PARTNERSHIP HEALTHPLAN of CALIFORNIA
A Public Agency

PHC Medi-Cal
Effective: January 1st, 2025

P & T: October 10th, 2024

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 PHC Policy #MPRP4033.

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15. Requirements for Elivaldogene Autotemcel (Skysona™)
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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.

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™) • 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. • Inability to remain in the vicinity of the REMS certified facility for a minimum of 4 weeks. • ECOG grade 4 or worse.
Required Medical Information	• Histologically confirmed diagnosis of one of the FDA approved indication for which therapy is being requested to treat. • 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 4 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 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

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

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. **Multiple myeloma, relapsed or refractory:** 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. **Large B-cell lymphoma, relapsed or refractory:** 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. 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™**.
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 members 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™:**

- 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).

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.*

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

Medical Billing:

Product	HCPCS	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	Recommended 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)
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	Recommended 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.	Recommended 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	Recommended 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 Leuprolide Acetate Injection (Lupron Depot™)

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	• Central precocious puberty • Endometriosis • Uterine leiomyomata (fibroids) • Breast cancer (off-label) (No TAR with diagnosis code for breast cancer) • Gender dysphoria in adolescents (off-label)
Exclusion Criteria	
Required Medical Information	**Documentation of the following is required per indication:** **Central precocious puberty (CPP):** 1) Specialist consult notes documenting diagnosis of CPP and treatment plan. 2) Baseline height and weight, growth velocity, bone age test results (within the past year. Note: leuprolide will not be approved for peripheral precocious puberty. **Endometriosis:** 1) Specialist consult notes documenting diagnosis of endometriosis, treatment history, and treatment plan. Diagnostic evaluation must include ONE of the following: a. Diagnosis confirmed by laparoscopy, OR b. Detailed evaluation which has ruled out other causes of pelvic pain including gastrointestinal, musculoskeletal, urinary, and neurologic conditions. 2) Member has had an adequate trial (at least 3 months of continuous use, verified through pharmacy claims if available), or contraindication to, an NSAID in combination with continuous hormonal contraceptive within the previous 12 months. 3) Member has had an adequate trial, or contraindication to, at least ONE of the following: a. PHC's preferred formulary GnRH agonist, goserelin (Zoladex™), OR b. GnRH antagonist therapy with elagolix (Orilissa™), which is covered as a pharmacy benefit through MediCal Rx for endometriosis, and 4) Dosing is 3.75 mg per month or 11.25 mg per 3 months for up to 6 months. **Uterine leiomyomata (fibroids):** 1) Diagnosis of uterine leiomyomas confirmed with pelvic imaging. 2) Documentation that member is experiencing symptoms such as heavy or prolonged menstrual bleeding, pelvic pressure or pain. 3) Documentation that therapy is being requested for ONE of the following: a. Request is for use 3-6 months prior to surgery for uterine leiomyomata OR b. Member has anemia due to uterine fibroids AND has failed a one-month trial of iron therapy alone AND request is for a short course of leuprolide to use along with iron preoperatively. 4) If requesting leuprolide to treat heavy menstrual bleed (HMB) due to uterine fibroids the following must be submitted: a. Member has tried and failed an adequate trial of first-line treatment options with one or more of the following:

Requirements for Leuprolide Acetate Injection (Lupron Depot™)

	i. Combined estrogen-progestin contraceptives ii. Levonorgestrel-releasing IUD iii. Tranexamic acid iv. Progestin only pills AND b. Member has tried and failed, or contraindication to, at least one of the following second-line preferred oral treatment options which are both a covered benefit with Medi-Cal Rx (Not required for treating primary bulk or pain symptoms with or without HMB): i. Elagolix-estradiol-norethindrone (Oriahnn™) OR ii. Relugolix-estradiol-norethindrone (Myfembree™) **Gender dysphoria (off-label):** 1) Evaluation by a mental health professional or other health care professional who has the appropriate experience and training treating gender dysphoria. 2) Confirmation of the following: a. Well-documented gender dysphoria/gender incongruence. b. Ability to make a well-informed decision. c. Stability of relevant medical and mental health. 3) Documentation that member has experienced puberty development to at least Tanner stage 2. 4) Documentation that pubertal changes have negatively affected member's psychological or social functioning due to increased gender dysphoria.
Age Restriction	-Central Precocious Puberty: ≥1 yr and ≤11 yrs for females; ≤12 yrs for males. -Endometriosis or uterine fibroids: females of reproductive age and beyond. -Gender dysphoria: adolescents who have experienced puberty development to at least Tanner stage 2.
Prescriber Restriction	-Central Precocious Puberty: Endocrinologist -Endometriosis/Uterine leiomyomata: Obstetrician gynecologist -Gender dysphoria: Pediatric Endocrinologist or other specialist with appropriate training and experience treating gender dysphoria in adolescents
Coverage Duration	-CPP: 12 months, until resumption of puberty is desired. Renewal requests require current bone age, growth velocity, height, weight and clinic notes with assessment of pubertal progression. -Endometriosis: Initial approval: 6 months. An additional 6 months of treatment may be considered when documentation of recurrence of symptoms and BMD results within normal limits. The total duration of therapy should not exceed 12 months due to concerns of adverse effects on BMD. -Uterine leiomyomata (fibroids): 3 months. An additional 3 months may be requested with documentation of medical necessity or reason for delay in surgical procedure. -Gender dysphoria: Initial approval: 6 months. For renewal, provider may request 12 months of therapy with documentation of improvement in gender dysphoria.
Other Requirements & Information	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

HCPCS	Description	Dosing, Units
J1950	Injection, leuprolide acetate (for depot suspension), 3.75 mg	Available formulations: Lupron Depot: 3.75 mg and 11.25 mg Lupron Depot-Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg, and 45 mg

Requirements for Fidanacogene Elaparvovec-dzkt) (Beqvez™)

