PARTNERSHIP HEALTHPLAN of CALIFORNIA
A Public Agency

PHC Medi-Cal
Effective: October 1st, 2024

P & T: July 11th 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.

1. Requirements for Tildrakizumab (Ilumya™)
2. Requirements for Spesolimab-sbzo (Spevigo™)
3. Requirements for Secukinumab IV (Cosentyx IV™)
4. Requirements for Beremagene geperpavec-svdt (Vyjuvek™)
5. Requirements for Ranibizumab (Lucentis™)
6. Requirements for Ranibizumab-eqrn (Cimerli™)
7. Requirements for Aflibercept HD (Eylea HD™)
8. Requirements for Faricimab (Vabysmo™)
9. Requirements for Bimatoprost intracameral implant (Durysta™)
10. Requirements for Travoprost implant (iDOSE TR™)
11. Requirements for Voretigene neparvovec (Luxturna™)
12. Requirements for Teprotumumab-trbw (Tepezza™)
13. Requirements for Enyzme replacement drugs
14. Requirements for Mirikizumab-mrkz (Omvoh™)
15. Requirements for Ustekinumab (Stelara™)
16. Requirements for Vedolizumab IV (Entyvio™)
17. Requirements for Infliximab biosimilars group 1 (Inflectra™)
18. Requirements for Infliximab biosimilars group 2 (Avsola, Renflexis™)
19. Requirements for Infliximab (Remicade™)
20. Requirements for Difelikefalin (Korsuva™)
21. Requirements for Collagenase Clostridium Histolyticum CCH (Xiaflex™)
22. Requirements for Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrullo™)
23. Requirements for Rozanolixizumab-noli (Rystiggo™)
24. Requirements for Bevacizumab-maly (Alymsys™) and bevacizumab-adcd (Vegzelma™)
25. Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

Requirements for Tildrakizumab (Ilumya™) IV injection

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	Moderate to severe plaque psoriasis (PSO)
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy.
Required Medical Information	<u>Moderate to severe PSO:</u> 1) 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). 2) Treatment plan. 3) Disease Activity Score. 4) 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). 5) Documentation to one of the following: a. ≥ 10% BSA affected OR b. <10% BSA affecting sensitive areas (palms of hands, soles of feet, head/neck, genitalia), OR c. Therapeutic failure after a 3-month trial of 2 or more non-biologic therapies (unless contraindicated): i. Methotrexate ii. Cyclosporine iii. Acitretin iv. Phototherapy in conjunction with methoxsalen 6) Documented therapeutic failure after a minimum 3-month trial of (or contraindication to) each of the following: a. A TNFi (adalimumab (Humira), etanercept (Enbrel), or certolizumab (Cimzia)), b. An inhibitor of IL-23 or related cytokine such as ustekinumab (Stelara), guselkumab (Tremfya) or risankizumab (Skyrizi). i.
Age Restriction	18 years and older
Prescriber Restriction	Dermatologist
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 PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Tildrakizumab (Ilumya™) IV injection

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3245	Injection, tildrakizumab, 1 mg	100 mg at week 0, 4 and then every 12 weeks.

Requirements for Spesolimab-sbzo IV injection (Spevigo™)

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

PA Criteria	Criteria Details
Covered Uses	Generalized pustular psoriasis (GPP) flares
Exclusion Criteria	• Primary plaque psoriasis vulgaris without presence of pustules • Pustules that are restricted to psoriatic plaques • Diagnosis other than for the treatment of a GPP flare
Required Medical Information	1) Initial dose, *each distinct flare*: a. Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). b. Current weight ≥40kg c. Clinical notes confirming a diagnosis of moderate to severe GPP flare, including: i. Skin biopsy results and ii. Presence of fresh or worsening pustules with both a. The mean Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 (at least moderate severity) b. GPPGA pustulation sub score of at least 2, with pustules & erythema covering an involved body surface area of 5% or greater. 2) Second dose per flare: a. Clinical notes with evaluation having occurred between 7-14 days after the first dose, and which include all of the following to confirm need for second dose: i. GPPGA score ≥ 2 ii. GPPGA pustulation sub score of ≥1 b. The second dose must be administered no sooner than 7 days and no later than 14 days after first dose (ie, with first dose being day 1, 2nd dose should be day 8 to day 15).
Age Restriction	12 years and older
Prescriber Restriction	Prescribed or recommended by a dermatologist
Coverage Duration	One dose (900 mg) per TAR request, with maximum of 1 TAR renewal if needed per flare (a 2nd 900 mg dose per flare when requirements are met).
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Spesolimab-sbzo IV injection (Spevigo™)

Medical Billing:

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

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

Requirements for Secukinumab IV injection (Cosentyx™ IV)

