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.

Anti-Infectives Anti-Bacterial Agents	Anti-Infectives Anti-Fungal	Anti-Infectives Anti-Viral
Eculizumab (Solilris™)	Edaravone (Radicava™)	Inclisiran (Leqvio™)
Inebilizumab-cdon (Uplizna™)	Octreotide LAR (Sandostatin™ LAR Depot)	OnabotulinumtoxinA (Botox™)
Risankizumab -rzaa (Skyrizi™)		

Requirements for Intravenous Risankizumab-rzaa (Skyrizi™)

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 plaque psoriasis (PSO) • Psoriatic arthritis • Moderate to severe Crohn's disease (CD)
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	Moderate to severe PSO and psoriatic arthritis: This medication is typically self-administered by the member or a caregiver at home. See the additional requirements for medical claim TARs in the PHC criteria document titled ***Standard Requirements for Self-Administered Drugs.*** Crohn's Disease: 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) 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). 4) Documented therapeutic failure to induce remission with or contraindication to: • TNF Inhibitor such as adalimumab (Humira™), certolizumab pegol (Cimzia™), or infliximab (Avsola™, Inflectra™, Renflexis™)
Age Restriction	18 years and older
Prescriber Restriction	Crohn's Disease: Gastroenterologist
Coverage Duration	Crohn's Disease: 3 months for induction dose only
Other Requirements & Information	Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Intravenous Risankizumab-rzaa (Skyrizi™)

Medical Billing:

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

HCPCS	Description	Dosing, Units
J2327	Intravenous injection, Risankizumab-rzaa, per dose ** TARs and claims must include NDC – add when the HCPCS is J3490, J3590	Loading Dose: 600 mg on weeks 0, 4 & 8 *(Followed by maintenance dose 180 mg to 360 mg SC starting at week 12 and then every 8 weeks thereafter)*

Requirements for Octreotide LAR (Sandostatin™ LAR Depot)

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

PA Criteria	Criteria Details
Covered Uses	• Acromegaly • Metastatic neuroendocrine (carcinoid) tumors (NETs) associated with severe diarrhea/flushing episodes • Vasoactive Intestinal Peptide (VIP) secreting tumors associated with profuse watery diarrhea • Moderate (grade 2) to severe (grade 3-4) chemotherapy induced diarrhea (CID) (*Accepted off label use*) Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***
Exclusion Criteria	Cause(s) of diarrhea other than the covered uses
Required Medical Information	<u>Acromegaly:</u> 1) Documentation of persistent disease (normalize serum IGF-1 levels and continued moderate to moderate - severe symptoms of GH excess) despite the following: • Endonasal Transsphenoidal surgery (≥ 12 weeks after) OR • Surgical debulking of macroadenomas abutting or adjacent to the optic chiasm (≥ 12 weeks after) OR • Reason(s) why a the patient is not a surgical candidate such as but not limited to: ○ Cannot be cured by surgery ○ Has extensive cavernous sinus invasion ○ Does not have chiasmal compression ○ High risk due to medical comorbidities <u>Carcinoid syndrome (flushing and diarrhea) OR VIP secreting tumors</u>: 1) Clinical documentation to confirm the diagnosis submitted. <u>Grade 2 or higher, CID</u>: 1) Confirmation that infectious (bacterial, virus or parasite) cause(s) of diarrhea had been ruled out. 2) Documentation of failure to respond with continued persistent diarrhea despite use of high dose loperamide (max dose of up to 16 mg/day) or diphenoxylate-atropine (Lomotil™). 3) Documentation of resolution or that successful treatment had been obtained with standard (immediate release) octreotide AND dosing used. 4) Anticipated duration remaining for chemotherapy treatment.
Age Restriction	18 years and older
Prescriber Restriction	Oncologist, gastroenterologist, endocrinologist

Requirements for Octreotide LAR (Sandostatin™ LAR Depot)