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 adults with moderate to severe hemophilia B (congenital FIX deficiency)
Exclusion Criteria	1. Treatment or use for anything other than hemophilia B 2. Positive Factor IX inhibitor titer test 3. Positive neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test 4. Previous gene therapy treatment with etranacogene dezaparvovec-drlb (Hemgenix™) or fidanacogene elparvovec-dzkt (Beqvez™)
Required Medical Information	Documentation of all of the following (1-7): 1. Clinic notes to confirm moderately severe or severe congenital hemophilia B along with baseline Factor IX level of ≤ 2% of normal 2. Clinic notes to confirm one of the following a. Current use of routine Factor IX prophylaxis as defined as the intent of treating with an a priori defined frequency of infusions for at least the previous 6 months, OR b. Historical life-threatening hemorrhage with required need for Factor IX therapy, OR c. Have repeated, serious spontaneous bleeding 3. Factor IX inhibitor titer test to confirm a negative results in the past 30 days 4. Testing to confirm no neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test 5. Current (within the past 30 days) labs to confirm adequate hepatic function including, ALT/AST/ALP/Total bilirubin less than 2x the upper limit of normal, and INR 6. Current Hepatitis B and Hepatitis C status 7. If HIV positive, current (within the past 30 days) CD4 cell level ≥ 200 cell/microL and a viral load <20 copies/mL Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals.
Age Restriction	18 years and older
Prescriber Restriction	Hematologist
Coverage Duration	Once per lifetime
Other Requirements & Information	No renewal

Requirements for Fidanacogene Elaparvovec-dzkt) (Beqvez™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
C9172	Injection, fidanacogene elparvovec-dzkt , per therapeutic dose (Beqvez™)	5×10^{11} vector genomes per kg (vg/kg) IV as a single, one-time dose

Requirements for Etranacogene Dezaparvovec-drlb (Hemgenix™)

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 adults with hemophilia B (congenital FIX deficiency) who: • Currently use FIX prophylaxis therapy, or • Have current or historical life-threatening hemorrhage, or • Have repeated, serious spontaneous bleeding episodes
Exclusion Criteria	1) Treatment or use for anything other than hemophilia B 2) Positive Factor IX inhibitor titer test 3) Previous gene therapy treatment with etranacogene dezaparvovec-drlb (Hemgenix™), fidanacogene elaparvovec-dzkt (Beqvez™) or other gene therapy
Required Medical Information	Documentation of all of the following (1-6): 1) Clinic notes to confirm moderately severe or severe congenital hemophilia B along with baseline Factor IX level of ≤ 2% of normal: 2) One of the following: a. Current use of routine Factor IX prophylaxis as defined as the intent of treating with an a priori defined frequency of infusions for at least the previous 6 months, OR b. Historical life-threatening hemorrhage with required need for Factor IX therapy, OR c. Have repeated, serious spontaneous bleeding episodes with required need for Factor IX therapy 3) Factor IX inhibitor titer test to confirm a negative results in the past 30 days 4) Current (within the past 30 days) labs to confirm adequate hepatic function including, ALT/AST/ALP/Total bilirubin less than 2x the upper limit of normal, and INR 5) Current Hepatitis B AND Hepatitis C status 6) If HIV positive, current (within the past 30 days) CD4 cell level lab results (≥ 200cell/microL) with anti-viral therapy. Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals.
Age Restriction	18 years and older
Prescriber Restriction	Hematologist
Coverage Duration	Once per lifetime
Other Requirements & Information	Allowed for once in a lifetime treatment. There will be no renewals or retreatment requests approved. *Note: Awareness of potential for hepatotoxicity and hepatocellular carcinoma is important when considering this treatment. Screening for hepatic impairment prior to starting treatment and continued monitoring of liver function for a minimum of 3 months is recommended after administration of etranacogene dezaparvovec-drlb (Hemgenix™).*

Requirements for Etranacogene Dezaparvovec-drlb (Hemgenix™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	2×10^{13} genome copies per kg (equivalent to 2 ml/kg) IV as a single one-time dose.

Requirements for Betibeglogene Autotemcel (Zynteglo™)

PA Criteria	Criteria Details
Covered Uses	Treatment of beta thalassemia in adult and pediatric patients who require regular red blood cell transfusions and for whom hematopoietic stem cell transplantation (HSCT) is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available
Exclusion Criteria	• Requests for treatment of indications other than beta thalassemia • Prior therapy with betibeglogene autotemcel (Zynteglo™) or exagamglogene autotemcel (Casgevy) or other gene therapy • Prior receipt of HSCT • HIV positive
Required Medical Information	Documentation that all conditions have been meet: 1) Genetic testing to confirm beta thalassemia with: a. History of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) OR b. 8 or more transfusions of pRBCs per year in the past 2 years 2) Reasons why preferred gene therapy option for transfusion dependent beta-thalassemia, exagamglogene autotemcel (Casgevy), cannot be used 3) Confirmation that the member does not have an available 10/10 human leukocyte antigen (HLA) matched related HSCT donor. 4) Confirmation that hematopoietic stem cell (HSC) transplantation is appropriate for the patient and documentation of the following: a. Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥ 60 (<16 years of age) b. No advanced liver disease; severe hepatic fibrosis or cirrhosis c. eGFR ≥ 60 ml/min/1.73m^2 d. No cardiomyopathy or severe congestive heart failure (NYHA class III or IV) e. Lung diffusing capacity for carbon monoxide (DLCO) is ≥40%, and baseline O2 saturation ≥85% without supplemental oxygen (excluding periods of severe anemia or infection) f. No clinically significant pulmonary hypertension at baseline g. WBC count ≥3x10^9/L and platelet count ≥50x10^9/L (unless related to hypersplenism) h. No Hypersplenism 5) No severe iron overload in the heart or liver or endocrine systems, evaluated within the last 6 months i. Cardiac T2* value must not be less than 10 msec by magnetic resonance imaging [MRI] j. Liver iron concentration must not be ≥15mg/g 6) Human immunodeficiency virus (HIV-1 and HIV-2), Hepatitis B virus (HBV), and Hepatitis C virus (HCV), Human T lymphotrophic virus 1 & 2 (HTLV 1/HTLV 2) testing, as well as documentation that the member does not have a clinically significant and active other viral, bacterial, fungal or parasitic infection 7) Treatment and medications required for mobilization, and myeloablative conditioning have been approved: a. Granulocyte-colony stimulating factor (G-CSF, TAR required) b. Plerixafor (Mozobil™, TAR required), for mobilization c. Busulfan (TAR required), for myeloablative conditioning Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals.