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	• Active psoriatic arthritis (PsA) • Active ankylosing spondylitis (AS) • Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
Exclusion Criteria	• Active, serious infection, or latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	<u>For all indications:</u> 1. Specialist's clinic notes documenting disease course (activity, progression, severity) with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated). 2. Treatment plan. 3. Disease Activity Score. 4. 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). <u>Active PsA:</u> 1. Documentation of evaluation from a rheumatologist to confirm diagnosis of psoriatic arthritis and one of a, b, or c: a. Severe psoriatic arthritis with erosive disease and functional limitation, or b. Moderate to severe axial involvement, or c. Documentation of trial and failure of, or contraindication to, a minimum of a 3-month trial of methotrexate, or other oral DMARD (disease-modifying antirheumatic drug) if member is unable to take methotrexate (MTX) 2. Documented therapeutic failure with at least one preferred TNFi: adalimumab (Humira), etanercept (Enbrel), subcutaneous golimumab (Simponi) or certolizumab (Cimzia). 3. Documentation of trial and failure of subcutaneous secukinumab (Cosentyx) or reasons why member cannot use the less invasive & self-administered Cosentyx pen or prefilled syringe <u>Active AS or nr-axSpA with objective signs of inflammation</u> 1. Adequate trial of at least two prescription-strength NSAIDs or COX-2 inhibitors 2. Documented therapeutic failure with at least one preferred TNFi: adalimumab (Humira), etanercept (Enbrel), subcutaneous golimumab (Simponi) or certolizumab (Cimzia). 3. Documentation of trial and failure of subcutaneous secukinumab (Cosentyx) or reasons why member cannot use the less invasive, self-administered Cosentyx pen or prefilled syringe
Age Restriction	18 years or older
Prescriber Restriction	Rheumatologist For PsA, a dermatologist may continue treatment that was initiated based on a rheumatologists recommendation.

Requirements for Secukinumab IV injection (Cosentyx™ IV)

Coverage Duration	Initial: 6 months Renewal: 12 months

Other Requirements & Information	Renewals: documentation of efficacy to support positive benefit when compared to baseline. 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
J3247	Injection, secukinumab, intravenous, 1 mg	Loading dose (optional): 6mg/kg at week 0 followed by maintenance dosing starting at 4 weeks Maintenance dosing: 1.75mg/kg every 4 weeks (maximum 300mg) **supplied in single use 125mg vials*

Requirements for Beremagene geperpavec-svdt (Vyjuvek™)

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 patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1) gene*
Exclusion Criteria	• Use outside FDA approved indication
Required Medical Information	1) Diagnosis of DEB with genetic testing confirming mutations(s) in the *COLA7A1* gene 2) Presence of open DEB skin wounds 3) 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	6 months and older
Prescriber Restriction	Dermatologist
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Information	Renewal requests: clinic notes documenting benefit from treatment

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml	Maximum weekly volume: • 6mo to <3 years: 0.8ml • ≥3 years: 1.6ml

Requirements for Ranibizumab (Lucentis™) Intravitreal Injection

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) Diabetic macular edema (DME) 2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME) 3) Neovascular (wet) age-related macular degeneration (AMD) 4) Macular edema following retinal vein occlusion (RVO) 5) Myopic Choroidal Neovascularization (mCNV)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 1)
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	Limited to a maximum of 13 injections per 12 months (per eye).
Other Requirements	Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline For members on Susvimo intravitreal implant, requiring additional ranibizumab doses: Documentation supporting the medical necessity of supplemental doses must include at least one of the following: 1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR 2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR 3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Ranibizumab (Lucentis™) Intravitreal Injection

Medical Billing:

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

HCPCS	Description	Dosing, Units
J2778	Intravitreal injection, ranibizumab, per 0.1 mg	AMD, RVO, mCNV: 0.5mg (5units) every 28 days DME/DR w/DME, PDR: 0.3mg (3 units) every 28 days

Requirements for Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

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) Diabetic macular edema (DME) 2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME) 3) Neovascular (wet) age-related macular degeneration (AMD) 4) Macular edema following retinal vein occlusion (RVO) 5) Myopic Choroidal Neovascularization (mCNV)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	Diagnosis of AMD, macular edema following RVO, or mCNV: 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Documentation of trial and failure to, or reason(s) why Lucentis or preferred biosimilar, Byooviz cannot be used Diagnosis of DME, DR w/DME, PDR: 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Documentation of trial and failure to, or reason(s) why Lucentis cannot be used
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	Limited to a maximum of 13 injections per 12 months (per eye).
Other Requirements	Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline For members on Susvimo intravitreal implant, requiring additional ranibizumab doses: Documentation supporting the medical necessity of supplemental doses must include at least one of the following: 1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR 2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR 3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

Medical Billing:

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

HCPCS	Description	Dosing, Units
Q5128	Intravitreal injection, ranibizumab-eqrn (cimerli), per 0.1 mg	AMD, RVO, mCNV: 0.5mg (5units) every 28 days DME/DR w/DME, PDR: 0.3mg (3 units) every 28 days

Requirements for Aflibercept HD Intravitreal Injection (Eylea™ HD)

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) Diabetic macular edema (DME) 2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME) 3) Neovascular (wet) age-related macular degeneration (nAMD)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	<u>Diagnosis of nAMD or DME:</u> 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Trial and failure to both of the following. a. Aflibercept 2mg (Eylea™) or aflibercept biosimilar, AND b. Facicimab (Vabysmo™) 4) For members with stable/controlled disease on Eylea 2mg, documentation of medical need for an extended frequency product is required <u>Diagnosis of PDR:</u> 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Trial and failure to both of the following. a. Aflibercept 2mg (Eylea™) or aflibercept biosimilar, AND a. One additional preferred agent such as ranibizumab-nuna (Byooviz™), ranibizumab (Lucentis™), ranibizumab-eqrn (Cimerli™), or off-label bevacizumab (Avastin™) or Facicimab (Vabysmo™) 4) For members with stable/controlled disease on Eylea 2mg, documentation of medical need for an extended frequency product is required
Age Restriction	18 years and older
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	First year: limit to maximum of 9 injections per eye over 12 months Subsequent years: limit to maximum of 7 injections per eye over 12 months
Other Requirements	<u>Renewal or retreatment requests:</u> Renewal will be based on documentation of benefit from therapy (may be indicated on the TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline OR 2) Decrease in rate of vision loss compared to baseline Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Aflibercept HD Intravitreal Injection (Eylea HD™)

