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

Tocilizumab (Actemra™)	Tocilizumab-anoh (Avtozma™)	Tocilizumab-bavi (Tofidence™)	Tocilizumab-aazg (Tyenne™)
Evinacumab-dgnb (Evkeeza™)	Inclisiran (Leqvio™)	Delandistrogene moxeparvovec-rokl (Elevidys™)	Onasemnogene Abeparvovec-brve (Itvisma™)
Prademagene zamikeracel (Zevaskyn™)	Idecabtagene vicleucel (Abecma™)	Obecabtagene autoleucel (Aucatzyl™)	Lisocabtagene maraleucel (Breyanzi™)
Ciltacabtagene autoleucel (Carvykti™)	Tisagenlecleucel (Kymriah™)	Brexucabtagene autoleucel (Tecartus™)	Axicabtagene ciloleucel (Yescarta™)

Requirements for IV Tocilizumab (Actemra and biosimilars)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. 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) Cytokine Release Syndrome (CRS) 2) Polyarticular Juvenile Idiopathic Arthritis (PJIA) 3) Systemic Juvenile Idiopathic Arthritis (SJIA) 4) Moderate to severely active Rheumatoid Arthritis (RA) 5) Giant Cell Arteritis (GCA)
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy.
Required Medical Information	<u>For all indications:</u> • Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated). • Treatment plan. • Disease Activity Score. • Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). • General dosing considerations for all indications, should include evaluation of baseline labs for ANC >2,000/mm3, Platelets >100,000/mm3) and ALT or AST <1.5 times ULN and throughout treatment of ensure safety. • General dosing consideration in addition (to ANC, platelets, LFTs) specifically for Giant Cell Arthritis & Rheumatoid Arthritis, should also include evaluation of baseline labs for alkaline phosphate and total bilirubin and throughout treatment to ensure safety. <u>Cytokine Release Syndrome (CRS):</u> • Documentation that the request is for treatment for chimeric antigen receptor (CAR) T-cell induced cytokine release syndrome. • Notes: (1) Studies have shown that the combination of tocilizumab and corticosteroids may be more effective than either agent is alone, depending on the affected organs/systems. (2) Although tocilizumab is FDA approved only for severe or life-threatening CRS, there are treatment guidelines that include tocilizumab in less-severely rated CRS, especially when a member is at risk for progression to severe CRS or is not responding to the usual treatments for mild to moderate CRS. Requests for use in scenarios other than severe CRS should include the clinical information necessary to document medical necessity for an off-label case-by-case review. <u>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</u>: • Documented therapeutic failure to induce remission with a TNF inhibitor (TNFi): Adalimumab (Humira), etanercept (Enbrel), or intravenous golimumab (Simponi Aria). • IL6i: Subcutaneous Tocilizumab (Actemra) or reason(s) why intravenous infusion is required. <u>Systemic Juvenile Idiopathic Arthritis (SJIA):</u> • Documentation of confirmed diagnosis of SJIA. • IL6i: subcutaneous tocilizumab (Actemra) or reason(s) why intravenous

Requirements for IV Tocilizumab (Actemra and biosimilars)

	infusion is required.
	
	Rheumatoid Arthritis (RA):
	• Documentation of trial and failure of, or contraindication to, a minimum 3-month trial each of:
	  ○ Methotrexate, or other oral DMARD if member is unable to take methotrexate AND
	  ○ TNFi: Adalimumab (Humira), etanercept (Enbrel), subcutaneous golimumab (Simponi), or certolizumab (Cimzia) AND
	  ○ IL6i: subcutaneous tocilizumab (Actemra) or reason(s) why intravenous infusion is required.
	
	Giant Cell Arteritis (GCA):
	• Documentation regarding need for adjunctive therapy for glucocorticoid-sparing agent due to:
	  ○ Preexisting conditions where long-term treatment with glucocorticoids cannot be used, such as diabetes or osteoporosis,
	  ○ Significant glucocorticoid related side effects during treatment OR
	  ○ Relapsing disease activity requiring long-term glucocorticoid use.
	• Documentation of trial and failure of, or contraindication to:
	  ○ IL6i: subcutaneous tocilizumab (Actemra) or reason(s) why intravenous infusion is required.
	