Requirements for Betibeglogene Autotemcel (Zynteglo™)

Age Restriction	4 years and older
Prescriber Restriction	Hematologist or Transplant Specialist at a Qualified Treatment Center
Coverage Duration	Once per lifetime
Other Requirements & Information	Limited to once per lifetime treatment. There will be no renewals or retreatment requests approved.

Medical Billing:

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

HCPCS	Description	Dosing, Units
J3393 (although PHC inpatient hospital billing does not generally utilize HCPCS codes)	Intravenous injection, betibeglogene, per dose (Zynteglo™)	Minimum recommended dose: 5 × 106 CD34+ cells/kg

Requirements for Exagamglogene Autotemcel (Casgevy™)

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 sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs). • The treatment of transfusion-depended β-thalassemia (TDT) in patients 12 years and older
Exclusion Criteria	1) Off-label use 2) Prior use of lovotibeglogene autotemcel (Lyfgenia™), betibeglogene autotemcel (Zynteglo™) or exagamglogene autotemcel (Casgevy™) or other gene therapy 3) Prior receipt of HSCT 4) For Sickle Cell Disease only: Inability to receive RBC transfusions
Required Medical Information	<u>Requirements for all indications:</u> 1) Confirmation that hematopoietic stem cell transplantation is appropriate for the patient and documentation of the following: a. Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥60 (<16 years of age) b. No advanced liver disease; severe hepatic fibrosis or cirrhosis c. eGFR is ≥ 60 ml/min/1.73m^2 d. No cardiomyopathy or severe congestive heart failure (NYHA class III or IV) and baseline LVEF is ≥45% e. Lung diffusing capacity for carbon monoxide (DLCO) is ≥40%, and baseline O2 saturation ≥85% without supplemental oxygen (excluding periods of SCD crisis, severe anemia or infection) f. No clinically significant pulmonary hypertension at baseline g. WBC count ≥3x10^9/L and platelet count ≥50x10^9/L (unless related to hypersplenism) h. Documentation that the member does not have any history of severe cerebral vasculopathy: defined by overt or hemorrhagic stroke; abnormal transcranial Doppler [≥200 cm/sec] needing chronic transfusion; or occlusion or stenosis in the polygon of Willis; or presence of Moyamoya disease. i. No hypersplensim 2) Confirmation that the member does not have an available 10/10 HLA matched related HSCT donor 3) Human immunodeficiency virus (HIV-1 and HIV-2), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) testing, as well as documentation that the member does not have a clinically significant and active other viral, bacterial, fungal or parasitic infection 4) Treatment and medications required for mobilization, and myeloablative conditioning have been approved: a. Plerixafor (Mozobil™, TAR required), for mobilization b. Busulfan (TAR required), for myeloablative conditioning 5) Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals (ie denials for medical necessity)

Requirements for Exagamglogene Autotemcel (Casgevy™)

	Additional Requirements for Sickle Cell Disease 1) Genetic testing to confirm severe sickle cell disease genotype: β^s/β^s, β^s/β^0, or β^s/β^+ a. Note that other genotypes may be considered if a severe disease phenotype is demonstrated on a case by case basis 2) Documentation that the member has had at least 4 severe vaso-occlusive events (VOE) in the prior 24 months as defined below while receiving appropriate supportive care (e.g. pain management plan, hydroxyurea) a. No medically determined cause other than a vaso-occlusion b. Event that requires at least one of the following: i. A visit to a medical facility and administration of pain medications (opioids or intravenous non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions ii. OR a ≥ 24-hour hospital or Emergency Room (ER) observation unit visit iii. OR at least 2 visits to a day unit or ER over 72 hours with both visits requiring intravenous treatment. iv. OR acute chest syndrome v. OR splenic sequestration vi. OR Priapism lasting >2 hours OR 4 priapism episodes that require a visit to a medical facility (without inpatient admission) are sufficient to meet criterion 3) Documentation that the member has failed hydroxyurea (HU) at any point in the past or must have intolerance to HU. Failure is defined as >1 VOE or ≥1 Acute Chest Syndrome after HU has been prescribed for at least 6 months Additional Requirements for Transfusion Dependent Beta Thalassemia 1) Genetic testing to confirm beta thalassemia 2) Documentation of transfusion dependence as evidenced by one of the following a. A history of at least 100 mL/kg/year of packed RBC in the prior 2 years OR b. 10 units/year of packed RBC transfusions in the prior 2 years 3) No severe iron overload in heart or liver or endocrine systems, evaluated within the last 6 months a. Cardiac T2* value must not be less than 10 msec by magnetic resonance imaging [MRI] b. Liver iron concentration must not be ≥15mg/g
Age Restriction	FDA indication: 12 years and older
Prescriber Restriction	Hematologist or Transplant Specialist at an Authorized Treatment Center
Coverage Duration	FDA labeling: Once per lifetime, approval will allow a 12 month duration
Other Requirements & Information	Limited to once per lifetime treatment. There will be no renewals or retreatment requests approved.

Requirements for Exagamglogene Autotemcel (Casgevy™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3590	Unclassified biologicals; exagamglogene autotemcel (Casgevy™)	The minimum recommended dose is 3×10^6 CD34+ cells/kg

Requirements for Lovotibeglogene Autotemcel (Lyfgenia™)