Medical Billing:

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

HCPCS	Description	Dosing, Units
J0177	Intravitreal injection, aflibercept hd, 1mg	AMD and DME: 8mg every 4 weeks (+/- 7 days) for 3 doses followed by 8 mg every 8-16 weeks (+/- 1 week) DR: 8mg every 4 weeks (+/- 7 days) for 3 doses followed by 8 mg every 8-12 weeks (+/- 1 week)

Requirements for Faricimab Intravitreal Injection (Vabysmo™)

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) Diabetic macular edema (DME) 2) Neovascular (wet) age-related macular degeneration (nAMD) 3) Macular edema following retinal vein occlusion (RVO)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Documentation of trial and failure or contraindication to at least 1 of PHC's preferred ophthalmic VEGF inhibitors: ranibizumab-nuna (Byooviz™), ranibizumab (Lucentis™), ranibizumab-eqrn (Cimerli™), aflibercept (Eylea™), brolucizumab-dbll (Beovu™), or off-label bevacizumab (Avastin™).
Age Restriction	18 years and older
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	Limited to a maximum of 13 injections per eye in 12 months
Other Requirements	Renewal authorization will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Faricimab Intravitreal Injection (Vabysmo™)

Medical Billing:

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

HCPCS	Description	Dosing, Units
J2777	Intravitreal injection, faricimab, per 0.1 mg	**nAMD:** • Initial -- 6 mg (60 HCPCS units) every 4 weeks for the first 4 doses (weeks 1-16): Total of 240 units authorized per eye (480 max units for bilateral treatment) for initial TARs. • Continuation – depending on evaluations at 8 & 12 weeks following the initial 4 doses, subsequent doses may be repeated at 4-16 week intervals. **DME:** Two regimens are FDA approved: • 6 mg every 4 weeks for at least 4 doses. Following resolution of edema, doses are continued every 4-8 weeks (intervals modified +/- depending on CST & visual acuity evaluations) through week 52 OR • 6 mg every 4 weeks for the first 6 doses, followed by 6 mg every 8 weeks over the next 28 weeks. Some may need every 4 weeks dosing after the first 4 doses. **RVO:** • 6 mg every 4 weeks for 6 doses, may be continued at intervals of every 4 weeks or greater for ongoing ME

Requirements for Bimatoprost, intracameral implant (Durysta™)

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 elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT)
Exclusion Criteria	• Ocular or periocular infections • Corneal endothelial dystrophy • Prior corneal transplantation • Absent or ruptured posterior lens capsule • Prior implantation of Durysta in the same eye • Concurrent use of iDOSE TR in the same eye
Required Medical Information	1) Baseline IOP 2) Trial and failure to a topical prostaglandin OR medical reasons why topical therapy cannot be used. Failure as evidenced by uncontrolled IOP. 3) Trial and failure or reasons why selective laser trabeculoplasty (SLT) cannot be used
Age Restriction	18 years or older
Prescriber Restriction	Must be prescribed by an ophthalmologist
Coverage Duration	One implant per eye 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
J7351	Injection, bimatoprost, intracameral implant, 1 microgram (Durysta™)	10mcg (1 implant) one time per eye

Requirements for Travoprost, Intracameral Implant (iDOSE™ TR)

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 elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT)
Exclusion Criteria	• Ocular or periocular infections • Corneal endothelial dystrophy • Prior corneal transplantation • Prior implantation of iDOSE TR in the same eye • Concurrent use (within the prior 6 months) of Durysta in the same eye
Required Medical Information	1) Baseline IOP 2) Trial and failure to a topical prostaglandin in combination with at least one other topical agent from the following classes OR medical reasons why topical therapy cannot be used. Failure as evidenced by uncontrolled IOP despite adequate trial. a. Beta-blockers b. Alpha-2 agonists c. Carbonic anhydrase inhibitor d. Prostaglandin analog e. Cholinergic agents f. Rho kinase inhibitors 3) Trial and failure or reasons why selective laser trabeculoplasty (SLT) cannot be used
Age Restriction	18 years or older
Prescriber Restriction	Must be prescribed by an ophthalmologist
Coverage Duration	One implant per eye 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
J7355	Injection, travoprost, intracameral implant , 1 micorgram (iDOSE TR™)	75mcg (1 implant) one time per eye

Requirements for Voretigene Neparvovec-rzyl (Luxturna™)

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	Biallelic RPE65 mutation-associated retinal dystrophy
Exclusion Criteria	• Prior treatment with Luxturna in the same eye • For use other than the FDA approved indication
Required Medical Information	1) Confirmation of biallelic genetic mutation in RPE65 gene 2) Presence of viable retinal cells as determined by the treating ophthalmologist 3) 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 months and older
Prescriber Restriction	Ophthalmologist
Coverage Duration	Once per eye per lifetime
Other Requirements & Information	No renewal requests will be approved.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	$1.5x10^{11}$ vg subretinal injection, total volume 0.3ml (150 units) per eye. Each eye should be injected on separate days but no fewer than 6 days apart.