Coverage Duration	Acromegaly: 3 months only, patient should then transition to oral octreotide (Mycapssa™) for long-term maintenance. Carcinoid syndrome & VIP secreting tumors: Initial request: 3 months Renewal: Up to 12 months CID: Initial: TBD based on the remaining number of chemotherapy treatment remaining. Renewal: 3 months
Other Requirements & Information Needed for Continuation Of Care	Acromegaly: 1) Documentation of trial and failure or reason(s) why the patient cannot transition to oral octreotide (Mycapssa™), if there is response (partial or complete) to octreotide (IR or LAR) 2) If the patient is approved to continue octreotide LAR: • Current lab for IGF-1 level • GH levels Carcinoid Syndrome & VIP secreting tumors: • Documentation of benefit with treatment CID: • Documentation of CID, despite completion of treatment with chemotherapy • Treatment plan regarding use of octreotide LAR and plan regarding, if the patient would be able to transition to standard octreotide.

Requirements for Octreotide LAR (Sandostatin™ LAR Depot)

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J2353</td><td>Intramuscular (IM) injection, octreotide depot, 1 mg</td><td>
<u>Acromegaly if IM injection is continued, dose depends on the GH level with dosing every 4 weeks</u>:
<table>
<tr><th>GH level</th><th>Dose Titration</th><th>IgF-1 level</th><th>Symptoms</th></tr>
<tr><td>≤1 ng/mL with symptoms controlled</td><td>Reduce to 10 mg</td><td>Normal</td><td>Controlled</td></tr>
<tr><td>> 1 mcg/L but <1.3 mcg/L</td><td>No change in dose with addition of cabergoline or submit information for reason(s) why this cannot be tried prior to dose increase</td><td>Normal</td><td>Mild</td></tr>
<tr><td>>1 to ≤2.5 ng/mL with symptoms controlled</td><td>20 mg</td><td>Normal</td><td>Controlled</td></tr>
<tr><td>>2.5 ng/mL</td><td>30 mg</td><td>Elevated</td><td>And/or uncontrolled</td></tr>
<tr><td>>2.5 ng/mL</td><td>40 mg</td><td>Remained Elevated after trial of 30 mg dose</td><td>And/or uncontrolled after trial of 30 mg dose</td></tr>
</table>
<u>Carcinoid tumors & VIPomas</u>:
<table>
<tr><th>Dose Titration</th><th>Response to initial dosing</th></tr>
<tr><td>Reduce dose to 10 mg after 2 months of</td><td>Positive</td></tr>
<tr><td>Increase to 30 mg after 2 months</td><td>Inadequate</td></tr>
</table>
</td></tr>
</table>

Requirements for OnabotulinumtoxinA (Botox™)

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) Cervical dystonia 2) Spasticity in patients 2 years of age and older 3) Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older 4) Chronic migraine prophylaxis 5) Severe primary axillary hyperhidrosis 6) Neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older 7) Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency 8) Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS)
Exclusion Criteria	None
Required Medical Information	Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that the member has met all approval criteria. 1) Criteria for start of treatment of: a. Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain. b. Upper or lower limb spasticity whose spasticity is refractory to a trial of at least 2 different oral medications listed below (unless member age prohibits use per FDA package labeling): i. Baclofen ii. Benzodiazepine (e.g. diazepam) iii. Dantrolene or Tizanidine 2) Strabismus and blepharospasm associated with dystonia. 3) Chronic migraine prophylaxis: a. Clinic notes documenting diagnosis of chronic migraines (at least 15 headache days per month [of which at least 8 were migraine days] lasting 4 hours or more) for at least 3 months. b. Adequate trial for a minimum of 8 weeks to at least 2 different drug classes of first line or second line agents for migraine prophylaxis: i. TCA ii. Beta-blocker (e.g. metoprolol, propranolol, timolol) iii. Anticonvulsant (e.g. divalproex, topiramate, valproate) iv. Calcium channel blocker (e.g. verapamil) 4) Severe Primary Axillary Hyperhidrosis: a. Inadequately managed by topical agent aluminum chloride (Drysol 20% topical solution) AND b. Hyperhidrosis Disease Severity Scale (HDSS) score is 3 and greater 6) Overactive bladder (non-neurogenic) and/or urinary incontinence due to detrusor overactivity (neurogenic): a. Documented trial of 2 months each at maximum tolerated dose (or documented intolerance) to 2 pharmacology class: i. Anticholinergic (i.e., oxybutynin, trospium, tolterodine) agents AND ii. Beta-3 agonist (Myrbetriq™)

