg	4 weeks
10 kg – 19 kg	600 mg	600 mg	
20 kg – 29 kg	900 mg	2,100 mg	8 weeks
30 kg – 39 kg	1,200 mg	2,700 mg	
40 kg – 59 kg	2,400 mg	3,000 mg	
60 kg – 99 kg	2,700 mg	3,300 mg	
≥ 100 kg	3,000 mg	3,600 mg	

gMG and NSMOD ≥18 years:

Weight	Loading Dose	Maintenance dose IV (start 14 days after loading dose)	Maintenance Interval
40 kg – 59 kg	2,400 mg	3,000 mg	8 weeks
60 kg – 99 kg	2,700 mg	3,300 mg	
≥ 100 kg	3,000 mg	3,600 mg	

Requirements for Romiplostim injection (Nplate™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Immune thrombocytopenia (ITP) with risk for bleeding • Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) *May be covered for off-label uses including chemotherapy induced thrombocytopenia (CIT) or thrombocytopenia post-hematopoietic cell transplant in accordance with National Comprehensive Cancer Network (NCCN) guidelines*
Exclusion Criteria	• Used to normalize platelet count

Required Medical Information	Requirements for Immune thrombocytopenia (ITP)
	• Clinical documentation to confirm diagnosis of ITP with platelet count <30,000/microL, or platelets count between 30,000 – 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) vs malignancy or other determinate cause of thrombocytopenia
	• Documentation, including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment with ALL of the following
	  ○ Oral glucocorticoids
	  ○ IVIG (e.g. Gammagard™) or AntiD immunoglobulin [Rho(D) immune globulin]
	  ○ Eltrombopag (Promacta) or avatrombopag (Doptelet)
	  ○ Splenectomy
	• Current weight, within past 30 days of request.
	• Members <18 years old will require documentation of ITP for at least 6 months.
	
	Requirements for Chemotherapy Induced Thrombocytopenia (CIT)
	• Clinical documentation including the current chemotherapy regimen, the expected duration of the chemotherapy regimen, and history of treatment delays due to thrombocytopenia.
	• Target platelet counts for chemotherapy administration.
	• Complete blood count with differential as well as additional laboratory evaluations as needed to document that alternative causes of thrombocytopenia (as listed in the NCCN Hematopoietic Growth Factor guidelines) have been ruled out.
	• Documentation of trial and failure to formulary preferred options (if any) that share the same or greater level of evidence in the NCCN Hematopoietic Growth Factor guidelines.
	
	Requirements for thrombocytopenia post-hematopoietic cell transplant
	• Clinical documentation including the date of transplant, duration and severity of thrombocytopenia, history of platelet transfusions and other treatments used with response to therapy.
	• Complete blood count with differential as well as additional laboratory evaluations as needed to document that alternative causes of thrombocytopenia (as listed in the NCCN Hematopoietic Growth Factor guidelines) have been ruled out.
	• Documentation of trial and failure to formulary preferred options (if any) that share the same or greater level of evidence in the NCCN Hematopoietic

Requirements for Romiplostim injection (Nplate™)

	Growth Factor guidelines.
Age Restriction	≥ 1 year
Prescriber Restriction	Must be prescribed or recommended by a hematologist
Coverage Duration	ITP: • Initial: 2 months • Renewal: 6 months Off-label uses: case by case, up to 6 months
Other Requirements & Information	Renewal Requirements: current CBC included to indicate benefit with treatment Requests for Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) and off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J2802	Injection, romiplostim, 1 microgram (Nplate)	Initial: 1mcg/kg (using actual body weight) Adjust the weekly dose of Nplate by increments of 1 mcg/kg until the patient achieves a platelet count ≥ 50k cells/L as necessary to reduce the risk for bleeding; do not exceed a maximum weekly dose of 10 mcg/kg Adjust the dose as follows: • If the platelet count is <50k, increase the dose by 1 mcg/kg. • If platelet count is >200k and ≤400k for 2 consecutive weeks, reduce the dose by 1 mcg/kg. • If platelet count is > 400k, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200k, resume Nplate at a dose reduced by 1 mcg/kg. Nplate should be discontinued if an increase in platelet count has not been achieved after 4 weeks at maximum allowed/tolerated dose for ITP

Requirements for lecanemab-irmb IV (Leqembi™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	For the treatment of Alzheimer's Disease (AD) in patients with mild cognitive impairment or mild dementia stage of disease.
Exclusion Criteria	Members with AD having advanced beyond mild stage.