Requirements for teprotumumab-trbw (Tepezza™)

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 Thyroid Eye Disease (TED)
Exclusion Criteria	• Use outside FDA approved indication • Use in combination with other biologic immunomodulators (eg, rituximab, tocilizumab)
Required Medical Information	All of the following criteria must be met: 1) Patient has a confirmed diagnosis of Graves' disease AND documentation of moderate-to-severe TED as represented by one or more of the following: a. Lid retraction of ≥2 mm b. Moderate or severe soft-tissue involvement c. Proptosis ≥3 mm above normal values for race and sex d. Periodic or constant diplopia 2) Patient does not require surgical ophthalmological intervention. 3) Laboratory results within the past 30 days confirming patient is euthyroid (T3 and T4 within normal limits) or mild hypo- or hyperthyroidism (T3 and T4 levels <50% above or below normal limits) and patient is undergoing treatment to correct and maintain euthyroid state prior to starting therapy with teprotumumab. 4) Clinical Activity Score (CAS) report with results ≥4 indicating active disease. If CAS is <4, documentation of presence of at least one of the following must be submitted to confirm treatment with teprotumumab is medically indicated: a. Debilitating diplopia b. Extreme proptosis 5) Documentation of prior trial and failure or contraindication to oral or intravenous glucocorticoids (at least 4 week trial) or documented medical justification why the use of glucocorticoids is not appropriate. 6) For patients of reproductive potential-submit attestation that patient is not pregnant and has been advised to implement appropriate contraception before initiation, throughout treatment, and continued for 6 months following the last dose of teprotumumab.
Age Restriction	18 years and older
Prescriber Restriction	Ophthalmologist or Endocrinologist
Coverage Duration	1 treatment course per lifetime consisting of 8 doses with 12 month approval window. Request for additional treatment course: 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.
Other Requirements & Information	Standard statement for all criteria: Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for teprotumumab-trbw (Tepezza™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3241	Injection, teprotumumab-trbw, 10 mg	IV: 10 mg/kg as a single dose, followed by 20 mg/kg every 3 weeks for 7 additional doses. Supplied as 500 mg lyophilized powder in a single-dose vial for reconstitution

Requirements for Enzyme Replacement Drugs

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	Aldurazyme™	Mucopolysaccharidosis I (MPS I) types: (1) Hurler, (2) Hurler-Scheie, and (3) Moderate to severe Scheie form.
	Brineura™	CLN2 Tripeptidyl Peptidase 1 (TPP1) Deficiency (aka Late Infantile Neuronal ceroid lipofuscinosis)
	Cerezyme™, Vpriv™	Gaucher Disease Type 1 (Cerezyme may be used off-label for Type 3)
	Eleprase™	Hunter syndrome (mucopolysaccharidosis II, MPS II
	Fabrazyme™	Fabry Disease
	Lumizyme,™ Nexviazyme™	Pompe Disease
	Mepsevii™	Mucopolysaccharidosis VII (MPS VII, Sly Syndrome)
	Naglazyme™	Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome)
	Vimizim™	Mucopolysaccharidosis IV (Morquio Syndrome)
	Xenpozyme™	Acid sphingomyelinase deficiency (Niemann-Pick disease)
Exclusion Criteria	None	
Required Medical Information	For all products – Clinic notes which include: • Documentation of the FDA approved indication • Subjective findings (complaints) • Objective finding (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight) • Complications (eg, bony changes or kidney failure) • Quality of life issues (eg, severe, unremitting pain or extreme fatigue) • Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counseling information for the patient and family members. • Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school, or to significantly improve quality of life. • Requests for Nexviazyme™ for members <30 kg require medical justification for inability to use PHC's preferred enzyme replacement therapy (ERT) for Pompe disease, Lumizyme™, which has the same mechanism of action as Nexviazyme™.	
Age Restriction	Vpriv™: ≥ 4 yrs Brineura™: 3-18 yrs Nexviazyme™: ≥ 1 yr	
Prescriber Restriction	Neurologist, endocrinologist, cardiologist, hepatologist, pulmonologist, genetic disease or other specialist familiar with treating lysosomal storage disorders.	
Coverage Duration	Initial & Renewal: 6 months	
Other Requirements & Information	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*	

Requirements for Enzyme Replacement Drugs

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses:

HCPCS	Description	Dosing, Package size
J0180	Injection, agalsidase beta, 1 mg (Fabrazyme™)	1 mg/kg every 2 weeks, 5 mg & 35 mg SDV
J0221	Injection, alglucosidase alfa, 10 mg (Lumizyme™)	20 mg/kg every 2 weeks, 50 mg SDV
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg (Nexviazyme™)	ABW < 30 KG: 40 mg/kg q 2 weeks; ABV ≥30 kg: 20 mg/kg q 2 weeks, 100 mg SDV
J0567	Injection, cerliponase alfa, 1 mg (Brineura™)	300 mg every other week (via aseptic intraventricular infusion into CSF), 150 mg/5mL kit (2 vials)
J1322	Injection, elosulfase alfa, 1 mg (Vimizim™)	2 mg/kg once weekly, 1 mg/mL, 5 mL SDV
J1458	Injection, galsulfase, 1 mg (Naglazyme™)	1 mg/kg once weekly, 5 mg/5 mL SDV
J1743	Injection, idursulfase, 1 mg (Elaprase™)	0.5 mg/kg once weekly, 2 mg/ml, 3ml SDV
J1786	Injection, imiglucerase, 10 units (Cerezyme™)	Individualized based on response. Some pts need more frequent dosing (up to TIW) while others can be dosed every other week. Doses range from 2.5 u/kg TIW to 60 u/kg QOW. State Medical maximum daily dose is 818 billed units (8,180 dose units), without documentation that weight is over 300 lbs, 400 unit SDV
J1931	Injection, laronidase, 0.1 mg (Aldurazyme™)	0.58 mg/kg once weekly, 2.9 mg/5 ml SDV
J0218	Injection, olipudase alfa-rpcp, 1 mg (Xenpozyme™)	Dose is titrated over the course of 14 weeks for adults and 16 weeks in pediatric patients up to a recommended maintenance dose of 3 mg/kg given q 2 weeks, 4 mg or 20 mg SDV.
J3385	Velaglucerase Alfa inj, 100 units (Vpriv™)	60 units/kg every other week, 400 unit SDV
J3397	Injection, vestronidase alfa-vjbk, 1 mg (Mepsevii™)	4 mg/kg every 2 weeks, 2 mg/ml 5 ml vials