Requirements for OnabotulinumtoxinA (Botox™)

Age Restriction	See dosing table located in Other Criteria.
Prescriber Restriction	1) Cervical dystonia: a. Neurologist b. Orthopedist or physical medicine c. Pain management specialist d. Rehabilitation specialist/physiatrist (PMR) 2) Upper limb or lower limb spasticity: a. Neurologist b. Orthopedist c. Pain management specialist d. PMR 3) Blepharospasm associated with dystonia: a. Neurologist b. Ophthalmologist 4) Severe Primary Axillary Hyperhidrosis: a. Neurologist b. Dermatologist 5) Strabismus: a. Neurologist b. Ophthalmologist 6) Overactive bladder (non-neurogenic) and/or urinary incontinence due to detrusor overactivity (neurogenic): a. Neurologist b. Urologist c. Urogynecologist 7) Chronic migraine prevention: a. Neurologist b. PMR
Coverage Duration	Initial: 12 months Renewal: 12 months with documentation of benefit with treatment
Other Requirements & Information Needed for Continuation of Care	For renewal or re-treatment: Documentation of positive clinical response and return of clinical symptoms indicating need for next treatment dose. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.*** Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.

Requirements for OnabotulinumtoxinA (Botox™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing based on diagnosis		
		Indication	**Age Limit (yrs)**	**Maximum Dose Limit**
J0585	Injection, onabotulinumtoxinA, per 1unit (Botox™)	Detrusor overactivity associated with neurologic condition	≥18	200 units q12 weeks
			≥5	Wt <34 kg: 6 units/kg Wt ≥34 kg: 200 units per treatment
		Overactive bladder	≥18	100 units q12 weeks
		Blepharospasm	≥12	Cumulative dose: ≤200 units in 30-day period q12 weeks.
		Cervical dystonia	≥18	Botox naïve: Cumulative dose: ≤100 units Botox experienced: Mean cumulative dose 236 units (25^{th} -75^{th} percentile range 198 - 300 units). Limit to no more than 50 units per site. Dosing q12 weeks
		Chronic Migraine	≥18	Cumulative dose: 155 units q12 weeks
		.Lower limb spasticity	≥18	300-400 units divided among 5 muscles q12 weeks. Max dose 50 units per site.
			2-17	8 units/kg or 300 units total, whichever is less. Max dose 50 units per site.
		Upper limb spasticity	≥18	75 -400 units divided among selected muscle groups q12 weeks. Max dose 50 units per site.
			2-17	6 units/kg or 200 units total, whichever is less. Max dose 50 units per site.
		Primary Axillary Hyperhidrosis	≥18	50 units per axilla. Repeat when clinical effect diminishes at q12 weeks or longer
		Strabismus	≥12	Max dose 25 units per muscle q12 weeks

Standard Requirements for Antibiotic Injections

(TAR review criteria when drug-specific criteria is not otherwise specified)