	Clinician notes or TAR must clearly indicate why member requires vials with IV administration rather than the less invasive subcutaneous route using prefilled syringes or pens when both subcutaneous and IV administration have the same indications.

Age Restriction	CRS, PJIA, SJIA: 2 years and older RA: 18 years and older
Prescriber Restriction	PJIA, SJIA, RA: Rheumatologist CRS: Oncologist
Coverage Duration	Initial: 6 months. Renewal: 12 months thereafter, with documentation of efficacy to support positive benefit when compared to baseline.
Other Requirements & Information	Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Actemra IV	J3262	Injection, Tocilizumab, 1 mg, for intravenous use	CRS: ≥30 kg, 8 mg/kg, <30 kg, 12 mg/kg for up to 4 doses total at least 8 hrs apart. PJIA: ≥30 kg, 8 mg/kg every 4 weeks, <30 kg, 10 mg/kg every 4 weeks. RA: 4 mg/kg - 8 mg/kg every 4 weeks.
Avtozma IV	Q5156	Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg	

Requirements for IV Tocilizumab (Actemra and biosimilars)

Tofidence IV	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg	SJIA: ≥30 kg, 8 mg/kg every 2 weeks, <30 kg, 12 mg/kg every 2 weeks. GCA: 6 – 8 mg/kg once every 4 weeks Max dose up to 800 mg per dose or 2,400 mg per day
Tyenne IV	Q5135 *(JA modifier for IV)*	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	

Requirements for Evinacumab-dgnb (Evkeeza™)

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	Homozygous familial hypercholesterolemia (HoFH)
Exclusion Criteria	• Pregnancy • Diagnosis other than HoFH
Required Medical Information	Clinical note documenting: 1) Diagnosis of homozygous familial hypercholesterolemia (HoFH) by genetic test to confirm mutation(s) in the LDLR, PCSK9, or APOB gene. 2) Treatment history confirming compliant trial and treatment failure, intolerance, or contraindication to maximally tolerated high dose statin therapy (atorvastatin ≥ 40mg or rosuvastatin ≥ 20mg), ezetimibe, and PCSK9 inhibitor. 3) Cholesterol lab confirming LDL-C level drawn within the past 90 days. 4) Confirmation of treatment plan to include continued use of current LDL-C lower therapies along with evinacumab. 5) Current weight.
Age Restriction	1 year of age and older
Prescriber Restriction	Cardiologist, diabetologist or endocrinologist
Coverage Duration	Initial: 6 months. Renewal: 12 months with documentation of positive treatment response as evidenced by reduction of LDL-C from baseline with cholesterol lab drawn within 90 days of request.
Other Requirements & Information	Use based on clinical presentation may be considered on a case-by-case basis if genetic testing cannot confirm diagnosis of HoFH. Clinical presentation: 1) Untreated total cholesterol > 500mg/dL AND cutaneous or tendon cholesterol deposits before age 10 years; OR 2) Documentation of untreated total cholesterol ≥ 250mg/dL in both parents. Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1305	Injection, evinacumab-dgnb, 5mg	15mg/kg every 4 weeks

Requirements for Inclisiran (Leqvio™)

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	As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).
Exclusion Criteria	Concurrent use of other PCSK9 inhibitors [i.e. Repatha™ (evolocumab) or Praluent™ (alirocumab)]
Required Medical Information	Clinical notes and laboratory values documenting the member is within one of the following categories for which the use of Leqvio is supported by medical guidelines: <u>Baseline LDL-C level of ≥190mg/dL</u>: 1) Documentation of baseline LDL-C level of ≥190mg/dL 2) LDL-C ≥100mg/dl (drawn within the past 3 months) despite compliant therapy with ALL of the following taken at the same time at the maximum tolerated doses: a) Maximally tolerated high dose statin therapy (atorvastatin ≥ 40mg or rosuvastatin ≥ 20mg), AND b) Ezetimibe (Zetia), AND c) Evolocumab (Repatha) or Alirocumab (Praluent). <u>Atherosclerotic cardiovascular disease (ASCVD)</u>: 1) History of clinical ASCVD. 2) LDL-C ≥70mg/dl (drawn within the past 3 months) despite compliant therapy with ALL of the following taken at the same time at the maximum tolerated doses: a. Maximally tolerated high dose statin therapy (atorvastatin ≥ 40mg or rosuvastatin ≥ 20mg), AND b. Ezetimibe (Zetia), AND c. Evolocumab or Alirocumab (Praluent).
Age Restriction	18 years and older
Prescriber Restriction	Cardiologist, Diabetologist or Endocrinologist
Coverage Duration	Initial: 9 months. Renewal: 12 months with documentation of positive treatment response as evidenced by reduction of LDL-C from baseline with cholesterol lab drawn within 90 days of request.
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.* Inclisiran should be administered by a healthcare professional.