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 patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events (VOEs).
Exclusion Criteria	1. Off-label use 2. Prior use exagamglogene autotemcel (Casgevy) or lovotibeglogene autotemcel (Lyfgenia) or other gene therapy 3. Prior receipt of an allogeneic transplant 4. Positive HIV test 5. Inability to receive RBC transfusions
Required Medical Information	1) Genetic testing to confirm severe sickle cell disease genotype: β^s/β^s, β^s/β^0, or β^s/β^+ a. Note that other genotypes may be considered if a severe disease phenotype is demonstrated on a case by case basis 2) Documentation that the member has had at least 4 severe vaso-occlusive events (VOE) in the prior 24 months as defined below, while receiving appropriate supportive care (e.g. pain management plan, hydroxyurea) a. No medically determined cause other than a vaso-occlusion b. Event that requires at least one of the following: i. A visit to a medical facility and administration of pain medications (opioids or intravenous non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions ii. OR a ≥ 24-hour hospital or Emergency Room (ER) observation unit visit iii. OR at least 2 visits to a day unit or ER over 72 hours with both visits requiring intravenous treatment. iv. OR acute chest syndrome v. OR splenic sequestration vi. OR Priapism lasting >2 hours OR 4 priapism episodes that require a visit to a medical facility (without inpatient admission) are sufficient to meet criterion 3) Documentation that the member has failed hydroxyurea (HU) at any point in the past or must have intolerance to HU. Failure is defined as >1 VOE or ≥1 Acute Chest Syndrome after HU has been prescribed for at least 6 months 4) Reasons why preferred gene therapy option for sickle cell disease, exagamglogene autotemcel (Casgevy), cannot be used 5) Human immunodeficiency virus (HIV-1 and HIV-2), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) testing, as well as documentation that the member does not have a clinically significant and active other viral, bacterial, fungal or parasitic infection 6) Confirmation that hematopoietic stem cell transplantation is appropriate for the patient and documentation of the following: a. Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥60 (<16 years of age) b. No advanced liver disease; severe hepatic fibrosis or cirrhosis c. eGFR is ≥ 60 ml/min/1.73m^2 d. No cardiomyopathy or severe congestive heart failure (NYHA class III or IV) and baseline LVEF is ≥45%

Requirements for Lovotibeglogene Autotemcel (Lyfgenia™)

	e. Lung diffusing capacity for carbon monoxide (DLCO) is ≥40%, and baseline O2 saturation ≥85% without supplemental oxygen (excluding periods of SCD crisis, severe anemia or infection) f. No clinically significant pulmonary hypertension at baseline g. WBC count ≥$3x10^9$/L and platelet count ≥$50x10^9$/L (unless related to hypersplenism) h. Documentation that the member does not have any history of severe cerebral vasculopathy: defined by overt or hemorrhagic stroke; abnormal transcranial Doppler [≥200 cm/sec] needing chronic transfusion; or occlusion or stenosis in the polygon of Willis; or presence of Moyamoya disease. i. No hypersplenism 7) Confirmation that the member does not have an available 10/10 HLA matched related HSCT donor 8) Treatment and medications required for mobilization, and myeloablative conditioning have been approved: a. Plerixafor (Mozobil™, TAR required), for mobilization b. Busulfan (TAR required), for myeloablative conditioning 9) Policy MCUP3138 External Independent Medical Review will 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	12 years and older
Prescriber Restriction	Hematologist or Transplant Specialist at a Qualified Treatment Center
Coverage Duration	FDA labeling: Once per lifetime, approval should be for a 12 month duration
Other Requirements & Information	Limited to once per lifetime treatment. There will be no renewals or retreatment requests approved.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3394	Injection, lovotibeglogene autotemcel, per treatment	The minimum recommended dose is 3×10^6 CD34+ cells/kg

Requirements for Crizanlizumab-tmca (Adakveo™)

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	Sickle Cell Disease
Exclusion Criteria	None
Required Medical Information	1) Current weight (kg) within the last 4 weeks, submitted with initial request and each renewal request. 2) Number of events in the past 365 days, prior to treatment with Adakveo. 3) Documentation of an inadequate response after at least a 3-month trial each of both hydroxyurea AND L-glutamine (Endari) despite compliant use. An inadequate response would be demonstrated when the member continues to have >2 events annually or no decrease in number of events prior to starting the medication.
Age Restriction	16 years and older
Prescriber Restriction	Must be prescribed or recommended by a hematologist
Coverage Duration	6 months
Other Requirements & Information	First renewal request: 1) Current weight (kg) within the last 4 weeks 2) Number of events in the past 180 days since starting Adakveo 3) Documentation that the member has continued adherence with their other current sickle cell disease modifying treatments if applicable 4) For members who do not demonstrate a reduction in vasoocclusive events, additional documentation supporting clinically meaningful benefit must be submitted Subsequent renewal requests: current weight (kg) within the last 4 weeks 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:

HCPCS	Description	Dosing, Units
J0791	Injection, crizanlizumab-tmca, 5 mg (Adakveo™)	Initial dosing limited to 5 mg/kg on week 0 and week 2. Maintenance dosing limited to 5 mg/kg once every 4 weeks. For missed doses – if administered within 2 weeks after missed dose, continued dosing according to original schedule, however if missed dose is administered greater than 2 weeks then then continue dosing every 4 weeks using last date of dosing

Requirements for Eculizumab (Soliris™)

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 (gMS) in adults 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 • Use along with ravulizumab (Ultomiris™) or efgartigimodum alfa-fcab (Vyvgart™) • NMOSD negative 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

Requirements for Eculizumab (Soliris™)

	f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following (i-vi): 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. 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 gMS, NMOSD, PNH: 18 years and older
Prescriber Restriction	• PNH: Hematologist • aHUS: Nephrologist, Hematologist • gMS: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial TAR for loading dose: Approved for 1 to 4 loading doses, depending on indication and weight of the patient (if relevant) Initial TAR for maintenance dose: 6 months Renewal TAR: Approved for 1 dose per fill for up to 6 months.
Other Requirements & Renewal Information	Renewal Requests: • Clinical notes with current: 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™)

Medical Billing:

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

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J1300	Injection, Eculizumab, 10 mg	aHUS, gMS, 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. aHUS (≥ 2 months): Weight / Induction dose (qwk) / Maintenance dose ≥ 40 kg / 900 mg x 4 / 1,200 mg at week 5, then q2wks 30 -39 kg / 600 mg x 2 / 30 -39 kg 600 mg x2 900 mg at week 3, then q2wks 0 – 29 kg / 600 mg x 2 / 600 mg at week 3, then q2wks 10 – 19 kg / 600 mg x 1 / 300 mg at week 2, then q2wks 5 - 9 kg / 300 mg x 1 / 300 mg at week 2 then q3wks PNH: • 600 mg IV qwk x 4 doses, then 900 mg for the 5th dose on week 5, then 900 mg q2wks thereafter.

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.