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) FDA approved indications 2) Accepted off-label indications/medically accepted indications: identified using the following standard reference compendia such as, but not limited to: • Infectious Diseases Society of America Guidelines • Centers for Disease Control and Prevention (CDC) • National Institute of Allergy and Infectious Diseases • American Academy of HIV Medicine • World Health Organization (WHO) • American Society of Transplantation • National Comprehensive Cancer Network (NCCN) • American Society of Transplantation (AST)
Exclusion Criteria	Varies based on manufacturer requirements
Required Medical Information	TAR must include all necessary/relevant clinical documentation to support medical justification with the request including: • Treatment history including prior regimen(s) • Documentation of contraindication or reason(s) why treatment with preferred regimens cannot be used including reason(s) why oral therapy cannot be used if treatment option(s) are available. • Culture and sensitivity lab reports • Treatment plan with anticipated duration of treatment including when or if the patient will be transitioned to oral treatment.
Age Restriction	Dependent on FDA approved age limit
Prescriber Restriction	Consultation or recommended by Infectious Disease specialist or appropriate specialist depending on the indication submitted.
Coverage Duration	Dependent on infection and recommended treatment standards.
Other Requirements & Renewal Information	Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Standard Requirements for Antibiotic Injections

(TAR review criteria when drug-specific criteria is not otherwise specified)

Medical Billing:

Medical Billing Requirements, with an approved TAR:

This table is a non-exhaustive list of drugs in PHC's medical drug benefit. The above criteria apply to all antibacterial products that require a TAR and are without drug-specific criteria.

** TARs and claims must include NDC – add when the HCPCS is J3490, J3590

HCPCS	Description
Aminoglycosides	
J0291	Plazomicin (Zemdri™), per 5 mg
Anti-infective Agents, Misc.	
J3490	Unclassified Drug (NDC billing): • Bacitracin 50,000 unit vials, IM (Baciim™) • PHC NDC billing: *Eaches* (1 unit=1 vial)
J0770	Colistimethate sodium (Coly-Mycin M™), per 150 mg
J0743	Imipenem/Cilastatin (Primaxin™), per 250 mg
J0742	Imipenem/Cilastatin/Relebactam 2 mg (Recarbrio™), per 10 mg
J0691	Lefamulin (Xenleta™), per 1 mg
J2184	Meropenem (B Braun, mfg), per 100 mg *(not therapeutically equivalent to J2185)*
J2185	Meropenem (Merrem™), per 100 mg *(not therapeutically equivalent to J2184)*
J2186	Meropenem/Vaborbactam (Vabomere™), per 20 mg
J2770	Quinupristin/Dalfopristin (Synercid™), per 500 mg
Antimycobacterial Agents	
J3490	Unclassified Drug (NDC billing): • Capreomycin 1 gram vials (Capastat™) • PHC NDC billing: *Eaches* (1 unit=1 vial)
J3490	Unclassified Drug (NDC billing): • Rifampin 600 mg vials (Rifadin™ IV) • PHC NDC billing: *Eaches* (1 unit=1 vial)
Cephalosporins	
J3490	Unclassified Drug (NDC billing): • Cefadroxil 500 capsules, oral (Duricef™) • Cefadroxil 100 mg/ml, oral suspension (Duricef™) • PHC NDC billing: *Eaches* (1 unit=1 capsule or 1 ml)
J3490	Unclassified Drug (NDC billing): • Cefiderocol sulfate 1 gram SDV (Fetroja™) • PHC NDC billing: *Eaches* (1 unit=1 vial)
J0712	Ceftaroline fosamil (Teflaro™), per 10 mg
J0695	Ceftolozane/Tazobactam (Zerbaxa™), per 50 mg/25 mg
Fluoroquinolones	
J2280	Moxifloxacin (Avelox™), per 100 mg
C9462	Delafloxacin Meglumine (Baxdela™), per 1 mg

Standard Requirements for Antibiotic Injections

(TAR review criteria when drug-specific criteria is not otherwise specified)

Continued from previous page

HCPCS	Description
Penicillins	
J2543	Piperacillin sodium/Tazobactam sodium (Zosyn™), per 1.125 gm
Tetracyclines	
J3490	Unclassified Drug (NDC billing): • Doxycycline Hyclate (Doxy-100,™ Doxy 100 Novaplus™) • PHC NDC billing: *Eaches* (1 unit=1 vial)
J0122	Eravacycline (Xerava™), per 1 mg
J0121	Omadacycline, (Nuzyra™), per 1 mg

Standard Requirements for Antifungal Agents

(TAR review criteria when drug-specific criteria is not otherwise specified)