Requirements for mirikizumab-mrkz (Omvoh™)

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	IV induction dosage for the treatment of moderately to severely active ulcerative colitis (UC) in adults.
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	1) 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). 2) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease. 3) Treatment plan (Note: the FDA approved induction dose of 300 mg IV given at week 0, week 4, and week 8 is recommended to be followed by 200 mg subcutaneous dose at week 12 and every 4 weeks thereafter) 4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (e.g., Quanti FERON-TB Gold test). 5) Baseline liver enzyme and bilirubin levels prior to treatment initiation. 6) Documented therapeutic failure to induce remission with (or contraindication to) at least two of the following: adalimumab, golimumab, infliximab, tofacitinib, ustekinumab, or vedolizumab.
Age Restriction	18 years and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
Coverage Duration	Initial approval for 3 doses of 300 mg for induction dose. Member will transition to subcutaneous form for self-administration for maintenance per FDA indicated dosage and will need to obtain through MediCal Rx benefit.
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
J2267	Injection, mirikizumab-mrkz, 1 mg	Induction: IV: 300 mg at weeks 0, 4, and 8. Maintenance: SUBQ dispensed as pharmacy benefit: 200 mg at week 12 and then q 4 weeks.

Requirements for Ustekinumab IV vials (Stelara™)

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	IV induction dosage (single dose) for the treatment of moderately to severely active Crohn's disease (CD) or ulcerative colitis (UC).
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	1) 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). 2) Treatment plan (Note: the single induction dose is recommended to be followed by 90 mg subcutaneous dose 8 weeks after induction dose, and every 8 weeks thereafter). 3) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease. 4) 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).
Age Restriction	18 years and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
Coverage Duration	Single fill/date of service. FDA indicated dosing is for a single IV dose for induction, followed by subcutaneous dosing thereafter.
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
J3358	Ustekinumab, for IV injections, 1 mg (only indicated for Crohn's or UC induction)	Member Weight / Recommended Dose ≤55 kg: 260 mg IV x 1 54-85 kg: 390 mg IV x 1 ≥86 kg: 520 mg IV x 1 *With transition to subcutaneous dosing after the initial IV induction dose*

Requirements for IV Vedolizumab (Entyvio™)

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) Crohn's disease (CD) 2) Ulcerative colitis (UC)
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy.
Required Medical Information	For all indications: 1) 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). 2) Treatment plan which includes consideration for transitioning to Entyvio Pen™ for SUBQ injection following first two doses of IV vedolizumab for induction dose. 3) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease. 4) 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). 5) Documentation of trial and failure at least 1 of the following a. TNF inhibitor (TNFi): adalimumab, infliximab (Inflectra™-preferred PA group 1) (Avsola™, Renflexis™-PA group 2), certolizumab (CD indication only) or subcutaneous golimumab (UC indication only) b. Ustekinumab
Age Restriction	18 yrs and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
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 PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3380	Injection, vedolizumab, 1 mg	300 mg at week 0, 2, 6 then every 8 weeks.

Requirements for Infliximab biosimilars, Group 1: infliximab-dyyb (Inflectra™)

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	Ankylosing spondylitis (AS), Crohn's disease (CD), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), and Ulcerative colitis (UC). In addition, infliximab biosimilars are coverable with an approved TAR for the off-label indication of nonradiographic axial spondyloarthritis (nr-axSpA).
Exclusion Criteria	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV).
Required Medical Information	All indications: • Specialist's clinic notes documenting disease course (activity, progression, severity), with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated) • Previous therapies tried and failed • Current evaluation (lab and imaging reports as appropriate for indication) • Treatment plan • 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) • Member's weight (dosing is weight-based, thus needed to confirm dose & billing units as part of TAR review process). • Documentation of trial and failure of at least 1 subcutaneously injected TNF inhibitor; which product would depend on the indication and recommendations from professional treatment guidelines &/or FDA approved indications. Other TNF inhibitors include: subcutaneously injected adalimumab, etanercept, golimumab, and certolizumab pegol. • CD/UC only: Please note, infliximab is now available in a subcutaneous formulation (Zymfentra™) and consideration for transitioning to this SUBQ formulation is recommended for convenience of self-administration and lower level of care. Zymfentra™ is FDA-approved for treating CD and UC. In addition, nr-axSpA, AS, CD, PsA, RA, and UC require a Disease Activity Score with TAR submission.
Age Restriction	For UC/CD: 6 years and older. For all other indications: 18 years or older
Prescriber Restriction	1) AS, RA, nr-axSpA: Rheumatologist 2) PsA: Dermatologist or Rheumatologist 3) HS, PP: Dermatologist 4) CD, UC: Gastroenterologist
Coverage Duration	Initial: up to 6 months (3 months for PP). Renewal: 12 months, with documentation of efficacy
Other Requirements & Information	For PP: Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Items (1), (2) and (3) must be met: (1) Patient has documented severe disease greater than 10% BSA affected OR b) less than10% BSA affected with involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlapping confirmed diagnosis of psoriatic arthritis AND (2) Patient has documented therapeutic failure of three months' trial, or inability to use, at least two non-biologic therapies: Methotrexate, Cyclosporin, Acitretin(Soriatane), Phototherapy w/ Methoxsalen (Oxsoralen); (3) Member has a documented history of an adequate (3 month) trial and failure/inadequate response (or contraindication) to