Required Medical Information	Initial Approval Criteria (Must meet all):
	• Specialist's clinic notes from in-person evaluation (telehealth/virtual visits not acceptable for criteria when establishing diagnosis and staging the illness)
	• Documentation of diagnostic workup which demonstrates other causes of dementia have been ruled out, such as:
	  ○ Parkinson's disease, vascular dementia, Lewy Body dementia (DLB), frontotemporal dementia (FTD)
	  ○ Specific alternative neurodegenerative disease or causative factors such as cobalamin (Vitamin B12) deficiency, Niacin (Vitamin B3) deficiency, meningitis and encephalitis infections, thyroid disease, head trauma, normal-pressure hydrocephalus.
	• Confirmed diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia and must have at least two of the following:
	  ○ Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0
	  ○ Mini-Mental Examination Status (MMSE) score of 22–30
	  ○ Montreal Cognitive Assessment (MoCA) score of ≥16
	  ○ Functional Assessment Staging Tool (FAST) score of 2–4
	• Medical imaging results or diagnostic immunoassay confirming the presence of amyloid pathology with one of the following:
	  ○ Amyloid PET
	  ○ Lumbar puncture: CSF assessment positive for amyloid beta plaque.
	• Must provide baseline brain magnetic resonance imaging (MRI) dated within 12 months prior to request and MRI must document all of the following:
	  ○ Less than 4 brain micro-hemorrhages
	  ○ No prior brain hemorrhage greater than 1cm within the past year
	  ○ No localized superficial siderosis
	  ○ No evidence of acute/subacute cerebral contusion, aneurysms, vascular malformations, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory.
	  ○ No evidence of vasogenic edema or brain tumors
	  ○ No severe small vessel, or white matter disease
	• ALL of the following MUST be documented:
	  ○ Member does NOT have a history of cerebrovascular abnormalities or bleeding disorder that would present a risk for ARIA-related bleeding
	  ○ Member does NOT have history of transient ischemic attack (TIA), stroke or seizures within the previous year of screening.
	  ○ Member does NOT have untreated bleeding disorder (platelet count

Requirements for lecanemab-irmb IV (Leqembi™)

	<50,000 or INR>1.5) ○ Member must NOT have contraindications to MRI or PET scans ○ Member does NOT have history of depression and/or clinically unstable psychiatric illness in the past 12 months ○ Member does NOT have a history of alcohol or substance abuse in the past 12 months • If member is receiving an approved AD treatment such as an acetylcholinesterase inhibitor (AChEI) or memantine or both, must be on a stable dose for at least 12 weeks prior to Leqembi treatment initiation • Member weight must be included • The requested dose and frequency must be in accordance with FDA-approved labeling and must not exceed dosing guidelines • Provider attestation that monitoring for ARIA will be conducted via MRI prior to the 3rd, 5th, 7th and 14th infusions.
Age Restriction	50 to 90 years old. Member under 50 years old with early onset Alzheimer's disease (AD) and met all criteria will be reviewed on a case-by-case basis.
Prescriber Restriction	Neurologist, geriatrician, psychiatrist.
Coverage Duration	Initial, doses 1-4: 2 months' duration (up to 4 doses of infusion) First Renewals, doses 5-12: 4 months' duration (up to 8 doses of infusion) Additional Renewals, dose 13 through 18 months total treatment course: 6 months' duration (up to 2 doses/month) Treatment Requests beyond 18 months of use: A subcutaneous autoinjector product, Leqembi IQLIK, is available for self-administration for patients who have completed 18-months treatment of intravenous infusions. Upon completing 18 months of treatment, prescriber should consider transitioning member to this subcutaneous formulation to make treatment less burdensome for the member. The subcutaneous formulation is a pharmacy benefit administered through Medi-Cal Rx. Treatment requests for the IV formulation beyond 18 months duration will be reviewed on a case-by-case basis.
Other Requirements & Information	First Renewal, must meet ALL: • Member continues to meet the indication-specific criteria identified in Required Medical Information initial criteria section AND • Continued evidence of mild cognitive impairment as evidenced by an updated CDR global scale score of 0.5-1, Montreal Cognitive Assessment (MoCA) score of ≥16, and MMSE score of 22-30, and/or FAST score of 2-4. • Provider attestation that monitoring for ARIA will be conducted via MRI prior to the 3rd, 5th, 7th and 14th infusion. • Absence of amyloid-related imaging abnormalities with edema (ARIA-E) or hemosiderin deposition (ARIA-H) before the 5th and 7th infusions as determined by brain MRI. • Patient is not receiving any new medications since last authorization that would increase risk for ARIA (e.g. tissue plasminogen activator (tPA), antiplatelets, anticoagulants). Additional Renewals (dose 13 and later), must meet ALL: • Provider's attestation that the potential benefit outweighs known risks as evidence by one of the following:

Requirements for lecanemab-irmb IV (Leqembi™)

	○ A reduction in amyloid beta plaque buildup compared from baseline in PET imaging of brain. ○ A slowing/reducing cognitive decline from baseline in CDR-SB score or MMSE score. • Member has not progressed to moderate or severe AD with continued evidence of mild cognitive impairment as evidenced by an updated CDR global scale score of 0.5-1, Montreal Cognitive Assessment (MoCA) score of ≥16, MMSE score of 22-30, and/or FAST score of 2-4. • Provider attestation that monitoring for ARIA will be conducted via MRI prior to the 14th infusion. • Patient is not receiving any new medications since last authorization that would increase risk for ARIA (e.g. tissue plasminogen activator (tPA), antiplatelets, or anticoagulants). • Member must continue maintenance therapy at the recommended dosage per product labeling Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J0174	Injection, lecanemab-irmb *Intravenous product only*	Initial dosing: 10 mg/kg once every 2 weeks for 18 months. Maintenance dosing: After 18 months, may continue 10 mg/kg once every 2 weeks or switch to 10 mg/kg once every 4 weeks or change to the subcutaneous formulation.

Note: Requests for the subcutaneous product, Leqembi IQLIK, should be submitted to Medi-Cal Rx as a pharmacy benefit

DHCS statement:
Guidance for Dually Eligible/Medi-Medi Enrollees: Leqembi is covered under Medicare Part B. Medi-Cal is obligated to pay the coinsurance and/or deductibles. Medicare covers the drugs with traditional FDA approval in this class when a prescribing clinician or their staff decides the Medicare coverage criteria is met and also submits information to help answer treatment questions in a qualifying study. Providers can participate in the CMS National Patient Registry (or another CMS-approved study) to get Medicare payment for treating their patients with Leqembi.

For additional details, see:
https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval

Requirements for Donanemab (Kisunla™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	For the treatment of Alzheimer's Disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia stage of disease.
Exclusion Criteria	Members with AD having advanced beyond mild stage.

Required Medical Information	Documentation must include all of the following:
	• Specialist's clinic notes from in-person evaluation (telehealth/virtual visits not acceptable for criteria when establishing diagnosis and staging the illness).
	• Documentation of diagnostic workup which demonstrates other causes of dementia have been ruled out, such as:
	  ○ Parkinson's disease, vascular dementia, Lewy Body dementia (DLB), frontotemporal dementia (FTD)
	  ○ Specific alternative neurodegenerative disease or causative factors such as cobalamin (Vitamin B12) deficiency, Niacin (Vitamin B3) deficiency, meningitis and encephalitis infections, thyroid disease, head trauma, normal-pressure hydrocephalus.
	• Gradual progressive change in memory function, reported by the patient or informant, over at least 6 months.
	• Confirmed diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia and must have at least two of the following:
	  ○ Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0
	  ○ Mini-Mental Examination Status (MMSE) score of 22-30
	  ○ Montreal Cognitive Assessment (MoCA) score of ≥16
	  ○ Functional Assessment Staging Tool (FAST) score of 2-4
	• Medical imaging results or diagnostic immunoassay confirming the presence of amyloid pathology with one of the following:
	  ○ Amyloid PET imaging
	  ○ Lumbar puncture: CSF assessment positive for amyloid beta plaque.
	• All of the following must be documented on baseline MRI:
	  ○ Member does NOT have presence of amyloid-related imaging abnormalities of edema/effusion at baseline
	  ○ Member does NOT have more than 4 cerebral microhemorrhages
	  ○ Member does NOT have more than 1 area of superficial siderosis
	  ○ Member does NOT have any intracerebral hemorrhage > 1cm
	  ○ Member does NOT have severe white matter disease
	• If the member is being treated with other medications for Alzheimer's disease, or others that may impact cognition, member must be on a stable dose for 30 days prior to initiating treatment with Kisunla™.
	• Testing for ApoE ε4 status should be performed or offered, and corresponding risk of ARIA considered by both provider and patient before initiating treatment.