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) FDA approved indications 2) Accepted off-label indications/medically accepted indications: Defined as using the following standard reference compendia, such as but not limited to: • Infectious Diseases Society of America Guidelines • Centers for Disease Control and Prevention (CDC) • National Institute of Allergy and Infectious Diseases • American Academy of HIV Medicine • World Health Organization (WHO) • National Comprehensive Cancer Network (NCCN) • American Society of Transplantation (ATS)
Exclusion Criteria	Varies based on manufacturer requirements
Required Medical Information	Clinic notes which include: • Detailed treatment history including contraindication or failure of preferred, first-line treatment options which may include the following preferred alternatives such as: amphotericin B products - Amphotericin B desoxycholate, Abelcet, AmBisome, Amphotec (QL: 600 mg/day), micafungin (Mycamine). • Current treatment plan. • Anticipated duration of therapy.
Age Restriction	Dependent on FDA approved ages for treatment
Prescriber Restriction	Consultation or recommended by Infectious Disease, HIV specialist, Pulmonology, Oncology or appropriate specialist, depending on the indication submitted.
Coverage Duration	Dependent on infection and recommended treatment standards.
Other Requirements & Renewal Information	Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Standard Requirements for Antifungal Agents

(TAR review criteria when drug-specific criteria is not otherwise specified)

Medical Billing:

Medical Billing Requirements, with an approved TAR:
This table is a non-exhaustive list of drugs in PHC's medical drug benefit. The above criteria apply to all antibacterial products that require a TAR and are without drug-specific criteria.

** TARs and claims must include NDC – add when the HCPCS is J3490, J3590

HCPCS	Description
J0348	Anidulafungin injection, 1 mg (Eraxis™)
J0637	Caspofungin injection, 5 mg (Cancidas™)
J3465	Voriconazole injection, 10 mg (Vfend™)
J1833	Isavuconazonium injection, 1 mg (Cresemba™)

Standard Requirements for Anti-Viral Injections

(TAR review criteria when drug-specific criteria is not otherwise specified)

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) FDA approved indications 2) Accepted off-label indications/medically accepted indications: Defined as using the following standard reference compendia, such as but not limited to: • Infectious Diseases Society of America Guidelines • Centers for Disease Control and Prevention (CDC) • National Institute of Allergy and Infectious Diseases • American Academy of HIV Medicine • World Health Organization (WHO) • American Society of Transplantation • National Comprehensive Cancer Network (NCCN) • American Society of Transplantation (AST)
Exclusion Criteria	Varies based on manufacturer requirements
Required Medical Information	Treatment plan with anticipated duration of treatment for: • Active infection • Prophylaxis due to immunosuppression • Prophylaxis due to transplant protocol (solid organ or hematopoietic cell transplant recipients)
Age Restriction	Dependent on FDA approved age limit
Prescriber Restriction	Consultation or recommended by Infectious Disease specialist, HIV specialist, Oncologist, Organ transplant surgeon or appropriate specialist depending on the indication submitted.
Coverage Duration	Dependent on infection and recommended treatment standards.
Other Requirements & Renewal Information	Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Standard Requirements for Anti-Viral Injections

(TAR review criteria when drug-specific criteria is not otherwise specified)

Medical Billing:

Medical Billing Requirements, with an approved TAR:
This table is a non-exhaustive list of drugs in PHC's medical drug benefit. The above criteria apply to all antiviral products that require a TAR and are without drug-specific criteria.

** TARs and claims must include NDC – add when the HCPCS is J3490, J3590

HCPCS	Description
J0740	Cidofovir (Vistide™), per 375 mg
J3485	Zidovudine (Retrovir™), per 10 mg
J3490	Unclassified Drug (NDC billing): • Letermovir inj, 240 mg/12 ml vials and 480 mg/24 ml single dose vials (Prevymis). • PHC NDC billing/ reimbursement is by *Eaches* (1 unit = 1 vial).