Requirements for Infliximab biosimilars, Group 1: infliximab-dyyb (Inflectra™)

	both adalimumab AND etanercept. Renewal: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. 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
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	CD, UC, PsA, PA, RA: Initiate at Weeks 0, 2 & 6; followed by every 8 weeks. AS, nr-axSpA: Same induction regimen as above, but maintenance is every 6 weeks (6-8 weeks per UpToDate).
		AS, nr-axSpA, PsA, PP, UC: 5 mg/kg CD: 5 mg/kg per dose (adults can be increased to 10 mg/kg) RA: Induction & maintenance is 3 mg/kg, but can be adjusted up to 10 mg/kg

Requirements for Infliximab biosimilars, Group 2: infliximab-axxq (Avsola™), infliximab-abda (Renflexis™)

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	Ankylosing spondylitis (AS), Crohn's disease (CD), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), and Ulcerative colitis (UC). In addition, infliximab biosimilars are coverable with an approved TAR for the off-label indication of nonradiographic axial spondyloarthritis (nr-axSpA).
Exclusion Criteria	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV).
Required Medical Information	All indications: • Specialist's clinic notes documenting disease course (activity, progression, severity), with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated) • Previous therapies tried and failed • Current evaluation (lab and imaging reports as appropriate for indication) • Treatment plan • 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) • Member's weight (dosing is weight-based, thus needed to confirm dose & billing units as part of TAR review process). • Documentation of trial and failure of at least 1 subcutaneously injected TNF inhibitor therapies; which product would depend on the indication and recommendations from professional treatment guidelines &/or FDA approved indications. Other TNF inhibitors include: subcutaneously injected adalimumab, etanercept, golimumab, and certolizumab pegol. • Documentation of trail and failure with preferred biosimilar to infliximab: Inflectra™ (PA group 1). • CD/UC only: Please note, infliximab is now available in a subcutaneous formulation (Zymfentra™) and consideration for transitioning to this SUBQ formulation is recommended for convenience of self-administration and lower level of care. Zymfentra™ is FDA-approved for treating CD and UC. In addition, nr-axSpA, AS, CD, PsA, RA, and UC require a Disease Activity Score with TAR submission.
Age Restriction	For UC/CD: 6 years and older. For all other indications: 18 years or older
Prescriber Restriction	1) AS, RA, nr-axSpA: Rheumatologist 2) PsA: Dermatologist or Rheumatologist 3) HS, PP: Dermatologist 4) CD, UC: Gastroenterologist
Coverage Duration	Initial: up to 6 months (3 months for PP). Renewal: 12 months, with documentation of efficacy
Other Requirements & Information	For PP: Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Items (1), (2) and (3) must be met: (1) Patient has documented severe disease greater than 10% BSA affected OR b) less than10% BSA affected with involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlapping confirmed diagnosis of psoriatic arthritis AND (2) Patient has documented therapeutic failure of three months' trial, or inability to use, at least two non-biologic therapies: Methotrexate, Cyclosporin, Acitretin (Soriatane), Phototherapy

Requirements for Infliximab biosimilars, Group 2: infliximab-axxq (Avsola™), infliximab-abda (Renflexis™)

	w/ Methoxsalen (Oxsoralen); (3) Member has a documented history of an adequate (3 month) trial and failure/inadequate response (or contraindication) to both adalimumab AND etanercept. Renewal: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. 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
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg	CD, UC, PsA, PA, RA: Initiate at Weeks 0, 2 & 6; followed by every 8 weeks. AS, nr-axSpA: Same induction regimen as above, but maintenance is every 6 weeks (6-8 weeks per UpToDate).
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	AS, nr-axSpA, PsA, PP, UC: 5 mg/kg CD: 5 mg/kg per dose (adults can be increased to 10 mg/kg) RA: Induction & maintenance is 3 mg/kg, but can be adjusted up to 10 mg/kg

Requirements for Infliximab (Remicade™)

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	Ankylosing spondylitis (AS), Crohn's disease (CD), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), and Ulcerative colitis (UC). In addition, infliximab biosimilars are coverable with an approved TAR for the off-label indication of non-radiographic axial spondyloarthritis (nr-axSpA).
Exclusion Criteria	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV).
Required Medical Information	All indications: • Specialist's clinic notes documenting disease course (activity, progression, severity), with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated) • Previous therapies tried and failed • Current evaluation (lab and imaging reports as appropriate for indication) • Treatment plan • 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) • Member's weight (dosing is weight-based, thus needed to confirm dose & billing units as part of TAR review process). • Documentation of trial and failure of at least 1 subcutaneously injected TNF inhibitor; which product would depend on the indication and recommendations from professional treatment guidelines &/or FDA approved indications. Other TNF inhibitors include: subcutaneously injected adalimumab, etanercept, golimumab, and certolizumab pegol. • Documentation of trail and failure with preferred biosimilar to infliximab: Inflectra™ (preferred PA group 1) or non-preferred biosimilar: Avsola™ or Renflexis™ (PA group 2). • CD/UC only: Please note, infliximab is now available in a subcutaneous formulation (Zymfentra™) and consideration for transitioning to this SUBQ formulation is recommended for convenience of self-administration and lower level of care. Zymfentra™ is FDA-approved for treating CD and UC. In addition, nr-axSpA, AS, CD, PsA, RA, and UC require a Disease Activity Score with TAR submission
Age Restriction	For UC/CD: 6 years and older. For all other indications: 18 years or older
Prescriber Restriction	1) AS, RA, nr-axSpA: Rheumatologist 2) PsA: Dermatologist or Rheumatologist 3) HS, PP: Dermatologist 4) CD, UC: Gastroenterologist
Coverage Duration	Initial: up to 6 months (3 months for PP). Renewal: 12 months, with documentation of efficacy
Other Requirements & Information	For PP: Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Items (1), (2) and (3) must be met: (1) Patient has documented severe disease greater than 10% BSA affected OR b) less than10% BSA affected with involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlapping confirmed diagnosis of psoriatic arthritis AND (2) Patient has documented therapeutic failure of three months' trial, or inability to use, at least two non-

