

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.

Aflibercept (Eylea™)	Aflibercept-yszy (Opuviz™)	Aflibercept-ayyh (Pavbu™)	Aflibercept-abzv (Enzeevu™)	Aflibercept-mrbb (Ahzantive™)
Aflibercept-jbvf (Yesafili™)	Aflibercept-boav (Eydenzelt™)	Aflibercept-hd (Eylea HD™)	Guselkumab IV (Tremfya™)	Guselkumab SC (Tremfya™)
Beremagene geperpavec- svdt (Vyjuvek™)	Pegcetacoplan (Syfovre™)	Avacincaptad pegol (Izervay™)	Travoprost Intracameral Implant (iDOSE TR™)	Capsaicin 8% patch (Qutenza™)
Lanreotide (Somatuline Depot™)	Lanreotide (Cipla 505(b)(2))	Pegzilarginase-nbln (Loargys™)	Teplizumab-mzwv (Tzield™)	Infliximab (Remicade™)
Infliximab-axxq (Avsola™)	Infliximab-dyyb (Inflectra™)	Infliximab-abda (Renflexis™)	Ustekinumab (Stelara IV™)	Ustekinumab-auub (Wezlana™)
Ustekinumab-ttwe (Pyzchiva™)	Ustekinumab-aekn (Selarsdi™)	Ustekinumab-aaaz (Otulfi™)	Ustekinumab-kfce (Yesintek™)	Ustekinumab-srlf (Imuldosa™)
Ustekinumab-stba (Steqeyma™)	Ustekinumab-hmny (Starjemza™)	Vedolizumab (Entyvio™)	Inebilizumab-cdon (Uplizna™)	Belimumab (Benlysta™)
Efgartigimod alfa-fcab (Vyvgart™)	Efgartigimod alfa and hyaluronidase- qvcf (Vyvgart Hytrulo™)	Rozanolixizumab-noli (Rystiggo™)	Nipocalimab-aahu (Imaavy™)	Anifrolumab-fnia (Saphnelo™)
Enzyme Replacement Drugs, multiple listed below Aldurazyme™; Brineura™; Cerezyme™; Vpriv™; Eleprase™; Fabrazyme™; Lumizyme™; Nexviazyme™; Mepsevii™; Naglazyme™; Vimizim™; Xenpozyme™)				

Requirements for Intravitreal Aflibercept (Eylea™ 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	FDA approved indications per product (not all biosimilars are approved for all conditions): 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) Retinopathy of prematurity (ROP)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	Diagnosis of AMD, macular edema following RVO, DME/DR+DME, or PDR: 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR) Diagnosis of ROP: 1) Must have a or b: a. Gestational age of ≤ 32 weeks b. Maximum birth weight of ≤ 1500 g (3.3 lb) 2) Must have diagnosis of a, b or c: a. ROP Zone I stage 1+, 2+, 3, & 3+ b. ROP Zone II Stage 2+, 3+ c. AP-ROP (aggressive posterior ROP) 3) Documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR)
Age Restriction	• DME, DR w/ DME, AMD, macular edema w/RVO: 18 years and older. • ROP: ≤ 52 weeks chronological age
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	• AMD, DME, DR w/ DME, & RVO: Limited to a maximum of 13 injections per 12 months (per eye). • ROP: 1 dose per affected eye per request
Other Requirements & Information	Renewal or retreatment requests: AMD, DME, DR w/ DME, PDR, & RVO: 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

Requirements for Intravitreal Aflibercept (Eylea™ and Biosimilars)

	<u>ROP:</u> 1) Current gestational age 2) Continues to be positive for diagnosis of a, b or c: a. ROP Zone I stage 1+, 2+, 3, & 3+ b. ROP Zone II Stage 2+, 3+ c. AP-ROP (aggressive posterior ROP) 3) Has had ≤ 2 prior treatments with aflibercept Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.
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Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Eylea™	J0178	Injection, aflibercept, 1 mg	AMD (all): 2mg every 4 weeks for 3 doses followed by 2 mg every 8 weeks (may be used monthly) DME & DR w/ DME, PDR (all): 2mg every 4 weeks for 5 doses followed by 2mg every 8 weeks (may be used monthly) RVO (all): 2mg every 4 weeks ROP (J0178 only): 0.4 mg into the affected eye, may repeat after a minimum interval of 10 days.
Opuviz™	Q5153	Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg	
Pavblu™	Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg	
Enzeevu™	Q5149	Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg	
Ahzantive™	Q5150	Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg	
Yesafili™	Q5155	Injection, aflibercept-jbvf (yesafili), biosimilar, 1 mg	
Eydenzelt™	Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg	

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) 4) Macular Edema Following Retinal Vein Occlusion (RVO)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	<u>Diagnosis of nAMD, DME, or RVO:</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. faricimab (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 faricimab (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	Limit to maximum of 13 injections per eye over 12 months 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, <i>Case-by-Case TAR Requirements and Considerations</i> .

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 8-20 weeks (+/- 1 week). Dose may be extended to every 20 weeks dosing schedule after completing 1 year of successful treatment. DR: 8mg every 4 weeks (+/- 7 days) for 3 doses followed by 8 mg every 8-12 weeks (+/- 1 week) RVO: 8mg every 4 weeks (+/- 7 days) for 3-5 doses followed by 8 mg every 8 weeks (+/- 1 week) Note: Some patients did not maintain a response with extended dosing intervals after success with the 3 to 5 initial monthly doses; these patients may benefit from resuming every-4-week (approximately every 21 to 35 days) dosing.

Requirements for Intravenous Guselkumab (Tremfya™)

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) Moderately to severely active ulcerative colitis (UC) 2) Moderately to severely active Crohn’s disease (CD) Note: please see Requirements for Subcutaneous Guselkumab (Tremfya) for criteria for plaque psoriasis, psoriatic arthritis, and maintenance dosing for UC and CD.
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. 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 of trial and failure to both of the following (a AND b) 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. 6) Reasons why Subcutaneous Guselkumab (Tremfya) cannot be used for induction dosing.
Age Restriction	18 years and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
Coverage Duration	Initial (induction dosing): 3 doses (8 weeks)
Other Requirements & Information	Following IV induction this medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled <i>Standard Requirements for Self-Administered Drugs</i>. Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.

Requirements for Intravenous Guselkumab (Tremfya™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1628	Injection, Guselkumab, 1 mg (intravenous product only)	Intravenous: - CD Induction: 200 mg at week 0, 4, and 8 OR 400mg at week 0, 4, and 8, transitioning to subcutaneous at week 12 or 16. - UC Induction: 200 mg at week 0, 4, and 8, transitioning to subcutaneous at week 12 or 16.