Requirements for Inclisiran (Leqvio™)

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

PA Criteria	Criteria Details
Covered Uses	Adjunct to diet and maximally tolerated statin therapy for treatment of adults with: 1. Heterozygous familial hypercholesterolemia (HeFH), or 2. Clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C)
Exclusion Criteria	Concurrent use of PCSK9 inhibitors [i.e. Repatha™ (evolocumab) or Praluent™ (alirocumab)]
Required Medical Information	Clinical note documenting: <u>Heterozygous familial hyperlipidemia (HeFH)</u>: 1) Diagnosis of HeFH by either: a) Genetic test (confirming mutation(s) in the *LDLR, PCSK9,* or *APOB* gene); OR b) Clinical presentation(s): i) Untreated LDL-C level of ≥190mg/dL, and ii) Presence of cutaneous or tendon cholesterol deposits, or iii) Strong family history of premature coronary artery disease (CAD). 2) LDL-C ≥100mg/dl (drawn within the past 3 months) despite compliant therapy with maximally tolerated high dose statin therapy (atorvastatin ≥ 40mg or rosuvastatin ≥ 20mg) and PCSK9 inhibitor. <u>Atherosclerotic cardiovascular disease (ASCVD)</u>: 1) History of clinical ASCVD or at high risk for developing ASCVD. 2) LDL-C ≥70mg/dl (drawn within the past 3 months) despite compliant therapy with maximally tolerated high dose statin therapy (atorvastatin ≥ 40mg or rosuvastatin ≥ 20mg) and PCSK9 inhibitor.
Age Restriction	18 years and older
Prescriber Restriction	Cardiologist, Diabetologist or Endocrinologist
Coverage Duration	Initial: 9 months. Renewal: 12 months with documentation of positive treatment response as evidenced by reduction of LDL-C from baseline with cholesterol lab drawn within 90 days of request.
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.* Inclisiran should be administered by a healthcare professional.

<u>Medical Billing:</u>

Dose limits & billing requirements (approved TAR is required)

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

Requirements for 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.

PA Criteria	Criteria Details
Covered Uses	Neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) IgG antibody positive.
Exclusion Criteria	• Use along with IV eculizumab (Soliris™) or SC satralizumab (Enspryng™) • NMOSD negative AQP4-IgG
Required Medical Information	1) 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 2) Seropositive for AQP4-IgG antibodies 3) Baseline Expanded Disability Status Scale (EDSS) score 4) Provider to submit reason(s) why satralizumab (Enspryng™) cannot be used, as the lower- level of care agent.
Age Restriction	18 years and older
Prescriber Restriction	Neurologist, Ophthalmologist
Coverage Duration	Initial request with loading dose: 6 months Renewal: 12 months
Other Requirements & Information Needed for Continuation of Care	Include with renewal request: • Documentation to indicate positive response to treatment. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Medical Billing:

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

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

Requirements for Eculizumab (Soliris™)

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

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy. 2) Refractory generalized myasthenia gravis (gMS) in adults who are anti-acetylcholine receptor antibody-positive (AChR+). 3) Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive. 4) Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Exclusion Criteria	• Unresolved serious Neisseria meningitides infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Use along with ravulizumab (Ultomiris™) or efgartigimodum alfa-fcab (Vyvgart™) • NMOSD negative AQP4-IgG
Required Medical Information	1) <u>Requirements for atypical hemolytic uremic syndrome or paroxysmal nocturnal hemoglobinuria indications:</u> a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Weight (kg, lb) d. Documentation that Shiga toxin has been ruled out e. Trial and failure with ravulizumab (Ultomiris™) 2) ~~Additional~~ <u>Requirement for those with a confirmed diagnosis of positive AChR, gMS:</u> a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies. b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta-blockers, hydroxychloroquine, gabapentin, lithium. d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline. e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following: i. Pyridostigmine ii. Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose iii. Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate iv. Efgartigimod alfa-fcab (Vyvgart™) AND v. Ravulizumab (Ultomiris™) 3) Requirements for Neuromyelitis optica spectrum disorder (NMOSD):

Requirements for Eculizumab (Soliris™)

	a. At least one of the following: • Optic neuritis • Acute myelitis • Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting • Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • Symptomatic cerebral syndrome with NMOSD-typical brain lesions b. Seropositive for AQP4-IgG antibodies c. Documentation of trial and failure or contraindication: • Satralizumab (Enspryng™) OR • Inebilizumab-cdon (Uplizna™)
Age Restriction	aHUS: 2 months of age and older gMS, NMOSD, PNH: 18 years and older
Prescriber Restriction	• PNH: Hematologist • aHUS: Nephrologist, Hematologist • gMS: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial TAR for loading dose: Approved for 1 to 4 loading doses, depending on indication and weight of the patient (if relevant) Initial TAR for maintenance dose: 6 months Renewal TAR: Approved for 1 dose per fill for up to 6 months.
Other Requirements & Renewal Information	Renewal Requests: • Clinical notes with current: ○ MG-ADL ○ MGFA classification Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Eculizumab (Soliris™)

Medical Billing:

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

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J1300	Injection, Eculizumab, 10 mg	aHUS, gMS, NMOSD (≥ 18 yrs): • 900 mg IV qwk x 4 doses, then 1,200 mg for the 5th dose on week 5, then 1,200 mg q2wks thereafter. aHUS (≥ 2 months): PNH: • 600 mg IV qwk x 4 doses, then 900 mg for the 5th dose on week 5, then 900 mg q2wks thereafter.

aHUS (≥ 2 months):

Weight	Induction dose (qwk)	Maintenance dose
≥ 40 kg	900 mg x 4	1,200 mg at week 5, then q2wks
30 -39 kg	600 mg x 2	30 -39 kg 600 mg x2 900 mg at week 3, then q2wks
0 – 29 kg	600 mg x 2	600 mg at week 3, then q2wks
10 – 19 kg	600 mg x 1	300 mg at week 2, then q2wks
5 - 9 kg	300 mg x 1	300 mg at week 2 then q3wks

Requirements for Edaravone, IV injection (Radicava™)

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	For the treatment of amyotrophic lateral sclerosis (ALS).
Exclusion Criteria	None
Required Medical Information	Initial therapy Documentation showing: • Definite or probable ALS based on El Escorial/Airlie House revised criteria or Awaji criteria, AND • Score of 2 or more on all items of the ALS Functional Rating Scale-Revised ALSFRS-R
Age Restriction	18 years and older
Prescriber Restriction	Neurologist
Coverage Duration	3 cycles (84 day supply) or 34 units
Other Requirements & Renewal Information	For continuation of treatment, the patient should be transitioned to the oral formulation (Radicava™ ORS) which can be administered orally or via a silicone, PVC, or polyurethane percutaneous endoscopic gastrostomy or NG tube. Renewal request to continue IV treatment: 1) Reason(s) why the patient cannot transition to the oral formulation (Radicava™ ORS). 2) Clinical documentation that edaravone use has slowed, stabilized or improved the member's overall function, relative to that projected for the natural course of ALS. The initial treatment cycle is 60 mg IV once daily dosing for 14 days, followed by14-day drug-free period. Subsequent treatment cycles are 60 mg once daily dosing for 10 days out of 14-day periods, followed by 14 days off the drug. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Edaravone, IV injection (Radicava™)

Medical Billing:

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

HCPCS	Description	Dosing, Units
J1301	Injection, edaravone (Radicava™), 1mg	Initial cycle: 60 mg IV qd x 14 days followed by a 14-day drug-free period. Maintenance cycle: 60 mg IV qd x 10 days (within a 14 day period), followed by a 14 day drug-free period. 60 units (60 mg) for each date of service. Maximum units per authorization: **Initial Authorization (new starts):** 64 doses (3,840 units) over 22 weeks. **Renewal:** 70 doses (4,200 units) over 26 weeks.