Age Restriction	60 years and older

Requirements for Donanemab (Kisunla™)

Prescriber Restriction	Neurologist, Geriatrician, Psychiatrist
Coverage Duration	Initial dose (Infusion 1): 1-month duration • Baseline MRI required before initiating treatment First Renewals (Infusion 2-4): 3-month duration • MRI required before 2nd, 3rd, and 4th infusions Additional Renewals (Infusion 5-7): 3-month duration • MRI required before 7th infusion Additional Renewals (Infusion 8 and beyond): 6-month duration Treatment duration beyond 18 months will be reviewed on a case-by-case basis
Other Requirements & Information	For first renewal, member must meet all of the following: • Member continues to meet the indication-specific criteria identified in Required Medical Information initial criteria section AND • Continued evidence of mild cognitive impairment as evidenced by an updated CDR global scale score ≤1 Montreal Cognitive Assessment (MoCA) score of ≥16, and MMSE score of ≥22, and/or FAST score of 2-4. • Provider attestation that monitoring for ARIA will be conducted via MRI prior to the 2nd, 3rd, 4th and 7th infusions. ○ Attestation that dosing will be suspended if results show moderate to severe ARIA-E or ARIA-H, or symptomatic ARIA-H of any severity. For additional renewals, member must meet all of the following: • Member has not progressed to moderate or severe AD with continued evidence of mild cognitive impairment as evidenced by an updated CDR global scale score ≤1, Montreal Cognitive Assessment (MoCA) score of ≥16, and MMSE score of ≥22, and/or FAST score of 2-4. • Provider attestation that the potential benefits outweigh the known risks. • Provider attestation that clinical evaluation (including MRI) will be performed if patient demonstrated symptoms suggestive or ARIA. • Treatment remains at the recommended dosing per package instructions. Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J0175	Injection, donanemab-azbt	Titrated dosing: • week 0: IV: 350 mg once • week 4: IV: 700 mg once • week 8: IV: 1050 mg once • week 12 and thereafter: 1400 mg once every 4 weeks

Requirements for ocrelizumab (Ocrevus™), ocrelizumab & hyaluronidase-ocsq (Ocrevus Zunovo™) and ublituximab-xiiy (Briumvi™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease in adults. • Ocrevus™ and Ocrevus Zunovo™ are also FDA-approved for treating primary progressive multiple sclerosis (PPMS) and as such PPMS is a covered use for these agents
Exclusion Criteria	• History of life-threatening infusion reaction to ocrelizumab or ublituximab. • Active hepatitis B virus (HBV) infection. • Concurrent use of other disease-modifying therapies or immunosuppressives.
Required Medical Information	New Start: Clinical evaluation by neurologist with documentation of the following: • For all 3 products, a diagnosis of relapsing form of MS, to include CIS, relapsing-remitting disease, and active secondary progressive disease OR for Ocrevus™ or Ocrevus Zunovo™, a diagnosis of primary progressive MS is also appropriate for requesting treatment • Documentation should include the diagnosis as confirmed by brain MRI reports, lab reports, documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. • Documentation that member does not have an active hepatitis B infection (as confirmed by Hepatitis B Surface Antigen [HBsAg] and anti-HBV tests). For patients who are negative for HBsAg and positive for Hepatitis B core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consultation with liver disease experts before starting and during treatment is required. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc.) and/or documentation of clinical response with therapy requested.
Age Restriction	Minimum Age: 18 years
Prescriber Restriction	Must be prescribed or recommended by a Neurologist
Coverage Duration	3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care with documentation of positive clinical response: 12 months
Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for ocrelizumab (Ocrevus™), ocrelizumab & hyaluronidase-ocsq (Ocrevus Zunovo™) and ublituximab-xiiy (Briumvi™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Ocrevus	J2350	Injection, Ocrelizumab, 1 mg	Initial Dose: 300 mg once on day 1, followed by 300 mg once 2 weeks later; Subsequent doses, starting 6 months after 1 st infusion: – 600 mg every 6 months
Ocrevus Zunovo	J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq	920 mg/23,000 units (920 mg ocrelizumab and 23,000 units hyaluronidase) as single 23-mL SC injection in abdomen over ~10 minutes every 6 months
Briumvi	J2329	Injection, ublituximab-xiiy, 1 mg	Initial Dose: 150 mg once on day 1, followed by 450 mg once 2 weeks later; Subsequent doses of 450 mg are administered once every 24 weeks (beginning 24 weeks after the first dose of 150 mg)