Requirements for Subcutaneous Guselkumab (Tremfya™)

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) Moderate to severe plaque psoriasis (PSO) 2) Active psoriatic arthritis (PsA) 3) Moderately to severely active ulcerative colitis (UC) 4) Moderately to severely active Crohn’s disease (CD) Note: please see Requirements for Intravenous Guselkumab (Tremfya) for criteria for IV induction dosing for Crohn’s Disease and Ulcerative Colitis.
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. 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) Reason(s) why the member is unable to obtain from a pharmacy for self-administration. 6) Current weight is ≥40kg Active PSO: 1) Documented therapeutic failure after a minimum 3-month trial of (or contraindication to) a TNFi: adalimumab (Humira), etanercept (Enbrel), or certolizumab (Cimzia). Note that at least one of (a, b, or c) is required for TNFi approval: a. Documentation of ≥ 10% BSA affected OR b. Documentation of <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 (TAR required) iv. Phototherapy in conjunction with methoxsalen (TAR required) Active PsA: 1) Rheumatology clinic notes to confirm diagnosis of PsA AND 2) Severe psoriatic arthritis with erosive disease and functional limitation or 3) Moderate to severe axial involvement or 4) Documented therapeutic failure after a minimum of a 3-month trial of (or contraindication to) at least one each from a (DMARD) and b (TNFi): a. Methotrexate, or other oral DMARD if member is unable to take methotrexate, AND b. TNFi: Adalimumab (Humira), etanercept (Enbrel), subcutaneous

Requirements for Subcutaneous Guselkumab (Tremfya™)

	golimumab (Simponi), or certolizumab (Cimzia). Moderately to severely active UC or CD (induction or maintenance dosing) 1) Documentation of trial and failure to both of the following (a AND b) 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	PSO & PSA: 6 years and older UC & CD: 18 years and older
Prescriber Restriction	PSO: Dermatologist PsA: Rheumatologist (prescribed or recommend by); a dermatologist may continue treatment that was initiated based on a rheumatologist's recommendation. UC & CD: Gastroenterologist
Coverage Duration	Case-dependent (medical office single dose requested vs outpatient hospital with multiple doses requested). Limited to the number of doses needed until the member is able to resume self-administration at home.
Other Requirements & Information	This medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled <i>Standard Requirements for Self-Administered Drugs</i>. Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1628	Injection, Guselkumab, 1 mg (subcutaneous product only)	Subcutaneous • PSO & PsA, 100 mg at week 0, 4 and then every 8 weeks. • CD & UC Induction: 400mg on weeks 0, 4, and 8. • CD & UC Maintenance:100 mg at week 16 and every 8 weeks thereafter OR 200mg at week 12 and every 4 weeks thereafter.



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 <i>collagen type VII alpha 1 chain (COL7A1) gene</i>
Exclusion Criteria	Use outside FDA approved indication
Required Medical Information	1) Diagnosis of DEB with genetic testing confirming mutations(s) in the <i>COLA7A1</i> gene 2) Presence of open DEB skin wounds 3) Medical reasons why the member or a caregiver is unable to self-administer at home 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	None
Prescriber Restriction	Dermatologist
Coverage Duration	Case-dependent (medical office single dose requested vs outpatient hospital with multiple doses requested). Limited to the number of doses needed until the member is able to resume self-administration at home.
Other Requirements & Information	Renewal requests: clinic notes documenting benefit from treatment This medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled <i>Standard Requirements for Self-Administered Drugs</i>.

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 Pegcetacoplan (Syfovre™)

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	Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
Exclusion Criteria	- Choroidal neovascularization (CNV) in either eye - GA is secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies) - Ocular or periocular infection - Active intraocular inflammation - GA lesions are exclusively subfoveal (also called foveal)
Required Medical Information	- Diagnosis of GA secondary to AMD - Best corrected visual acuity (BCVA) ≥ 24 ETDRS letters (20/320 Snellen equivalent or better) - GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2 - Presence of non-subfoveal lesions (also called extrafoveal lesions, or lesions that are not affecting the foveal center point)
Age Restriction	60 years and older
Prescriber Restriction	Ophthalmologist
Coverage Duration	Initial and renewal: 12 months
Other Requirements & Information	Renewal criteria: documentation of a positive clinical response to therapy which may include a reduction or stabilization in the rate of vision decline, or stabilization or reduction in total area of GA lesions. Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.

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

HCPCS	Description	Dosing, Units
J2781	Injection, pegcetacoplan, intravitreal, 1 mg	15 mg (0.1 mL) into affected eye(s) once every 25 to 60 days



Requirements for Avacincaptad Pegol (Izervay™)

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	Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
Exclusion Criteria	- Choroidal neovascularization (CNV) in either eye - GA is secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies) - Ocular or periocular infection - Active intraocular inflammation - GA lesions are exclusively subfoveal (also called foveal)
Required Medical Information	- Diagnosis of GA, secondary to AMD - Best corrected visual acuity (BCVA) between 20/25 and 20/320 - GA lesion size ≥ 2.5 and ≤ 17.5 mm² with at least 1 lesion ≥ 1.25 mm² - Presence of non-subfoveal lesions (also called extrafoveal lesions, or lesions that are not affecting the foveal center point)
Age Restriction	50 years or older
Prescriber Restriction	Ophthalmologist
Coverage Duration	Initial and renewal: 12 months
Other Requirements & Information	Renewal criteria: documentation of a positive clinical response to therapy which may include a reduction or stabilization in the rate of vision decline, or stabilization or reduction in total area of GA lesions. Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J2782	Injection, avacincaptad pegol, 0.1 mg	2 mg (0.1 mL) into affected eye(s) once monthly (~every 21 to 35 days)

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 - Concurrent use (within the prior 6 months) of Durysta in the same eye
Required Medical Information	- Baseline IOP - 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. - Beta-blockers - Alpha-2 agonists - Carbonic anhydrase inhibitor - Prostaglandin analog - Cholinergic agents - Rho kinase inhibitors - 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	12 months: One implant per eye per year
Other Requirements & Information	Renewal requests will require clinic notes documenting all of the following (1-5) - IOP was controlled following initial administration of iDose TR - Medical necessity of re-administration at the time of TAR submission, such as, documented loss of IOP control - Current/Prior iDose TR implant has not dislocated from implantation site - There is no ocular or periocular infection - The member has not experienced central corneal endothelial cell loss of 10% or greater from pre-administration baseline (adjusted for age-related 1% loss per year and for a 10% loss following an anterior segment surgical procedure [e.g., cataract surgery]) Requests for off-label use: See PHC criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.



Requirements for Travoprost, Intracameral Implant (iDOSE TR)

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 Capsaicin 8% patch (Qutenza™)

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	- Neuropathic pain associated with postherpetic neuralgia (PHN) - Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
Exclusion Criteria	None
Required Medical Information	<u>Requirements for PHN</u> - Clinic notes documenting focal neuropathic or neuralgic pain persisting for ≥3 months in the same dermatomal distribution as a preceding episode of acute herpes zoster - Trial and failure of a ≥30-day trial while at an effective target dose of at least TWO of the following oral options (a, b, c, or d): - Amitriptyline or Nortriptyline at a dose of ≥50mg/day - Gabapentin ≥900mg/day or Pregabalin ≥300mg/day - Duloxetine ≥60mg/day or Venlafaxine ≥150mg/day - Oxcarbazepine ≥900mg/day or Carbamazepine ≥600mg/day <i>Note: if the target dose cannot be reached due to tolerability, a ≥30-day trial of the maximum tolerated dose is accepted</i> <u>Requirements for DPN</u> - Clinic notes documenting a diagnosis of pain associated with diabetic peripheral neuropathy of the feet - For patients on metformin, vitamin B12 deficiency has been ruled out - Trial and failure of a ≥30-day trial while at an effective target dose of at least ONE of the following oral options (a, b, or c): - Amitriptyline ≥100mg/day or other tricyclic antidepressant at comparable dose - Gabapentin ≥900mg/day or Pregabalin ≥300mg/day - Duloxetine ≥60mg/day or Venlafaxine ≥150mg/day <i>Note: if the target dose cannot be reached due to tolerability, a ≥30-day trial of the maximum tolerated dose is accepted</i>
Age Restriction	18 years and older
Prescriber Restriction	None
Coverage Duration	12 months
Other Requirements & Information	<u>First Renewal Requirements:</u> Updated clinic notes documenting member has experienced an improvement in their neuropathic pain and is tolerating Qutenza Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>

Requirements for Capsaicin 8% patch (Qutenza™)

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

HCPCS	Description	Dosing, Units
J7336	Capsaicin 8% patch, per square centimeter	The recommended dose of QUTENZA for neuropathic pain associated with postherpetic neuralgia is a single, 60-minute application of up to four topical systems The recommended dose of QUTENZA for neuropathic pain associated with diabetic peripheral neuropathy is a single, 30-minute application on the feet of up to four topical systems Treatment with QUTENZA may be repeated every three months or as warranted by the return of pain (not more frequently than every three months) One patch is 280cm² (280 HCPCS units), maximum dosing allows up to 4 patches (1120 HCPCS units) every 3 months for an annual maximum of 4480 HCPCS units

Requirements for Lanreotide Depot (Somatuline Depot™)

cUnless 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	Acromegaly, carcinoid syndrome, and Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
Exclusion Criteria	None
Required Medical Information	1) Acromegaly, carcinoid syndrome: Requires clinical notes confirming diagnosis. 2) Gastroenteropancreatic neuroendocrine tumors (GEP-NETs): Clinical notes and imaging (MRI or multiphase CT AND somatostatin receptor-based imaging) confirming diagnosis of loco regional advanced and/or metastatic neuroendocrine tumor(s) of the GI tract, lung, or thymus.
Age Restriction	18 years and older
Prescriber Restriction	Oncologist, gastroenterologist or endocrinologist
Coverage Duration	Up to 12 months
Other Requirements & Information	Records from member’s prescriber must show prior use and failure (or contraindication) of both octreotide acetate (immediate-release) AND octreotide LAR Depot. Requests for off-label use: See PHC criteria document <i>Case-by-Case TAR Requirements and Considerations</i> .

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

Product	HCPCS	Description	Dosing, Units
Somatuline™ Depot Injection 60 mg/0.2 ml 90 mg/0.3 ml 120 mg/0.5 ml	J1930	Injection, lanreotide, 1 mg	1 billing unit = 1 mg <u>Acromegaly:</u> Recommended starting dose is 90 mg by deep subcutaneous injection every 4 weeks for 3 months, adjusted thereafter based on GH and/or IGF-1 levels: • GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot dose at 90 mg every 4 weeks • GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot dose to 120 mg every 4 weeks • GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot dose to 60 mg every 4 weeks <u>Carcinoid Syndrome and GEP-NETs:</u> • 120 mg every 4 weeks
Lanreotide Acetate (depot) 120 mg/0.5 ml	J1932	Injection, lanreotide, (Cipla), 1 mg	

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™. 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	Vpriv™: ≥ 4 yrs Brineura™: 3-18 yrs Nexviazyme™: ≥ 1 yr Fabrazyme™: ≥ 2 yrs Elaprase™: ≥ 5 yrs; 16 months to <5 years-limited data available
Prescriber Restriction	Neurologist, endocrinologist, cardiologist, hepatologist, pulmonologist, genetic disease or other specialist familiar with treating lysosomal storage disorders.
Coverage Duration	Initial & Renewal: 6 months



Requirements for Enzyme Replacement Drugs

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 <i>Case-by-Case TAR Requirements and Considerations</i>.
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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 (Eleprase™)	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 pegzilarginase-nbln injection (Loargys™)

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 hyperargininemia in adult pediatric patients ≥2 years of age with arginase 1 deficiency (ARG1-D), in conjunction with dietary protein restriction
Exclusion Criteria	• Symptomatic hyperammonemia (ammonia ≥100 μM requiring acute care or hospitalization) within 6 weeks before first Loargys dose • Extreme mobility impairment (i.e. unable to complete assessment) • Prior liver or hematopoietic transplant
Required Medical Information	1. Documented diagnosis of ARG1-D: biochemical evidence of the disease with one of the following: a. Plasma amino acid panel showing persistently elevated plasma arginine (pArg) levels (mean of all screening values with pArg ≥250 μmol/L) b. Molecular genetic test identifying biallelic pathogenic variants in ARG1, OR c. RBC arginase activity assay showing diminished erythrocyte ARG1 activity 2. Impairment on any secondary functional mobility assessment 3. Documentation that patient will use the drug in conjunction with a protein-restricted diet 4. Documentation of recent weight to confirm dose requested 5. Dose requested is to start at 0.1 mg/kg once weekly (dose adjustments not to exceed 0.2 mg/kg once weekly) 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 of age and older
Prescriber Restriction	Metabolic (genetic) specialist or neurologist experienced in urea cycle disorders (UCDs)
Coverage Duration	• Initial approval of 6 months in order to verify response to treatment (reduction in pArg) • Continued approval can be granted in 12-month cycles with documented response (pARG levels below the upper limit of normal)
Other Requirements & Information	Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i> . .



Requirements for pegzilarginase-nbln injection (Loargys™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Loargys	J3590 (NOC)	Unclassified biologics: pegzilarginase-nbln	0.1-0.2 mg/kg injected intravenously once weekly. After 8 weeks on once-weekly IV dosing, can switch to once-weeklySUBQ under healthcare professional supervision.

Requirements for Teplizumab-mzwv (TzielTM)

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	- Delay onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 1 year an older with Stage 2 T1D - Delay decline in insulin production in pediatric patients (ages 8-17) who have been diagnosed with stage 3 T1D within the last 12 weeks
Exclusion Criteria	Stage 3 T1D: Diagnosis of stage 3 T1D longer than 12 weeks ago
Required Medical Information	Diagnosis of Stage 2 type 1 diabetes confirmed by all of the following: - Documentation of at least 2 of the following type 1 diabetes-related autoantibodies within the last 6 months. Any positive test should have repeat confirmatory testing completed: - Islet cell autoantibody (ICA) - Glutamic acid decarboxylase 65 (GAD) autoantibody - Zinc transporter 8 autoantibody (ZnT8A) - Insulinoma-associated antigen 2 autoantibody (IA-2A) - Insulin autoantibody (IAA) - Documentation of dysglycemia without overt hyperglycemia within the preceding 2 months defined as one of the following: - Fasting plasma glucose level 100-125 mg/dL; OR - Two-hour postprandial plasma glucose 140-199 mg/dL; OR - Postprandial glucose level at 30, 60 or 90 minutes ≥ 200 mg/ dL; OR - A1C 5.7-6.4% - Documentation type 2 diabetes has been ruled out based on clinical history. - Body surface area (BSA) needed for dosing. - Administering facility must be able to accommodate 14 consecutive calendar days of administration. Diagnosis of Stage 3 type 1 diabetes confirmed by all of the following: - Documentation of at least 1 of the following type 1 diabetes-related autoantibodies within the last 6 months Any positive test should have repeat confirmatory testing completed: - Islet cell autoantibody (ICA) - Glutamic acid decarboxylase 65 (GAD) autoantibody - Zinc transporter 8 autoantibody (ZnT8A) - Insulinoma-associated antigen 2 autoantibody (IA-2A) - Insulin autoantibody (IAA) - Residual β-cell function, defined as a peak stimulated C-peptide level ≥0.2 pmol/mL on a mixed-meal stimulation test - Stage 3 type 1 diabetes diagnosed within the last 12 weeks - Documentation type 2 diabetes has been ruled out based on clinical history. - Body surface area (BSA) needed for dosing. - Administering facility must be able to accommodate 12 consecutive calendar days of administration every 6 months for 2 courses.
Age Restriction	Stage 2 T1D: 1 year and older Stage 3 T1D: ages 8-17 years
Prescriber Restriction	Endocrinologist or diabetologist or in consultation and recommendation by endocrinologist or diabetologist

Requirements for Teplizumab-mzwv (TzielTM)

Coverage Duration	Stage 2 T1D: 14-day treatment course only, once per lifetime. Stage 3 T1D: Two 12-day treatment courses once every 6 months only, once per lifetime.
Other Requirements	Note, prior to initiating therapy, provider must have awareness of the following: 1) Completion of age-appropriate vaccinations. 2) No evidence of active serious infections (i.e. Epstein-Barr virus or cytomegalovirus infection). 3) Adequate hepatic function at baseline (i.e. ALT/AST, bilirubin) 4) Adequate hematologic function at baseline (i.e. platelets, hemoglobin, absolute neutrophil count, lymphocytes). 5) Member is not pregnant. Note that each 2 ml single dose vial (SDV) contains 2,000 mcg (2 mg), equivalent to 400 HCPCS billing units per vial. Vials are diluted to 100 mcg/ml and must be administered within 4 hours of being diluted, with remainder discarded (see Partnership Drug Waste policy for billing waste with JW modifier. TARs must include both the dose and anticipated waste amounts. Waste units must be billed separately from the administered dose units, using the JW modifier as stated in Policy MPRP4062, Drug Wastage Payments. The number of units on the authorized TAR will be sufficient for both dose and waste claims. 1 vial per day is sufficient for all doses up to a BSA of 1.94 m². Requests for more than 1 vial (400 billing units) per day must include the member’s current BSA.

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

HCPCS	Description	Dosing, Units
J9381	Injection, teplizumab-mzwv, 5 mcg	A single vial (2 ml=2,000 mcg) is 400 HCPCS units (5 mcg/unit). For BSA <= 1.94 m2, maximum reimbursement is for 1 vial, 400 units (includes dose + waste). Stage 2 T1D: Administer once daily for 14 consecutive days. <u>Day 1:</u> 65 mcg/m2 body surface area (BSA) IV once daily <u>Day 2:</u> 125 mcg/m2 BSA <u>Day 3:</u> 250 mcg/m2 BSA <u>Day 4:</u> 500 mcg/m2 BSA <u>Day 5 to day 14:</u> 1,030 mcg/m2 BSA once daily If a planned infusion dose is missed, resume dosing by administering all remaining doses on consecutive days to complete the 14-day treatment course. Stage 3 T1D: Administer once daily for 12 consecutive days once every 6 months for 2 courses. <u>Day 1:</u> 106 mcg/m2 body surface area (BSA) <u>Day 2:</u> 425 mcg/m2 BSA <u>Day 3-12:</u> 850 mcg/m2 BSA

Requirements for Infliximab (Remicade™) and biosimilars

cUnless 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). Please note-use of biosimilars are preferred: Avsola, Inflectra, and Renfлексis Non-preferred brand: Remicade.
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 biosimilars to infliximab: Inflectra, Avsola or Renfлексis . • 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. • If requesting use of brand Remicade, please submit additional information regarding reason(s) why preferred biosimilars cannot be used. 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

Requirements for Infliximab (Remicade™) and biosimilars

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 than 10% 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 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 <i>Case-by-Case TAR Requirements and Considerations</i>.
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Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1745	Infliximab inj., excludes biosimilar, (Remicade), 10 mg	<u>CD, UC, PsA, PA, RA</u> : Initiate at Weeks 0, 2 & 6; followed by every 8 weeks.
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg	<u>AS, nr-axSpA</u> : Same induction regimen as above, but maintenance is every 6 weeks (6-8 weeks per UpToDate).
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	<u>AS, nr-axSpA, PsA, PP, UC</u> : 5 mg/kg <u>CD</u> : 5 mg/kg per dose (adults can be increased to 10 mg/kg)
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	<u>RA</u> : Induction & maintenance is 3 mg/kg, but can be adjusted up to 10 mg/kg



Requirements for IV Ustekinumab (Stelara™) and biosimilars (IV products only)

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). Please note the following are preferred brands: Stelara, Steqeyma, Wezlana, and Pyzchiva. Non-preferred brands: Imuldosa, Yesintek, Selarsdi, Otulfi, and Starjemza.
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). 5) If requesting use of Imuldosa, Yesintek, Selarsdi, Otulfi, or Starjemza, please submit additional information regarding reason(s) why preferred options cannot be used.
Age Restriction	Crohn’s Disease: ≥2 years Ulcerative Colitis: ≥18 years
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 Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i> .

Requirements for IV Ustekinumab (Stelara™) and biosimilars (IV products only)

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)	<table><tr><th>Member Weight</th><th>Recommended Dose</th></tr><tr><td>≤55 kg</td><td>260 mg IV x 1</td></tr><tr><td>54-85 kg</td><td>390 mg IV x 1</td></tr><tr><td>≥86 kg</td><td>520 mg IV x 1</td></tr></table> <i>With transition to subcutaneous dosing after the initial IV induction dose</i>	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
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									
Q5138	Injection, ustekinumab-auub (Wezlana), biosimilar, intravenous, 1 mg (only indicated for Crohn’s or UC induction)									
Q9997	Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg (only indicated for Crohn’s or UC induction)									
Q9998	Injection, ustekinumab-aekn (Selarsdi), 1 mg (only indicated for Crohn’s or UC induction)									
Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg									
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg									
Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg									
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg									
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg									



Requirements for IV Vedolizumab (Entyvio™)

cUnless 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: - 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 which includes plan for transitioning to Entyvio Pen for subcutaneous injection following first two to three doses of IV vedolizumab for induction only. - Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease. - 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). - Documentation of trial and failure at least 1 of the following - TNF inhibitor (TNFi): adalimumab, infliximab, certolizumab (CD indication only) or subcutaneous golimumab (UC indication only) - Ustekinumab
Age Restriction	18 yrs and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
Coverage Duration	Initial: up to 3 doses for IV induction dose only Renewal: Requires medical justification for inability to transition to subcutaneous product (Entyvio Pen) .
Other Requirements & Information	Requests for off-label use: See PHC criteria document <i>Case-by-Case TAR Requirements and Considerations</i> .

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. Partnership requires transition to subcutaneous pen after initial induction dose

Requirements for Inebilizumab-cdon (Uplizna™)

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	- Neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) IgG antibody positive. - Immunoglobulin G4-related disease (IgG4-RD) - Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive
Exclusion Criteria	- History of a life-threatening infusion reaction to inebilizumab; active hepatitis B infection; tuberculosis (TB) disease (active TB) or untreated TB infection (latent TB). - NMOSD: Use along with IV eculizumab (Soliris™) or SUBQ satralizumab (Enspryng™) - NMOSD negative AQP4-IgG - IgG4-RD: Use along with rituximab - gMG: LRP4 antibody positive or triple seronegative - gMG: Concurrent use with other systemic biologic agents for refractory gMG (such as Complement Inhibitors, Neonatal Fc Receptor Antagonists, or anti-CD20 monoclonal antibodies)
Required Medical Information	All requests should include documentation that member has been screened for hepatitis B virus (HBsAg and anti-HBc measurements) and active tuberculosis prior to treatment initiation. Submit the following per indication: <u>Requests for neuromyelitis optica spectrum disorder (NMOSD) (AQP4 IgG positive) required documentation of ALL of the following:</u> - At least one of the following: - Optic neuritis - Acute myelitis - Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting - Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions - Symptomatic cerebral syndrome with NMOSD-typical brain lesions - Seropositive for AQP4-IgG antibodies - Baseline Expanded Disability Status Scale (EDSS) score - Provider to submit reason(s) why satralizumab (Enspryng™) cannot be used, as the lower- level of care agent. <u>Requests for Immunoglobulin G4-related disease (IgG4-RD) require documentation of ALL the following:</u> - Diagnosis of IgG4-RD including documentation to show BOTH of the following: - Clinical or radiologic evidence of tumor-like swelling of organs

Requirements for Inebilizumab-cdon

(Uplizna™)

	involved. b. Biopsy of the involved organs that demonstrates ALL of the following: i. Lymphoplasmacytic infiltrate enriched in IgG4-positive plasma cells ii. Storiform fibrosis (typified by a cartwheel appearance of the arranged fibroblasts and inflammatory cells) iii. Obliterative phlebitis 2) Other conditions (eg. malignancy, infection, other autoimmune disorders etc) have been ruled out. 3) IgG4-RD affecting 2 or more of the following organ/sites at any time: a. Pancreas b. Bile ducts/biliary tree c. Orbits d. Lungs e. Kidneys f. Lacrimal glands g. Major salivary glands h. Retroperitoneum i. Aorta j. Pachymeninges k. Thyroids glands 4) Member is experiencing (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoid treatment and/or recurrent disease. a. Flare is defined as new or worsening clinical features of IgG4-RD for which no clear alternative diagnosis exists. 5) Refractory to or unable to use glucocorticoids (including glucocorticoid dependence). a. Refractory to glucocorticoids is defined as inability to experience symptom relief, reduction in mass/organ size, improvement in organ function, or adequate decreases in serum IgG4 concentrations from glucocorticoids alone. b. This includes patients who are glucocorticoid-dependent (i.e. unable to reduce glucocorticoid dose to <5 mg/day) without causing disease flare or worsening of symptoms. 6) Trial and failure, or contraindication to, rituximab (biosimilar preferred).or explanation from the provider as to why rituximab is not appropriate. Generalized Myasthenia Gravis (gMG): 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 with at least 50% of the score coming from non-ocular symptoms 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: a. Pyridostigmine AND b. Moderate to high dose glucocorticoids (onset 2-3 weeks and
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Requirements for Inebilizumab-cdon (Uplizna™)

	peaks 5.5 months), tapered to the lowest effective dose AND c. Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate (prior use of rituximab may also meet this requirement for MuSK+ disease), AND d. Self-administered efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™), or reasons why the member is unable to use a self-administered product.
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Age Restriction	18 years and older
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Prescriber Restriction	NMOSD: Specialty providers may include neurologist, ophthalmologist, immunologist, hematologist or other physician with experience treating NMOSD. IgG4-RD: Specialty providers may include rheumatologists, immunologists, endocrinologists, nephrologists, hepatologists, or other physician with experience in treating IgG4-RD. gMG: Neurologist
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Coverage Duration	<u>Initial request with loading dose:</u> 6 months <u>Renewal:</u> 12 months with documentation to indicate a positive response to treatment.
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Other Requirements & Information	<u>Renewal requests gMG:</u> Clinical notes with current MG-ADL and MGFA classification Requests for off-label use: See Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i> .
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Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1823	Intravenous injection, Inebilizumab-cdon, 1 mg	<u>Loading Dose:</u> IV: 300 mg on day 1, followed by 300 mg 2 weeks later on day 15. <u>Maintenance Dose:</u> IV: 300 mg every 6 months (6 months starts after the first 300 mg dose)

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) 2) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo only) Vyvgart Hytrulo PFS is a self-administered product and will fall under Partnership's Standard Requirements for Self-Administered Drugs
Exclusion Criteria	• Concurrent use with other systemic biologic agents for refractory gMG (such as Complement Inhibitors, Neonatal Fc Receptor Antagonists, or anti-CD19 monoclonal antibodies)
Required Medical Information	<u>Generalized Myasthenia Gravis (gMG):</u> 1) Diagnosis of generalized MG with documentation of ONE of the following (a or b) a) Positive immunologic binding assay to confirm MG due to the presence of antibodies to one of the following: acetylcholine receptor (AChR), muscle-specific tyrosine kinase (MuSK), or low-density lipoprotein receptor-related protein 4 (LRP4), OR b) If triple seronegative, the diagnosis of MG has been confirmed with electrodiagnostic studies including both nerve conduction testing with repetitive nerve stimulation (RNS) AND electromyography (EMG). Single-fiber electromyography (SFEMG) may be required if the results of RNS and EMG are inconclusive. 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 ≥5 with at least 50% of the score coming from non-ocular symptoms 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: a) Pyridostigmine b) Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND c) Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate, (prior use of rituximab may also meet this requirement for MuSK+ disease), AND d) Self-administered efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™) <u>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo only):</u> 1) Confirmation of diagnosis based on the European Academy of Neurology (EAN/PNS) guidelines (see Other Requirements and Information for EAN/PNS criteria) 2) Electro diagnostic findings of peripheral nerve demyelination 3) Exclusion of other similar disease states that overlap with similar symptoms, such as but not limited to: a. Neuropathy probably caused by B. burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure

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

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

		4. At least two motor nerves must have abnormalities which fulfil the motor conduction criteria. If criteria are fulfilled in only one nerve, the diagnosis is possible typical CIDP. See Box: Motor Nerve Conduction Criteria below. 5. Sensory conduction abnormalities must be present in at least two nerves. See Box: Sensory Nerve Conduction Criteria below. Note: In patients suspected of having typical CIDP because they fulfil clinical criteria but not minimal electrodiagnostic criteria, the diagnosis of possible typical CIDP may be made if there is objective improvement following treatment with IVIg, corticosteroids or plasma exchange AND if at least one additional supportive criterion (2-5) is fulfilled. See Box: Supportive Criterion below.	
	Distal CIDP	1. Progressive or relapsing, symmetric, distal sensory loss and muscle weakness predominantly in lower limbs 2. Developing over at least 8 weeks 3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs). 6. Motor conduction criteria fulfilment is required in at least two upper limb nerves to confirm the clinical diagnosis of distal CIDP. The distal negative peak CMAP amplitude should be at least 1 mV. When criteria are fulfilled in two lower limb but not upper limb nerves or if criteria are fulfilled in only one upper limb nerve, the maximum diagnostic certainty is possible distal CIDP. See Box: Motor Nerve Conduction Criteria below. 4. Sensory conduction abnormalities must be present in at least two nerves. See Box: Sensory Nerve Conduction Criteria below.	
	Multifocal CIDP	1. Progressive or relapsing, sensory loss and muscle weakness in a multifocal pattern, usually asymmetric, upper limb predominant, in more than one limb 2. Developing over at least 8 weeks 3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs). 7. Motor conduction criteria fulfilment is required in at least two nerves in total in more than one limb. When criteria are fulfilled in only one nerve, the maximum diagnostic certainty is possible multifocal CIDP. See Box: Motor Nerve Conduction Criteria below. 4. Sensory conduction abnormalities must be present in at least two nerves of the affected limbs for the diagnosis of multifocal CIDP. See Box: Sensory Nerve Conduction Criteria below.	
	Focal CIDP	1. Progressive or relapsing, sensory loss and muscle weakness in only one limb. 2. Developing over at least 8 weeks. 3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs). 8. Motor conduction criteria fulfilment is required in at least two nerves in total in more than one limb to confirm the clinical	

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		diagnosis of multifocal CIDP and in at least two nerves in one limb for the diagnosis of focal CIDP. When criteria are fulfilled in only one nerve, the maximum diagnostic certainty is possible multifocal or possible focal CIDP. See Box: Motor Nerve Conduction Criteria below. 4. Sensory conduction abnormalities must be present in at least two nerves of the affected limb for the diagnosis of focal CIDP and in one nerve of the affected limb for the diagnosis of possible focal CIDP. See Box: Sensory Nerve Conduction Criteria below.	
	Motor CIDP (and motor-predominant)	1. Progressive or relapsing, symmetric, proximal and distal muscle weakness of upper and lower limbs, without sensory involvement. 2. Developing over at least 8 weeks 3. Absent or reduced tendon reflexes in all limbs 9. Motor CIDP must fulfil motor conduction criteria in at least two nerves and sensory conduction must be normal in all of at least four nerves (median, ulnar, radial, and sural) to confirm the clinical diagnosis of motor CIDP. If criteria are fulfilled in only one motor nerve, the diagnosis is possible motor CIDP. See Box: Motor Nerve Conduction Criteria below. Note: Motor CIDP with sensory conduction abnormalities in two nerves is diagnosed as motor-predominant CIDP.	
	Sensory CIDP (and sensory predominant)	1. Progressive or relapsing, symmetric sensory involvement of at least two limbs, without motor involvement. 2. Developing over at least 8 weeks 3. Absent or reduced tendon reflexes in all limbs 4. Sensory CIDP must fulfil sensory conduction criteria and motor conduction must be normal in all of at least four nerves (median, ulnar, peroneal, and tibial) to confirm the clinical diagnosis. The maximum diagnostic certainty is possible sensory CIDP. See Box: Sensory Nerve Conduction Criteria below. Note: Sensory CIDP with motor conduction criteria fulfilled in one nerve is diagnosed as possible sensory-predominant CIDP. If motor conduction criteria are fulfilled in two nerves, the diagnostic certainty increases to sensory-predominant CIDP.	
	Motor Nerve Conduction Criteria:	One of the following strongly supports demyelination (if the criteria only applies to 1 nerve, it is weakly supportive): 1. Motor distal latency prolongation $\geq 50\%$ above ULN in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome), or 2. Reduction of motor conduction velocity $\geq 30\%$ below LLN in two nerves, or 3. Prolongation of F-wave latency $\geq 20\%$ above ULN in two nerves ($\geq 50\%$ if amplitude of distal negative peak CMAP $< 80\%$ of LLN), or 4. Absence of F-waves in two nerves (if these nerves have distal negative peak CMAP amplitudes $\geq 20\%$ of LLN) + ≥ 1 other demyelinating parameters in ≥ 1 other nerve, or	

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		5. Motor conduction block: $\geq 30\%$ reduction of the proximal relative to distal negative peak CMAP amplitude, excluding the tibial nerve, and distal negative peak CMAP amplitude $\geq 20\%$ of LLN in two nerves; or in one nerve + ≥ 1 other demyelinating parameters except absence of F-waves in ≥ 1 other nerve, or 6. Abnormal temporal dispersion: $>30\%$ duration increase between the proximal and distal negative peak CMAP (at least 100% in the tibial nerve) in ≥ 2 nerves, or 7. Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) prolongation in ≥ 1 nerveb + ≥ 1 other demyelinating parameters in ≥ 1 other nerve (LFF 2 Hz) median > 8.4 ms, ulnar > 9.6 ms, peroneal > 8.8 ms, tibial > 9.2 ms (LFF 5 Hz) median > 8.0 ms, ulnar > 8.6 ms, peroneal > 8.5 ms, tibial > 8.3 ms (LFF 10 Hz) median > 7.8 ms, ulnar > 8.5 ms, peroneal > 8.3 ms, tibial > 8.2 ms (LFF 20 Hz) median > 7.4 ms, ulnar > 7.8 ms, peroneal > 8.1 ms, tibial > 8.0 ms	
	Sensory Nerve Conduction Criteria	1. For a diagnosis of CIPD: Sensory conduction abnormalities (prolonged distal latency, or reduced SNAP amplitude, or slowed conduction velocity outside of normal limits) in two nerves. 2. For a diagnosis of “possible CIPD”: - sensory nerve conduction velocity $<80\%$ of LLN (for SNAP amplitude $>80\%$ of LLN) or $<70\%$ of LLN (for SNAP amplitude $<80\%$ of LLN) in at least two nerves (median, ulnar, radial, sural nerve), OR - Sural sparing pattern (abnormal median or radial sensory nerve action potential [SNAP amplitude] with normal sural nerve SNAP amplitude) (excluding carpal tunnel syndrome).	
	Supportive Criterion	1. Objective response to treatment with immunomodulatory agents (IVIg, plasma exchange, corticosteroids). The changes required to define improvement have not been adequately validated. The following which have been used in clinical trials can serve as a guide: - I-RODS: + ≥ 4 centile points - INCAT disability scale: - ≥ 1 point - mISS: - ≥ 2 points - MRC sum score (0-60): + ≥ 2 to 4 points* - Grip strength: Martin Vigorimeter: + ≥ 8 to 14 kPa* OR Jamar hand grip dynamometer: + $\geq 10\%^{**}$ 2. Imaging: only recommended when diagnosis is “possible CIPD”: before concluding that ultrasound or MRI abnormalities are supportive of CIDP, there should be no laboratory/clinical features that suggest other diseases that mimic CIDP (these are listed). - Ultrasound showing nerve enlargement of at least two sites in proximal median nerve segments	

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

		and/or the brachial plexus b. MRI showing enlargement and/or increased signal intensity of nerve root(s) on T2 weighted MRI sequences (DIXON/STIR, coronal + sagittal planes) 3. CSF evaluation: only recommended when diagnosis is “possible CIDP”: sensitivity of CSF protein elevation for CIDP was 68% using cut-offs of ≥ 0.5 g/L under the age of 50 years and > 0.6 g/L over the age of 60 years. 4. Nerve Biopsy: only recommended when CIDP is suspected but cannot be confirmed with other tests. Factors probably supporting the diagnosis of CIDP may be: a. thinly myelinated axons and small onion bulbs. b. thinly myelinated or demyelinated internodes in teased fibers. c. perivascular macrophage clusters. d. supportive features of demyelination on electron microscopy	
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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 28 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 28 days from the start of the previous cycle. CIDP: 1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase once weekly

Vyvgart Hytrulo PFS is a self-administered product and will fall under Partnership’s Standard Requirements for Self-Administered Drugs

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 triple seronegative - Concurrent use with other systemic biologic agents for refractory gMG (such as Complement Inhibitors, Neonatal Fc Receptor Antagonists, or anti-CD19 monoclonal antibodies)
Required Medical Information	- Positive immunologic binding assay to confirm MG due to the presence of AChR or MuSK antibodies - Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium - Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline - Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV - 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, (prior use of rituximab may also meet this requirement for MuSK+ disease) AND - Efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFSTM) (preferred), or Efgartigimod alfa-fcab (VyvgartTM) or efgartigimod alfa, 2 mg and hyaluronidase-qvfc (Vyvgart HytruloTM)
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 Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.



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 Intravenous Nipocalimab-aahu (Imaavy™)

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 myasthenia gravis (MG) in patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.
Exclusion Criteria	- Myasthenia gravis LRP4 antibody positive or triple seronegative - Concurrent use with other systemic biologic agents for refractory gMG (such as Complement Inhibitors, Neonatal Fc Receptor Antagonists, or anti-CD19 monoclonal antibodies)
Required Medical Information	- Positive immunologic binding assay to confirm MG due to the presence of AChR or MuSK antibodies - Avoidance of drugs that may exacerbate MG if possible, such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium - Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline - Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV - Current weight - 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, (prior use of rituximab may also meet this requirement for MuSK+ disease) AND - Efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFSTM) (preferred) or Efgartigimod alfa-fcab (VyvgartTM) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart HytruloTM).
Age Restriction	12 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 Partnership criteria document <i>Case-by-Case TAR Requirements and Considerations</i>.



Requirements for Intravenous Nipocalimab-aahu (Imaavy™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J9256	Injection, nipocalimab-aahu, 3 mg (Imaavy)	30mg/kg as a single dose, followed 2 weeks later by 15mg/kg given every 2 weeks thereafter.

Requirements for Anifrolumab-fnia Intravenous Injection (Saphnelo™)

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	Moderate to severe systemic lupus erythematosus in adults who are receiving standard therapy. Standard therapy would include medications such as NSAIDs, corticosteroids, antimalarials (eg, chloroquine, hydroxychloroquine) and immunosuppressives (eg, cyclophosphamide, azathioprine, mycophenolate or methotrexate).	
Exclusion Criteria	- Severe active lupus nephritis - Severe active central nervous system lupus	
Required Medical Information	- Positive anti-nuclear antibody test with titer of $\geq 1:80$ HEp2 or equivalent positive test - Current standard treatment being used - Comprehensive metabolic panel (CMP-14), urinalysis, or kidney biopsy to rule out active lupus nephritis - Lab reports to indicate active inflammation: - CBC to indicate low hematocrit, hemoglobin, WBC and platelets - High erythrocyte sedimentation rate (ESR) - High C-Reactive Protein (CRP) - Positive anti-double-stranded DNA (anti-dsDNA) antibodies - Low levels of (complement proteins) C3 <60 and/or C4 <15 - Documentation of failure with or reason(s) why subcutaneous self-administered Saphnelo Pen Auto-injector or Saphnelo Prefilled Syringe cannot be used - Documentation of failure with or reason(s) why subcutaneous belimumab (Benlysta™) cannot be used.	
Age Restriction	18 years and older	
Prescriber Restriction	Rheumatologist	
Coverage Duration	Initial: 6 months Renewal: 12 months	
Other Requirements & Information	Renewal Requests: Clinic notes which document benefit from treatment with and tolerance to anifrolumab- fnia (Saphnelo™). Requests for off-label use: See PHC criteria document <i>Case-by-Case TAR Requirements and Considerations</i>	
Medical Billing: Dose limits & billing requirements (approved TAR is required)		
HCPCS	Description	Dosing, Units
J0491	Injection, anifrolumab-fnia, 1 mg	300 mg IV q4weeks



Requirements for Belimumab Intravenous Injection (Benlysta™)

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	- Active, autoantibody- positive, systemic lupus erythematosus (SLE) in combination with standard therapy (≥ 5 yrs) - Active lupus nephritis who are receiving standard therapy Standard therapy would include medications such as NSAIDs, corticosteroids, antimalarials (eg, chloroquine, hydroxychloroquine) and immunosuppressives (eg, cyclophosphamide, azathioprine, mycophenolate or methotrexate).
Exclusion Criteria	- Severe active CNS lupus - Use in combination with other biologics, including B- cell targeted therapies or IV cyclophosphamide
Required Medical Information	<u>Active, autoantibody- positive, systemic lupus erythematosus (SLE):</u> - Positive anti-nuclear antibody test with titer of ≥ 1:80 HEp2 or equivalent positive test - Age must be ≥ 5 yrs - Current standard treatment being used - Member weight - Lab reports, including references ranges, to indicate active inflammation: - CBC to indicate low hematocrit, hemoglobin, WBC and platelets - Creatinine - High erythrocyte sedimentation rate (ESR) - High C-Reactive Protein (CRP) - Positive anti-double-stranded DNA (anti-dsDNA) antibodies - Low levels of (complement proteins) C3 <60 and/or C4 <15 - Reason(s) why less invasive treatment option Benlysta subcutaneous (SC) pens or prefilled syringes cannot be considered. - Anticipated length of time required for IV administration prior to transitioning to SC administration. <u>Active lupus nephritis:</u> - Kidney biopsy results confirm active lupus nephritis and to stage the severity - Current standard treatment being used - Urinalysis to indicate proteinuria - Comprehensive metabolic panel (CMP-14) to indicate status of kidney - Member weight - Reason(s) why less invasive treatment option Benlysta subcutaneous (SC) pens or prefilled syringes cannot be considered. - Anticipated length of time required for IV administration prior to transitioning to SC administration.
Age Restriction	Vials (IV): 5 yrs and older
Prescriber Restriction	Rheumatologist or Nephrologist
Coverage Duration	<u>For IV administration (for ages 5-17 yrs):</u> Initial: 6 months Renewal: 12 months Adults (18 yrs and older): TBD, case-dependent

Requirements for Belimumab Intravenous Injection (Benlysta™)

Other Requirements & Information	<u>Renewal Requests:</u> Clinic notes which document benefit from treatment with and tolerance to belimumab (Benlysta™). <u>Requests for off-label use:</u> See PHC criteria document <i>Case-by-Case TAR Requirements and Considerations</i>
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Medical Billing: Dose limits & billing requirements (approved TAR is required)		
HCPCS	Description	Dosing, Units
J0490	Injection, belimumab, 10 mg	<u>Lupus nephritis:</u> 10 mg/kg IV at 2-week intervals for the first 3 doses, and at 4-week intervals thereafter. <u>Switching from IV to SC:</u> • Administer the first subcutaneous dose of 200 mg 1 to 2 weeks after the last IV dose. • Patients may switch to subcutaneous therapy after completion of 2 IV doses. <u>Systemic lupus erythematosus:</u> 10 mg/kg IV at 2-week intervals for the first 3 doses, and at 4-week intervals thereafter. <u>Switching from IV to SC:</u> • Administer the first subcutaneous dose 1 to 4 weeks after the last IV dose. <u>Billing Unit Equivalence:</u> 1 billing unit is 10 mg. Doses are calculated as 10 mg/kg. Determine the correct number of billing units by dividing the administered dose in milligrams by 10. Example: 80 kg member receives 800 mg dose. 800 mg ÷ 10 mg per unit = 80 code units.