Requirements for Inclisiran (Leqvio™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J1306	Injection, inclisiran, 1mg	284mg SC initially, again at 3 months, and then every 6 months thereafter

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

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 Duchenne muscular dystrophy (DMD) in patients who are ambulatory and have a confirmed mutation in the DMD gene.
Exclusion Criteria	1. Treatment or use for anything other than DMD. 2. Prior administration of delandistrogene moxeparvovec-rokl (Elevidys™). 3. Deletions in exon 8 and/or exon 9 in the DMD gene. 4. Preexisting liver impairment defined as gamma-glutamyl transferase (GGT) >2 x upper limit of normal (ULN), or total bilirubin > ULN (and not due to Gilbert's syndrome). 5. Active viral hepatic infection. 6. Concurrent use with exon skipping therapies.
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records detailing the clinical course and confirming a mutation of the DMD gene. a. Genetic mutation test results must be submitted with request. b. Skeletal muscle biopsy results characterizing dystrophin by western blot and immunohistochemistry may be required, such as in the case of genetic testing showing a variant of uncertain significance, or a clinical course and laboratory findings deviating from the traditional trajectory of DMD. c. For mutations in exons 1-17, provider must attest that they are aware of the increased risk for severe myositis associated with these mutations. 2. Baseline Serum Creatine Kinase level with laboratory reference range. 3. Documentation of ambulatory status in the medical records AND as evidenced by North Star Ambulatory Assessment (NSAA) score of ≥1 (or equivalent on another recognized scale) completed within the 3 months prior to TAR submission. 4. Documentation of anti-AAVrh74 total antibody titers <1:400 using a Total Binding Antibody enzyme linked immunosorbent assay (ELISA) completed within the 30 days prior to TAR submission. 5. Documentation of baseline liver function tests, platelet counts, left ventricular ejection fraction (LVEF) and troponin I levels completed within the 30 days prior to TAR submission. Elevidys is not recommended in patients with pre-existing liver impairment (GGT >2x ULN) or total bilirubin >ULN. Elevidys administration should be postponed until acute liver disease has resolved or been controlled. 6. Documentation that the member does not have any signs or symptoms of infection currently or within 4 weeks of receiving Elevidys. 7. Concurrent use corticosteroids (prednisone, prednisolone, deflazacort (Emflaza™), vamorolone (Agamree™) etc.) at a stable dose for at least 12 weeks, unless contraindicated or intolerant. Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

	approvals.
Age Restriction	Ages 4 years and older
Prescriber Restriction	Prescribed by, or under supervision and monitoring of a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy
Coverage Duration	Once per lifetime
Other Requirements & Information	Requests for use in members who are considered non-ambulatory: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.*** Prescriber must attest or otherwise document member will receive prophylactic prednisolone (or glucocorticoid equivalent) (in addition to baseline corticosteroid dose) one day prior to Elevidys™ infusion and for 60 days following therapy to monitor liver function.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose (Elevidys™)	$1.33x10^{14}$ vector genomes per kg (vg/kg) of body weight (or 10mL/kg) Supplied in 10ml vials packaged into single dose kits ranging from 10 to 70 vials per kit.