Requirements for Remestemcel-L-rknd (Ryoncil™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	The treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients
Exclusion Criteria	• Age ≥18 years • Skin only grade B aGVHD
Required Medical Information	1) Diagnosis of grade B–D aGVHD with symptoms involving skin, liver, and/or GI tract (excluding skin-only grade B aGVHD) a. See definition of grading in the Other Requirements & Information section. b. For cases for aGVHD outside of the classical presentation (such as occurring >100 days post-transplant, or presenting with symptoms usually associated with chronic GVHD) histologic confirmation of diagnosis is required. 2) Baseline staging of disease by organ with relevant labs or descriptions as found in the Bone Marrow Transplant Registry Severity Index (see Other Requirements & Information section). 3) Steroid refractory disease defined as progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent). 4) Documentation that the GVHD prophylactic regimen has been optimized based on the transplant type, for example, achieving adequate trough concentrations of calcineurin inhibitors (200-300ng/ml for cyclosporine, or 15ng/ml for tacrolimus), or reasons why these levels cannot be achieved. 5) Documentation of trial and failure or reasons why Ruxolitinib (Jakafi™) cannot be used (in members ≥12 years old only). Policy MCUP3138 External Independent Medical Review may apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals (ie denials for medical necessity).
Age Restriction	2 months to 17 years only
Prescriber Restriction	Oncologist, hematologist, BMT specialist, or other qualified prescriber
Coverage Duration	Initial or subsequent flare following complete response: 4 weeks (8 doses) Renewal for partial or mixed response: 4 weeks (4 doses)
Other Requirements & Information	Renewal requirements: • Requests for continuation following a partial or mixed response: ○ Documentation of partial response (organ improvement of ≥1 stage without worsening of any other organ) or mixed response (improvement in ≥1 evaluable organ stage with worsening in another) following an initial 4-week course of 8 doses. • Requests for re-treatment following a complete response: ○ Documentation showing complete response defined as resolution of aGVHD in all involved organs following the initial 4-week course of Ryoncil. ○ Current aGVHD flare (grade B–D progression after achieving

Requirements for Remestemcel-L-rknd (Ryoncil™)

complete response)

Definition of International Bone Marrow Transplant Registry Severity Index grades A - D:

Organ	Stage	Description
Skin	1	Maculopapular rash over <25% of body area
	2	Maculopapular rash over 25-50% of body area
	3	Generalized erythroderma
	4	Generalized erythroderma with bullous formation and often with desquamation
Liver	1	Bilirubin 2.0-3.0 mg/dL
	2	Bilirubin 3.1-6.0 mg/dL
	3	Bilirubin 6.1-15.0 mg/dL
	4	Bilirubin >15.0 mg/dL
Gut	1	Diarrhea >30ml/kg or >500ml/day
	2	Diarrhea >60ml/kg or >1000ml/day
	3	Diarrhea >90ml/kg or >1500ml/day
	4	Diarrhea >90ml/kg or >2000ml/day; or severe abdominal pain with or without ileus
International Bone Marrow Transplant Registry Severity Index		
A – stage 1 skin involvement; no liver or gut involvement		
B – stage 2 skin involvement; stage 1 to 2 gut or liver involvement		
C – stage 3 skin, liver, or gut involvement		
D – stage 4 skin, liver, or gut involvement		

Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3402	Injection, remestemcel-L-rknd, per therapeutic dose (Ryoncil)	Initial: IV: 2 × 10^6 mesenchymal stromal cells (MSC)/kg/dose twice weekly for 4 consecutive weeks (total of 8 infusions). Doses should be separated by at least 3 days. Assess clinical response after 28 ± 2 days Retreatment: May consider retreatment after 28 days if: Partial or mixed response or GVHD recurs after complete response; • *Partial or mixed response:* IV: 2 × 10^6 mesenchymal stromal cells (MSC)/**kg**/dose once weekly for 4 additional weeks (total of 4 infusion). • *Recurrence of GVHD after complete remission*: IV: 2 × 10^6 mesenchymal stromal cells (MSC)/**kg**/dose twice weekly for 4 consecutive weeks (total of 8 infusions). Doses should be separated by at least 3 days. • *No response*: Consider alternative therapy.

Requirements for Spesolimab-sbzo IV injection (Spevigo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Generalized pustular psoriasis (GPP) flares *For the treatment of generalized pustular psoriasis NOT in a flare, please see Requirements for Spesolimab-sbzo SC injection (Spevigo)*
Exclusion Criteria	• Primary plaque psoriasis vulgaris without presence of pustules • Pustules that are restricted to psoriatic plaques • Diagnosis other than for the treatment of a GPP flare
Required Medical Information	1) Initial dose, *each distinct flare*: a. Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). b. Current weight ≥40kg c. Clinical notes confirming a diagnosis of moderate to severe GPP flare, including: i. Skin biopsy results and ii. Presence of fresh or worsening pustules with both a. The mean Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 (at least moderate severity) b. GPPGA pustulation sub score of at least 2, with pustules & erythema covering an involved body surface area of 5% or greater. 2) Second dose per flare: a. Clinical notes with evaluation having occurred between 7-14 days after the first dose, and which include all of the following to confirm need for second dose: i. GPPGA score ≥ 2 ii. GPPGA pustulation sub score of ≥1 b. The second dose must be administered no sooner than 7 days and no later than 14 days after first dose (ie, with first dose being day 1, 2nd dose should be day 8 to day 15).
Age Restriction	12 years and older
Prescriber Restriction	Prescribed or recommended by a dermatologist
Coverage Duration	One dose (900 mg) per TAR request, with maximum of 1 TAR renewal if needed per flare (a 2nd 900 mg dose per flare when requirements are met).
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Spesolimab-sbzo IV injection (Spevigo™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J1747	Injection, spesolimab-sbzo, 1 mg *Intravenous product only*	900 mg IV once; if flare persists, an additional 900 mg IV may be given one week later. Each dose is billed as 900 HCPCS units.

Requirements for Spesolimab-sbzo SC injection (Spevigo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Generalized pustular psoriasis maintenance therapy not in a flare *For Generalized pustular psoriasis flare treatment, please see Requirements for Spesolimab-sbzo IV injection (Spevigo IV)*
Exclusion Criteria	• Primary plaque psoriasis vulgaris without presence of pustules • Pustules that are restricted to psoriatic plaques
Required Medical Information	1. Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). 2. Current weight ≥40kg 3. Clinical notes confirming a diagnosis of moderate to severe GPP, NOT experiencing a flare, including all of the following: a. Skin biopsy results and b. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1 4. Documentation of at least two moderate to severe flares in the past 12 months with at least one associated with fever, elevated C-reactive protein level, elevated white blood cell count, asthenia or myalgia. a. If on concomitant GPP treatment with retinoids, methotrexate or cyclosporine, must have had at least one flare during treatment or following dose reduction/treatment discontinuation. 5. Medical reasons why the member or a caregiver cannot be trained to self-administer Spevigo in the home. Loading doses of 600mg may be self-administered using the 300mg/2ml syringe product.
Age Restriction	12 years and older
Prescriber Restriction	Prescribed or recommended by a dermatologist
Coverage Duration	Case-dependent (medical office single dose requested vs outpatient hospital with multiple doses requested). Limited to the number of doses needed until the member is able to resume self-administration at home.
Other Requirements & Information	This medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled *Standard Requirements for Self-Administered Drugs.* Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Spesolimab-sbzo SC injection (Spevigo™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J1747	Injection, spesolimab-sbzo, 1 mg *Subcutaneous products only*	Subcutaneous Dosage for Treatment of GPP When Not Experiencing a Flare: • Loading dose of 600mg, followed by 300mg every 4 weeks. Initiating or Reinitiating Subcutaneous Spevigo After Treatment of a GPP Flare with Intravenous Spevigo: • 300mg every 4 weeks, starting 4 weeks after treatment with IV Spevigo

Note: Spevigo SC is available in a 300mg/2 mL and 150mg/1 mL prefilled syringe:

- When using Spevigo 300 mg/2 mL prefilled syringe: If the healthcare professional determines that it is appropriate, a patient 12 years of age or older may self-inject or the caregiver may administer the loading dose and the subsequent doses of Spevigo after proper training in subcutaneous injection technique.
- When using Spevigo 150 mg/mL prefilled syringe: If required, the 600 mg subcutaneous loading dose of Spevigo is to be administered by a healthcare professional. For subsequent 300 mg doses a patient 12 years of age or older may self-inject or the caregiver may administer Spevigo.