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 • Use along with Eculizumab (Soliris™) or efgartigimod alfa-fcab (Vyvgart™) • NMOSD negative 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 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

Requirements for Ravulizumab (Ultomiris™)

	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. 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: • Optic neuritis Acute myelitis • Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting • Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • 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 current: ○ MG-ADL ○ MGFA classification Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations*

Requirements for Ravulizumab (Ultomiris™)

Medical Billing:

Use is available only through the restricted Ultomiris™ REMS program.
Dose limits & billing requirements, with an approved TAR:

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td rowspan="2">J1303</td><td rowspan="2">Injection, Ravulizumab, 10mg</td><td>aHUS and PNH ≥ 1 month:
<table>
<tr><th>Weight</th><th>Loading Dose</th><th>Maintenance dose IV (start 14 days after loading dose)</th><th>Maintenance Interval</th></tr>
<tr><td>5 kg – 9 kg</td><td>600 mg</td><td>300 mg</td><td rowspan="2">4 weeks</td></tr>
<tr><td>10 kg – 19 kg</td><td>600 mg</td><td>600 mg</td></tr>
<tr><td>20 kg – 29 kg</td><td>900 mg</td><td>2,100 mg</td><td rowspan="5">8 weeks</td></tr>
<tr><td>30 kg – 39 kg</td><td>1,200 mg</td><td>2,700 mg</td></tr>
<tr><td>40 kg – 59 kg</td><td>2,400 mg</td><td>3,000 mg</td></tr>
<tr><td>60 kg – 99 kg</td><td>2,700 mg</td><td>3,300 mg</td></tr>
<tr><td>≥ 100 kg</td><td>3,000 mg</td><td>3,600 mg</td></tr>
</table></td></tr>
<tr><td>gMG and NSMOD ≥18 years:
<table>
<tr><th>Weight</th><th>Loading Dose</th><th>Maintenance dose IV (start 14 days after loading dose)</th><th>Maintenance Interval</th></tr>
<tr><td>40 kg – 59 kg</td><td>2,400 mg</td><td>3,000 mg</td><td rowspan="3">8 weeks</td></tr>
<tr><td>60 kg – 99 kg</td><td>2,700 mg</td><td>3,300 mg</td></tr>
<tr><td>≥ 100 kg</td><td>3,000 mg</td><td>3,600 mg</td></tr>
</table></td></tr>
</table>

Requirements for Crovalimab-akkz (PiaSky™)

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 adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg
Exclusion Criteria	• Unresolved serious *Neisseria meningitidis* infection • Use along with Eculizumab (Soliris), ravulizumab (Ultomiris™), pegcetacoplan (Empaveli™) or (Fabhalta™)
Required Medical Information	Documentation of all of the following: 1) Flow cytometry analysis confirming presence of PNH clones 2) Presence of laboratory results, signs and/or symptoms attributed to PNH (Lactate dehydrogenase >1.5x upper limit of normal, hemoglobin <10g/dL, abdominal pain, anemia, dyspnea, extreme fatigue, unexplained/unusual thrombosis) 3) Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. 4) Weight (kg, lb) 5) Trial and failure or reasons why iptacopan (Fabhalta™) OR pegcetacoplan (Empaveli™) cannot be used 6) Trial and failure or contraindication to ravulizumab (Ultomiris™)
Age Restriction	13 years and older
Prescriber Restriction	Hematologist
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Information	Renewal Requirements: updated clinic notes documenting benefit from treatment and current weight. 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:

HCPCS	Description	Dosing, Units
J3590	Unclassified biologics; crovalimab-akkz (PiaSky™)	Weight ≥40 to <100kg: • 1000mg IV on day 1 • 340mg SC on day 2, 8, 15, 22 • maintenance 680mg SC every 4 weeks starting on day 29 Weight ≥100kg • 1500mg IV on day 1 • 340mg SC on day 2, 8, 15, 22 • Maintenance 1020mg SC every 4 weeks starting on day 29

Note: For patients switching from another complement inhibitor, the first loading dose of PiaSky should be administered no sooner than the time of the next scheduled complement inhibitor administration.

Requirements for Lucpatercept-aamt (Reblozyl™)

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 in adults with beta (β) thalassemia who require regular RBC transfusions. • Anemia in adults with myelodysplastic syndromes (MDS). • Anemia in adults with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).
Exclusion Criteria	• Non-transfusion dependent β-thalassemia • Treatment of other causes of anemia • Deep vein thrombosis or stroke within the past 24 weeks prior to start of treatment • Pregnant or breastfeeding
Required Medical Information	For initial requests: 1) Clinic notes to confirm the diagnosis with one of the following: • β–thalassemia • Myelodysplastic Syndrome (MDS) • Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) 2) Other causes of anemia (e.g. bleeding, vitamin deficiency, iron deficiency, acute leukemia) have been ruled out. 3) Weight (kg, lb) 4) Requirement for those with a confirmed diagnosis of β–thalassemia: • Transfusion records to showing member is transfusion dependent, as evidenced by both of the following within the past 24 weeks: ○ Requires regular RBC transfusions with ≥ 6 units of packed red blood cells (PRBC) AND ○ No transfusion free period ≥ 35 days ○ Serum ferritin levels >1,000 ng/ml 5) Requirements for those with a confirmed diagnosis of MDS • Documented lower risk disease as defined by one of the following: ○ Revised International Prognostic Scoring System (IPSS-R) - Very Low, Low, Intermediate (Score 0 to ≤ 4.5) ○ IPSS - Low/Intermediate-1 (Score 0 to 1) ○ WHO-Based Prognostic Scoring System (WPSS) - Very Low, Low, Intermediate (Score 0 to 2) • Member requires at least 2 units of packed red blood cells (pRBCs) in the prior 8 weeks 6) Requirements for those with a confirmed diagnosis of MDS/MPN-RS-T: • Documented lower risk disease as defined by one of the following: ○ Revised International Prognostic Scoring System (IPSS-R) - Very Low, Low, Intermediate (Score 0 to ≤ 4.5) ○ IPSS - Low/Intermediate-1 (Score 0 to 1) ○ WHO-Based Prognostic Scoring System (WPSS) - Very Low, Low, Intermediate (Score 0 to 2) • Documentation of either: ○ Ring sideroblasts ≥ 15% OR ○ Ring sideroblasts ≥ 5% with an SF3B1 mutation