Requirements for Infliximab (Remicade™)

	biologic therapies: Methotrexate, Cyclosporin, Acitretin (Soriatane), Phototherapy w/ Methoxsalen (Oxsoralen); (3) Member has a documented history of an adequate (3 month) trial and failure/inadequate response (or contraindication) to both adalimumab AND etanercept. Renewal: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. 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
J1745	Infliximab inj., excludes biosimilar, 10 mg (Remicade)	CD, UC, PsA, PA, RA: Initiate at Weeks 0, 2 & 6; followed by every 8 weeks. AS, nr-axSpA: Same induction regimen as above, but maintenance is every 6 weeks (6-8 weeks per UpToDate).
		AS, nr-axSpA, PsA, PP, UC: 5 mg/kg CD: 5 mg/kg per dose (adults can be increased to 10 mg/kg) RA: Induction & maintenance is 3 mg/kg, but can be adjusted up to 10 mg/kg

Requirements for difelikefalin (Korsuva™)

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 moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).
Exclusion Criteria	• CKD not on dialysis • CKD on peritoneal dialysis
Required Medical Information	1) Clinic notes documenting the duration and severity of pruritus and showing all of the following: a. Hemodialysis has been received 3 times per week for at least 3 months b. The pruritus is not attributed to a cause other than end stage renal disease or its complications c. The pruritus is not limited to occurring only during the dialysis session 2) Documentation that the dialysis dose has been optimized to reduce pruritus with a minimum delivered single-pool Kt/V of ≥1.2 3) Documentation that hyperparathyroidism and hyperphosphatemia are being adequately treated as evidenced by all of the following: a. Serum phosphorus concentration between 3.5 and 5.5 mg/dL (1.13-1.78 mmol/L) b. Serum corrected total calcium <9.5mg/dL (<2.37 mmol/L) c. Parathyroid hormone (PTH) <2-9x upper limit of normal (ULN) 4) Documentation of trial and failure to all of the following a. At least one topical therapy (pramoxine, corticosteroids) AND b. At least one oral therapy (antihistamine, gabapentin or pregabalin)
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by, or on the recommendation of a nephrologist
Coverage Duration	Initial: 3 months Renewal: 12 months
Other Requirements & Information	Renewal requests: the first renewal request should provide documentation of efficacy. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for difelikefalin (Korsuva™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	0.5mcg/kg at the end of each hemodialysis session

Requirements for Collagenase Clostridium Histolyticum CCH (Xiaflex™)

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 adults with Dupuytren's contracture with a palpable cord. 2) Treatment of adults with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy
Exclusion Criteria	Treatment of Peyronie plaques that involve the penile urethra
Required Medical Information	<u>Information requested for each indication:</u> 1) Clinic notes from specialist to confirm the diagnosis submitted and severity of disease (limited to FDA approved indications, found in the manufacturer's package labeling) 2) Treatment plan 3) Anticipated duration of treatment (if applicable) 4) Prescriber has completed the required Xiaflex training program -Risk Evaluation and Mitigation Strategy (REMS) due to Boxed warning: Corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease (Xiaflex). <u>For Dupuytren's contracture:</u> 1) Palpable cord. 2) Evidence of discomfort/functional impairment of hand interferes with ADLs. 3) Physical findings of either contracture at MCP joint greater than 30 degrees flexion or contracture at PIP joint greater than 20 degrees flexion. 4) Surgical interventions (percutaneous, open, or needle fasciectomy) option has been addressed are not preferred. <u>For Peyronie's disease:</u> 1) Palpable plaque. 2) Evidence of penile pain, nodule/plaque, indentation, curvature, deformity, functional impairment which interferes with ADLs such as Sexual Health Inventory for Men (SHIM) score. 3) Physical findings of curvature deformity of at least 30 degrees. 4) Surgical options (tunical shortening (eg, plication), tunical lengthening (eg, grafting), or implantation of penile prostheses) for stable disease have been addressed. 5) Prior treatment(s) that have been tried: • Pentoxifylline oral therapy for three months with no improvement in symptoms.
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with healthcare provider experienced in injection procedures of the hand for the treatment of Dupuytren's contracture. Prescribed by or in consultation with a urologist experienced in injection procedures for the treatment of Peyronie's disease
Coverage Duration	Dupuytren's contracture: TBD per number of palpable cords 6 month duration

Requirements for Collagenase Clostridium Histolyticum CCH (Xiaflex™)

	Peyronie's disease: 4 injections 6 month duration

Other Requirements & Information	For Peyronie's disease: Renewal: If more than 2 cycles (2 injections per cycle): Continued penile curvature >15 degrees and confirmed penile modeling or penile traction therapy for four to six weeks after CCH injections. 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
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg	**Dupuytren's contracture:** The usual dose is 0.58 mg, injected into a palpable Dupuytren's cord with a contracture followed 24 hours later by a finger extension procedure if a contracture persists. Injections and finger extension procedures may be administered up to 3 times per cord separated by ~4-week intervals. ***Note:*** Up to 2 injections per hand may be used during a treatment; 2 palpable cords affecting 2 joints or 1 palpable cord affecting 2 joints in the same finger may be injected at 2 locations during a treatment. Other palpable cords with contractures of MP or PIP joints may be injected at other treatment visits ~4 weeks apart. **Peyronie's disease:** The usual dose is 0.58 mg, injected into a palpable Peyronie plaque; repeat injection 1 to 3 days later. A penile modeling procedure should be performed 1 to 3 days after the second injection. Administer a second treatment cycle (two 0.58 mg injections and a penile modeling procedure) in ~6 weeks if needed. Subsequent treatment cycles should not be administered if the curvature deformity is <15 degrees after a treatment cycle or health care provider determines further treatment is not indicated. ***Note:*** If more than 1 plaque is present, inject into the plaque causing the curvature deformity. **Maximum dosage:** 4 treatment cycles (a total of 8 injection procedures and 4 penile modeling procedures). The safety of more than 1 treatment course (ie, 4 treatment cycles) is not known

Requirements for Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™)

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) Generalized myasthenia gravis (MG) in adults who are anti-acetylcholine receptor (AChR) antibody positive. 2) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo only)
Exclusion Criteria	• Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Concurrent use with ravulizumab (Ultomiris™), eculizumab (Soliris™), rozanolixizumab (Rystiggo™) or zilucoplan (Zilbrysq™)
Required Medical Information	MG 1) Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies 2) Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium 3) Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline 4) Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV 5) Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following: • Pyridostigmine • Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND • Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate CIDP (Vyvgart Hytrulo only): See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*
Age Restriction	18 years and older
Prescriber Restriction	Neurology
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 Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Vyvgart	J9332	Injection, efgartigimod alfa-fcab, 2 mg	10 mg/kg IV once weekly for 4 weeks. Subsequent cycles are repeated at least 50 days from the start of the previous cycle. Members weighing more than 120 kg: Maximum dose is 1.2 g IV.
Vyvgart Hytrulo	J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc	MG: 1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase once weekly for 4 weeks. Subsequent cycles are repeated at least 50 days from the start of the previous cycle. CIDP: 1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase once weekly

Requirements for Rozanolixizumab-noli (Rystiggo™)

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	Generalized myasthenia gravis (MG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.
Exclusion Criteria	• Myasthenia gravis LRP4 antibody positive or seronegative • Concurrent use with ravulizumab (Ultomiris™), eculizumab (Soliris™), zilucoplan (Zilbrysq™) or efgartigimod alfa-fcab (Vyvgart™)
Required Medical Information	1) Positive immunologic binding assay to confirm MG due to the presence of AChR or MuSK antibodies 2) Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium 3) Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline 4) Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV 5) Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to ALL of the following: • Pyridostigmine AND • Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND • Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate, AND • For anti-AChR antibody positive only: Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa, 2 mg and hyaluronidase-qvfc (Vyvgart Hytrulo)
Age Restriction	18 years and older
Prescriber Restriction	Neurology
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 Rozanolixizumab-noli (Rystiggo™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J9333	Injection, rozanolixizumab-noli, 1 mg	Weight based dosing: • Less than 50kg: 420mg • 50kg to less than 100kg: 560mg • 100kg and above: 850mg Dose given by subcutaneous infusion once weekly for 6 weeks. Subsequent cycles are repeated at least 63 days from the start of the previous cycle.

Requirements for Bevacizumab-maly (Alymsys™) and Bevacizumab-adcd (Vegzelma™)

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	• All FDA approved indications • Additional off-label uses as supported by national medical guidelines such as the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	None
Required Medical Information	1) Documented medical reason why a preferred biosimilar bevacizumab product cannot be used: a. Bevacizumab-awwb (Mvasi) OR b. Bevacizumab-bvzr (Zirabev)
Age Restriction	18 years or older
Prescriber Restriction	Oncologist or hematologist
Coverage Duration	Duration as determined by the specific regimen, up to 12 months
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
Alymsys	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	5-15mg/kg no more frequently than every 14 days
Vegzelma	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	5-15mg/kg no more frequently than every 14 days

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 (either due to intolerable adverse reaction or lack of efficacy) with ≥1 prior line of therapy which includes a protease 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: • 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 • 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 evidence of disease progression after two or more chemotherapy regimens recommended as first or second-line in compendia such as NCCN which may or may not have included therapy supported by allogeneic stem cell transplant. • Limitations of use: Not indicated for treatment of primary CNS lymphoma. **Follicular lymphoma, relapsed or refractory:** FDA-approved CAR-T therapies with this indication: **Kymriah™, Yescarta™.** • Documentation of treatment of relapsed or refractory follicular lymphoma in adults after two or more chemotherapy regimens recommended as first or second line in compendia such as NCCN that includes a combination of an anti-CD20 monoclonal antibody (e.g. rituximab, obinutuzumab) and an alkylating agent (e.g. bendamustine, cyclophosphamide, chlorambucil) **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™**.

- Documentation of treatment of relapsed or refractory B-cell precursor ALL.
- 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.

Mantle cell lymphoma, relapsed or refractory:

FDA-approved CAR-T therapies with this indication: **Tecartus™.**

- Documentation of treatment of relapsed or refractory mantle cell lymphoma (MCL) in adults.
- Documentation of prior treatment with, or intolerance or contraindication to, all of the following:
  a) Anthracycline or bendamustine containing chemotherapy
  b) An anti-CD20 antibody (rituximab)
  c) BTK (bruton tyrosine kinase) inhibitor (acalabrutinib, ibrutinib, zanubrutinib).

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