Requirements for Onasemnogene Abeparvovec-brve (Itvisma™) Intrathecal

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 spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in the survival motor neuron 1 (SMN1) gene.
Exclusion Criteria	1. Prior treatment with Zolgensma™ IV or Itvisma™ IT. 2. Concurrent treatment with nusinersen (Spinraza™) or risdiplam (Evrysdi™). 3. Treatment or use for anything other than SMA.
Required Medical Information	1. Diagnosis of spinal muscular atrophy with documentation of genetic testing confirming mutation in survival motor neuron 1 (SMN1) gene. 2. Documentation that member has been evaluated for risk of serious systemic immune response and member is clinically stable in overall baseline health status (e.g., hydration and nutritional status, absence of infection, respiratory status) prior to administration of Itvisma. 3. Member must have an anti-AAV9 antibody titer below or equal to (≤) 1:50 as determined by Enzyme-Linked Immunosorbent Assay (ELISA) binding immunoassay within 90 days of planned administration. 4. Documentation supporting no indication of significant liver injury. Requests should include assessment of liver function (baseline liver function testing to include aspartate aminotransferase (AST), alanine aminotransferase (ALT), albumin, prothrombin time, partial thromboplastin time (PTT), international normalized ratio (INR), and total bilirubin). 5. Documentation that liver function (AST, ALT, total bilirubin) will be monitored following treatment with Itvisma for at least 3 months after injection, and at other times as clinically indicated. 6. Creatinine and complete blood count (including hemoglobin and platelet count) prior to administration of Itvisma and documentation that platelet counts will be monitored weekly for the first month and as clinically indicated after administration until platelet counts return to baseline. 7. Documentation that member will receive the recommended corticosteroid regimen pre- and post- Itvisma injection for a total of 30 days. 8. Documentation of at least one neuromotor assessment, performed within past 12 months with a score used to establish a clinical baseline. 9. Member must not have received this therapy previously with either Zolgensma IV or Itvisma IT. 10. 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	2 years and older (per FDA labeling)
Prescriber Restriction	Neurologist or pediatric neurologist

Requirements for Onasemnogene Abeparvovec-brve (Itvisma™) Intrathecal

Coverage Duration	Once per lifetime
Other Requirements & Information	Prescriber must attest or otherwise document member will receive prophylactic prednisolone (or glucocorticoid equivalent) one day prior to Itvisma injection and for 30 days following therapy to monitor liver function. Treatment with nusinersen (Spinraza) or risdiplam (Evrysdi) must be discontinued prior to the administration of onasemnogene abeparvovec-brve (Itvisma).

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3590	Itvsma, 4 x 10^{13} vg per mL	Each carton of Itvisma contains a single-dose vial with an extractable volume of not less than 3 mL, containing 1.2 × 10^{14} vg (4 x 10^{13} vg/mL)

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

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

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

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

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
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™, Aucatzyl™**:

For **Kymriah™**:

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

For **Tecartus™ and Aucatzyl™:**

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

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

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

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

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

Mantle cell lymphoma, relapsed or refractory:
FDA-approved CAR-T therapies with this indication: **Breyanzi™**, **Tecartus™.**

- Documentation of treatment of relapsed or refractory mantle cell lymphoma (MCL) in adults after 2 or more lines of systemic therapy, including a Burton tyrosine kinase (BTK) inhibitor.

Marginal Zone Lymphoma (MZL), relapsed or refractory:
FDA-approved CAR-T therapies with this indication: **Breyanzi™**

- Documentation of treatment of relapsed or refractory marginal zone lymphoma in adults after 2 or more lines of systemic therapy.

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

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

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

Yescarta™	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	2 x 10^6 CAR-T cells, not to exceed maximum dose of 200 million CAR-T cells (provided in single IV bag).

Requirements for Prademagene Zamikeracel (Zevaskyn™)

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 wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (R-DEB). • Off-label requests for adult and pediatric patients with severe cases of dominant dystrophic epidermolysis bullosa (D-DEB) will be considered using the D-DEB specific criteria below.
Exclusion Criteria	1. Treatment or use for anything other than dystrophic epidermolysis bullosa (DEB). 2. The use of beremagene geperpavec (Vyjuvek) or birch triterpenes (Filsuvez) on the wound site intended to be treated with prademagene zamikeracel within the 3 months prior to scheduled administration of prademagene zamikeracel, or within the 24 weeks after the administration of prademagene zamikeracel (use of Vyjuvek and Filsuvez on other wound sites is permitted). 3. Current squamous cell carcinoma (SCC) in the area where prademagene zamikeracel will be administered. Note: for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance for the use of prademagene zamikeracel by dermatology or oncology with confirmatory pathology is required.
Required Medical Information	<u>General requirements for all requests:</u> 1. Negative pregnancy test. 2. Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV) testing. If positive, additional information may be required such as viral load, treatment status, and evidence of stable or controlled infection. 3. Attestation that the member can undergo the required immobilization and post-operative management. 4. Documentation of current medical therapies for DEB the member is using, such as beremagene geperpavec (Vyjuvek) or birch triterpenes (Filsuvez), including photographs of the specific areas where those treatments are applied and attestation that their use at the target wound(s) site will be discontinued at least 3 months prior to prademagene zamikeracel administration and for at least 24 weeks after. 5. Positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin, or reason why this testing cannot be performed. 6. Documentation, including photographs, of the wound location(s) where prademagene zamikeracel will be applied. <u>Requests for the treatment of R-DEB:</u> 1. Notes documenting a clinical diagnosis of R-DEB and that the member has at least one clinical feature of R-DEB (for example, blistering, wounds, scarring). 2. Genetic testing documenting two confirmed pathogenic mutations in the collagen type VII alpha 1 chain (COL7A1) gene with recessive inheritance patterns (or confirmation that parents don't have any evidence of dominant disease). a. Note: for mutations classified as variants of uncertain significance, documentation of diagnostic confirmation by additional testing, such as immunofluorescence mapping (IFM) may be required. 3. Target wound(s) meets ALL of the following, according to prescriber attestation (a, b, c, d, and e): a. Target wound(s) is clean in appearance and does not appear to be infected; AND

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	b. Target wound(s) has adequate granulation tissue and vascularization; AND c. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND d. Target wound is (i, ii, or iii): i. Chronic (present ≥ 6 months without healing) and size is ≥20cm^2; OR ii. The wound has had an inadequate response or intolerance to beremagene geperpavec (Vyjuvek); OR iii. reasons why Vyjuvek is not clinically appropriate for the wound have been provided; AND e. Prademagene zamikeracel has NOT been previously applied to the target wound(s) OR the wound meets requirements for retreatment of the same wound site specified under Other Requirements & Information. <u>Requests for the off-label treatment of severe D-DEB</u>: 1. Notes documenting a clinical diagnosis of severe D-DEB, that the member has at least one clinical feature of D-DEB (for example, blistering, wounds, scarring) and that wounds have chronicity, depth and functional impacts similar to R-DEB. 2. Genetic testing documenting one confirmed pathogenic mutation in the collagen type VII alpha 1 chain (COL7A1) gene consistent with dominant disease. a. Note: for mutations classified as variants of uncertain significance, documentation of diagnostic confirmation by additional testing, such as immunofluorescence mapping (IFM) may be required. 3. Target wound(s) meets ALL of the following, according to prescriber attestation (a, b, c, d, and e): a. Target wound(s) is clean in appearance and does not appear to be infected; AND b. Target wound(s) has adequate granulation tissue and vascularization; AND c. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND d. Documentation that beremagene geperpavec (Vyjuvek) is either not clinically appropriate for the specific wound, or was applied at the target wound(s) for at least 6 months without adequate healing; AND e. Prademagene zamikeracel has NOT been previously applied to the target wound(s) OR the wound meets requirements for retreatment of the same wound site specified under Other Requirements & Information. 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	None
Prescriber Restriction	Dermatologist or wound care specialist with experience in the management of DEB

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Coverage Duration	1 treatment per authorization
Other Requirements & Information	<u>Renewal requests R-DEB:</u> 1. Documentation of current medical therapies for DEB the member is using, such as beremagene geperpavec (Vyjuvek) or birch triterpenes (Filsuvez), including photographs of the specific areas where those treatments are applied and attestation that their use at the target wound(s) site will be discontinued at least 3 months prior to prademagene zamikeracel administration and for at least 24 weeks after. 2. Documentation, including photographs, of the wound location(s) where prademagene zamikeracel will be applied. 3. Treatment of a new wound site never previously treated with prademagene zamikeracel: a. Target wound(s) meets ALL of the following, according to prescriber attestation (i, ii, iii, and iv): i. Target wound(s) is clean in appearance and does not appear to be infected; AND ii. Target wound(s) has adequate granulation tissue and vascularization; AND iii. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND iv. Target wound is (1, 2, or 3): 1. Chronic (present ≥ 6 months without healing) and size is ≥20cm^2; OR 2. The wound has had an inadequate response or intolerance to beremagene geperpavec (Vyjuvek); OR 3. reasons why Vyjuvek is not clinically appropriate for the wound have been provided. 4. Treatment of a wound site previously treated with prademagene zamikeracel: a. Target wound(s) meets ALL of the following, according to prescriber attestation (i, ii, iii, iv, v, vi, and vii): i. ≥24 weeks since the initial prademagene zamikeracel graft; AND ii. Documentation, including photographs, that full epithelial closure was achieved, followed by recurrence; AND iii. Documentation that the member has not developed anti-C7 antibodies following the initial prademagene zamikeracel graft; AND iv. Target wound(s) is clean in appearance and does not appear to be infected; AND v. Target wound(s) has adequate granulation tissue and vascularization; AND vi. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND vii. Target wound is (1, 2, or 3): 1. Chronic (present ≥ 6 months without healing) and size is ≥20cm^2; OR 2. The wound has had an inadequate response or intolerance to beremagene geperpavec (Vyjuvek); OR 3. reasons why Vyjuvek is not clinically appropriate for the wound have been provided. 5. Negative pregnancy test.

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Renewal Requests D-DEB:

1. Documentation of current medical therapies for DEB the member is using, such as beremagene geperpavec (Vyjuvek) or birch triterpenes (Filsuvez), including photographs of the specific areas where those treatments are applied and attestation that their use at the target wound(s) site will be discontinued at least 3 months prior to prademagene zamikeracel administration and for at least 24 weeks after.
2. Documentation, including photographs, of the wound location(s) where prademagene zamikeracel will be applied.
3. Treatment of a new wound site never previously treated with prademagene zamikeracel:
    a. Target wound(s) meets ALL of the following, according to prescriber attestation (i, ii, iii, and iv):
        i. Target wound(s) is clean in appearance and does not appear to be infected; AND
        ii. Target wound(s) has adequate granulation tissue and vascularization; AND
        iii. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND
        iv. Documentation that beremagene geperpavec (Vyjuvek) is either not clinically appropriate for the specific wound, or was applied at the target wound(s) for at least 6 months without adequate healing.
4. Treatment of a wound site previously treated with prademagene zamikeracel:
    a. Target wound(s) meets ALL of the following, according to prescriber attestation (i, ii, iii, iv, v, vi, and vii):
        i. ≥24 weeks since the initial prademagene zamikeracel graft; AND
        ii. Documentation, including photographs, that full epithelial closure was achieved, followed by recurrence; AND
        iii. Documentation that the member has not developed anti-C7 antibodies following the initial prademagene zamikeracel graft; AND
        iv. Target wound(s) is clean in appearance and does not appear to be infected; AND
        v. Target wound(s) has adequate granulation tissue and vascularization; AND
        vi. There is no current evidence or clinical suspicion of SCC identified at the target wound(s) (for wounds that have a history of SCC within the prior 12 months that was excised with complete resolution, clearance by dermatology or oncology with confirmatory pathology is required); AND
        vii. Documentation that beremagene geperpavec (Vyjuvek) is either not clinically appropriate for the specific wound, or was applied at the target wound(s) for at least 6 months without adequate healing.
5. Negative pregnancy test.

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Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3389	Topical administration, prademagene zamikeracel, per treatment	1 unit = 1 treatment (up to 12 sheets) Only 1 treatment should be approved per TAR