Requirements for Lucpatercept-aamt (Reblozyl™)

	• Non-responsive to or intolerant to erythropoiesis stimulating agents (ESA) or ESA is not indicated due to serum erythropoietin > 200 mU/mL • Member requires at least 2 units of packed red blood cells (pRBCs) in the prior 8 weeks
Age Restriction	18 years and older
Prescriber Restriction	Must be prescribed or recommended by a Hematologist or Hematologist–Oncologist
Coverage Duration	Initial approval: 6 months Renewal: up to 12 months
Other Requirements & Information	Documentation requirement for renewal: • Decrease in transfusion burden after 3 maximally tolerated doses (9 weeks of treatment). *Note: Treatment should be discontinued if there has not been a reduction in transfusion requirements per manufacturer's recommendation.* 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:

HCPCS	Description	Dosing, Units
J0896	Injection, luspatercept-aamt, 0.25 mg	β-thalassemia: 1 mg/kg SC q3weeks Max dose: 1.25 mg/kg q3weeks MDS or MDS/MPN-RS-T: 1 mg/kg SC q3weeks Max dose: 1.75 mg/kg q3weeks

Recommended dosing adjustment based on hemoglobin (Hgb) level (per manufacturer package insert:

1) Pre-dose hemoglobin ≥11.5 g/dL (in the absence of transfusions):
Interrupt luspatercept; resume when hemoglobin is ≤11 g/dL.

2) Increase Hgb > 2 g/dl within 3 weeks (in absence of transfusions):

β – Thalassemia	
Current Dose	Reduce to x mg/kg once every 3 weeks
1.25 mg/kg	1 mg/kg
1 mg/kg	0.8 mg/kg
0.8 mg/kg	0.6 mg/kg
0.6 mg/kg	*Discontinue*
MDS or MDS/MPN-RS-T	
Current Dose	Reduce to x mg/kg once every 3 weeks
1.75 mg/kg	1.33 mg/kg
1.33 mg/kg	1 mg/kg
1 mg/kg	0.8 mg/kg
0.8 mg/kg	0.6 mg/kg
0.6 mg/kg	*Discontinue*

Requirements for ADAMTS13, Recombinant-krhn IV Injection (Adzynma™)

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	Prophylactic or on demand enzyme replacement therapy (ERT) for congenital thrombotic thrombocytopenic purpura (cTTP).
Exclusion Criteria	Other causes of thrombotic thrombocytopenic purpura (TTP)
Required Medical Information	1) Documented diagnosis of cTTP with both of the following: a. Confirmed molecular genetic testing b. ADAMTS13 activity <10% as measured by the fluorescent resonance energy transfer-von Willebrand factor 73 (FETS-VWF73) assay 2) Requests for prophylactic therapy must have a history of at least one documented TTP event or currently be receiving prophylactic therapy
Age Restriction	None
Prescriber Restriction	Hematologist
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Information	Renewal requests: current weight 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:

HCPCS	Description	Dosing, Units
J7171	Injection, adamts13, recombinant-krhn, 10 iu	Prophylactic therapy: • 40 IU/kg every other week, may adjust to 40 IU/kg weekly based on clinical response On-demand therapy: • Day 1: 40 IU/kg • Day 2: 20 IU/kg • Day 3 until 2 days after event resolves: 15 IU/kg once daily

Requirements for Pegfilgrastim (Neulasta/Neulasta Onpro™), Pegfiltrastim-fpgk (Stimufend™) & Pegfilgrastim-bmez (Ziextenzo™

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 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	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response to a preferred biosimilar product (Fulphila, Fylnetra, Nyvepria, or Udenyca) 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. OR (2) 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. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Pegfilgrastim (Neulasta/Neulasta Onpro™), Pegfiltrastim-fpgk (Stimufend™) & Pegfilgrastim-bmez (Ziextenzo™

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Neulasta, Neulasta Onpro	J2506	Injection, pegfilgrastim, excludes 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	
Ziextenzo	Q5120	Injection, pegfilgrastim-bmez (ziextenzo), biosimilar, 0.5 mg	

Requirements for Elivaldogene Autotemcel (Skysona™)

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 early, active Cerebral Adrenoleukodystrophy (CALD) in boys 4-17 years old.
Exclusion Criteria	• Prior receipt of allogeneic stem cell transplant (allo-HSCT) or gene therapy • Patients with full deletion of the human adenosine triphosphate binding cassette, subfamily D, member 1 (ABCD1) gene • CALD secondary to head trauma
Required Medical Information	1. Diagnosis of early, active CALD as confirmed by ALL of the following criteria: a. Elevated very long chain fatty acid (VLCFA) values per standard reference values of the performing laboratory. b. Genetic testing confirming ABCD1 mutation. c. Active CNS disease established by central radiographic review of brain MRI demonstrating both of the following: i. Loes score between 0.5 and 9 on the 34-point scale. ii. Gadolinium enhancement on MRI of demyelinating lesions. d. Neurologic function score (NFS) ≤1. 2. Member is eligible for a hematopoietic stem cell transplant (HSCT) but does not have a matched sibling donor. 3. Documentation of screening for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus 1 & 2 (HIV-1/HIV-2), and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) prior to collection of cells for manufacturing. Please confirm the following if applicable: a. The patient must discontinue anti-retroviral medications for at least one month before mobilization, and until all apheresis cycles have been completed. b. For patients who require anti-retrovirals for HIV prophylaxis, mobilization and apheresis should be delayed until HIV infection is ruled out. 4. Provider has consulted with a hematology expert prior to requesting treatment with Skysona to ensure adequate monitoring for hematologic malignancy. Consider performing baseline complete blood count with differential, hematopathology review of peripheral blood smear, and bone marrow biopsy (core and aspirate) with flow cytometry, conventional karyotyping, and next generation sequencing (NGS). 5. Policy MCUP3138 External Independent Medical Review may apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both approvals and denials not meeting medical necessity.
Age Restriction	Males 4 to 17 years old
Prescriber Restriction	Neurologist, Endocrinologist, Hematologist/Oncologist
Coverage Duration	Once per lifetime
Other Requirements & Information	Allowed for once per lifetime treatment. There will be no renewals or retreatment requests approved *Note: Hematologic malignancies have occurred in patients after administration of*

Requirements for Elivaldogene Autotemcel (Skysona™)

	Skysona; the cancers appear to be caused by the lentiviral vector (Lenti-D). Patients should be monitored for evidence of hematologic malignancy by way of complete blood counts at least every three months. Patients should be assessed for evidence of clonal expansion or predominance at least twice in the first year, and then continue assessments annually. 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:

HCPCS	Description	Dosing, Units
J3590	Unclassified drugs or biologicals, unclassified biologics (Skysona™)	Minimum Dose: 5.0 x 10^6 CD34+ cells/kg Supplied as one to two infusion bags containing 20mL of a frozen suspension of genetically modified autologous cells enriched for CD34+ cells.

Requirements for Lecanemab-irmb (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 <50,000 or INR>1.5)
	  ○ Member must NOT have contraindications to MRI or PET scans

Requirements for Lecanemab-irmb (Leqembi™)

	○ 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
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 and later: 6 months' duration (up to 2 doses/month). Treatment duration beyond 18 months 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 5th and 7th 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: ○ 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),

Requirements for Lecanemab-irmb (Leqembi™)

	antiplatelets, or anticoagulants). • Member must continue maintenance therapy at the recommended dosage per product labeling 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:

HCPCS	Description	Dosing, Units
J0174	Injection, lecanemab-irmb	Injection: NDC 62856-0215-01: 500 mg/5 mL (100 mg/mL) in a single-dose vial NDC 62856-0212-01: 200 mg/2 mL (100 mg/mL) in a single-dose vial

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 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 2nd, 3rd, and 4th 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 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 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 PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Kisunla™ (Donanemab-azbt)	J0175	Injection, donanemab-azbt	NDC: 00002-9401-01 350mg/20mL (17.5mg/mL)
First 3 infusions: 700mg IV every 4 weeks Maintenance dosing: 1400mg IV every 4 weeks			

Requirements for Atidarsagene Autotemcel (Lenmeldy™)

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 presymptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ), or early symptomatic early juvenile (PSEJ) metachromatic leukodystrophy (MLD) in pediatric patients.
Exclusion Criteria	• Prior use of gene therapy with atidarsagene autotemcel • Treatment of adult onset MLD
Required Medical Information	**For all requests, documentation of the following must be submitted**: Testing results to confirm diagnosis of MLD to include ALL the following: 1) Lysosomal enzyme arylsulfatase A (*ARSA*) activity below the normal range in leukocytes or cultured fibroblasts 2) Presence of 2 disease-causing mutations of either known or novel alleles (biallelic pathogenic variants in *ARSA*) 3) Urine sulfatide analysis confirming presence of sulfatides **In addition, documentation of the following must be submitted per subtype**: For presymptomatic late-infantile subtype (PSLI) MLD: 1) Disease onset ≤ 30 months of age (expectant disease onset may be determined by data from older siblings) 2) *ARSA* genotype consistent with PSLI MLD (biallelic null [0] variants) 3) Provider attestation that patient is presymptomatic (negative for neurological signs or symptoms of MLD) For presymptomatic early-juvenile subtype (PSEJ) MLD: 1) Disease onset between 30 months and < 7 years of age (expectant disease onset may be determined by data from older siblings) 2) *ARSA* genotype consistent with PSEJ MLD (one null [0] and one hypomorphic [R-residual] variant) 3) Provider attestation that patient is presymptomatic (negative for neurological signs and symptoms of MLD or physical examination limited to abnormal reflexes or clonus) For early symptomatic early-juvenile (ESEJ) MLD: 1) Disease onset between 30 months and < 7 years of age (expectant disease onset may be determined by data from older siblings) 2) *ARSA* genotype consistent with ESEJ MLD (one null [0] and one hypomorphic [R-residual] variant) 3) Patient is early symptomatic as exemplified by both of the following: a) Gross Motor Function Classification (GMFC)-MLD score of 0 with ataxia or 1 with or without ataxia b) Intelligence quotient (IQ) ≥ 85 on age appropriate neurodevelopment testing For all requests: Policy MCUP3138 External Independent Medical Review may apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both approvals and denials not meeting medical necessity.

Requirements for Atidarsagene Autotemcel (Lenmeldy™)

Age Restriction	Pediatric patients age 6 and under (prior to 7th birthday)
Prescriber Restriction	Neurologist, Oncologist/Hematologist
Coverage Duration	1 treatment per lifetime
Other Requirements & Information	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:

HCPCS	Description	Dosing, Units
J3590	Unclassified drug or biologicals, Unclassified biologics (Lenmeldy™)	Recommended dosing varies by disease subtype and the number of CD34+ cells in the infusion bag per kg body weight: Subtype / Min. dose (CD34+ cells/kg) / Max dose (CD34+ cells/kg) PSLI / 4.02×10^6 / 30×10^6 PSEJ / 9×10^6 / 30×10^6 ESEJ / 6.6×10^6 / 30×10^6 Lenmeldy is supplied as one to eight infusion bags of 10-20mL, containing 2 to 11.8x106 cells/mL

Requirements for Patisiran (Onpattro™)

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	Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR).
Exclusion Criteria	1) Concurrent use with any of the following: • Inotersen (Tegsedi™) • Diflunisal, tafamidis meglumine (Vyndaqel™) • Tafamidis (Vyndamax™) • Vutrisiran (Amvuttra™) 2) Cause of polyneuropathy other than hATTR
Required Medical Information	Submit medical records with TAR. Must have all of the following documented in the medical record: 1) Biopsy verification of amyloidosis 2) Genetic testing results confirming a TTR gene mutation 3) Patient is experiencing clinical signs and symptoms of the disease such as but not limited to: • Peripheral sensorimotor polyneuropathy • Autonomic neuropathy • Motor disability 4) Baseline assessment of disease with at least one of the following: • Baseline Polyneuropathy Disability (PND) score • Familial Amyloidotic Polyneuropathy (FAP) stage • Modified Neuropathy Impairment Score + 7 (mNIS + 7) Note: Onpattro™ treatment leads to a decrease in serum vitamin A levels and supplementation with recommended daily allowance (RDA) of vitamin A is recommended for patients taking Onpattro™.
Age Restriction	18 years and older
Prescriber Restriction	Neurologist, Cardiologist, Hematologist
Coverage Duration	Initial: 6 months. Renewal: 12 months with documentation of response to treatment (see Other Requirements & Information)
Other Requirements & Information	Renewal requests: • Documentation to indicate benefit with treatment with current PND score, FAP stage, or mNIS + 7 used to compare benefit from baseline. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J0222	Injection, patisiran, 0.1 mg	Dose based on weight: • ≥100 kg 30 mg IV once every 3 weeks • <100 kg 0.3 mg/kg IV once every 3 weeks *Maximum dose: 30 mg (300 billing units) per treatment

Requirements for Romosozumab-aqqg SC injection (Evenity™)

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 severe osteoporosis in members who are at high risk for osteoporotic fracture, defined as a history of osteoporotic fracture, or who have multiple risk factors for fracture.
Exclusion Criteria	• Risk for osteosarcoma (Paget's disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). • Primary or secondary hyperparathyroidism. • Other hypercalcemic disorders. • Members who have significant cardiovascular risk such as myocardial infarction or stroke in the preceding 12 months.
Required Medical Information	**All Requests**: 1. Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2. BMD T-Score. **For High Fracture Risk**: 1. Trial and failure (or contraindication) to **both** preferred treatments (bisphosphonate AND denosumab). a. Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with a bisphosphonate and/or denosumab (Prolia™) therapy (both if failure to one; just one if there's a contraindication to the other). 2. Trial and failure or reasons why teriparatide (Forteo™) and abaloparatide (Tymlos™) cannot be used. 3. Documentation of high fracture risk with one of the following: a. History of a prior spine fracture, hip fracture, or fragility fracture; OR b. Femoral neck, total hip, or lumbar spine T-Score < - 2.5; OR c. Femoral neck, total hip, or lumbar spine T-Score between -1 and -2.4, together with a FRAX score ≥ 3% for hip fracture risk or ≥ 20% for major osteoporotic fracture risk. **For Very High Fracture Risk:** 1. Trial and failure or reasons why teriparatide (Forteo™) and abaloparatide (Tymlos™) cannot be used. 2. Documentation of high fracture risk with one of the following: a. Femoral neck, total hip, or lumbar spine T-Score < -2.5, with spine, hip, or fragility fracture, OR b. Femoral neck, total hip, or lumbar spine T-Score < -3.5, regardless of fracture history or status.
Age Restriction	18 years and older.
Prescriber Restriction	Prescribed by or recommended by an Endocrinologist or Orthopedist.
Coverage Duration	12 months maximum treatment duration per lifetime.

Requirements for Romosozumab-aqqg SC injection (Evenity™)

Other Requirements & Information	Renewal requests beyond the 12 month lifetime maximum will not be approved. 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:

HCPCS	Description	Dosing, Units
J3111	Injection, romosozumab-aqqg, 1 mg	210mg injected subcutaneously once monthly for a maximum duration of 12 doses.

Requirements for Denosumab (Prolia™) and Denosumab-bbdz (Jubbonti™)

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) Treatment of osteoporosis in men and postmenopausal women at high risk for fracture 2) Prevention of bone loss in members at high risk for fracture receiving aromatase inhibitor therapy in women with breast cancer or androgen deprivation therapy in men with non-metastatic prostate cancer
Exclusion Criteria	None
Required Medical Information	All Indications: 1) Documentation of treatment failure with oral bisphosphonates and zoledronic acid OR clinical reason to avoid treatment with bisphosphonates. a. Treatment failure is defined as a decline in T-score of greater than/equal to 5% after 2 years of compliant use with bisphosphonate therapy. Additional requirements for the treatment of osteoporosis in men and postmenopausal women at high risk for fracture: 1) Documentation that the member is at high risk for fracture with ONE of the following: a. Osteoporotic vertebral or hip fracture, history of fragility fracture, OR b. Hip or lumbar spine T-Score of -2.5 or less, OR c. If T-score is between -1 and -2.5 must have FRAX score of greater than/equal to 3% for hip fracture or greater than/equal to 20% for combined major osteoporotic fracture. Additional requirements for bone loss prevention in breast or prostate cancer: 1) Currently on aromatase inhibitor therapy for breast cancer, or androgen deprivation therapy for non-metastatic prostate cancer unless the member has undergone an orchiectomy.
Age Restriction	18 years or older.
Prescriber Restriction	None
Coverage Duration	12 months
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Denosumab (Prolia™) and Denosumab-bbdz (Jubbonti™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Prolia	J0897	Injection, denosumab, 1 mg	60mg subcutaneously every 6 months
Jubbonti	Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg	

Requirements for Denosumab (Xgeva™) and Denosumab-bbdz (Wyost™)

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) Prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors. 2) Giant cell tumor of bone. 3) Hypercalcemia of malignancy refractory to bisphosphonate therapy.
Exclusion Criteria	None
Required Medical Information	1) Prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors: a. Treatment failure or intolerance/contraindication to zoledronic acid. b. For consideration outside of PHC criteria, submit additional patient factors that need to be considered along with the reason why zoledronic acid (Zometa) cannot be used in place of Xgeva. 2) Giant cell tumor of bone: a. Documentation that the tumor is unresectable or surgical resection is likely to result in severe morbidity. 3) Hypercalcemia of malignancy: a. Documentation that hypercalcemia is refractory to zoledronic acid (or member has a contraindication to zoledronic acid) b. Albumin-corrected serum calcium which is reported as greater than 12 mg/dL while member was on prior zoledronic acid therapy
Age Restriction	13 and older when DX is Giant Cell tumor of the bone. 18 and older for other indications. CCS screening and referral occurs as part of TAR review for ages 0 through 20.
Prescriber Restriction	None
Coverage Duration	TBD
Other Requirements & Information	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, Units
Xgeva	J0897	Injection, denosumab, 1 mg	Multiple myeloma and bone metastasis from solid tumor: • 120mg subcutaneously weekly Giant cell tumor of bone and Hypercalcemia of malignancy: 120mg subcutaneously weekly for 4 doses, then every 4 weeks
Wyost	Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg	