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 Policy #MPRP4033.

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) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain. 2) 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 3) Strabismus and blepharospasm associated with dystonia. 4) 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. Tricyclic antidepressant (TCA) (e.g. amitriptyline) ii. Beta-blocker (e.g. metoprolol, propranolol, timolol) iii. Anticonvulsant (e.g. divalproex, topiramate, valproate) iv. Calcium channel blocker (e.g. verapamil) v. Calcitonin-gene related peptide (CGRP), such as: erenumab (Aimovig™), fremenezumab (Ajovy™), galcanezumab (Emgality™), or atogepant (Qulipta™) 5) 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

Requirements for OnabotulinumtoxinA (Botox™)

	ii. Beta-3 agonist mirabegron (Myrbetriq™) or vibegron (Gemtesa™)
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

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Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

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

PA Criteria	Criteria Details
Covered Uses	Treatment of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.
Exclusion Criteria	1. Treatment or use for anything other than DMD 2. Prior administration of delandistrogene moxeparvovec-rokl (Elevidys™) 3. Deletions in exon 8 and/or exon 9 in the DMD gene 4. Concurrent use with exon skipping therapies
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the DMD gene. a. Genetic mutation test results must be submitted with request b. For mutations in exons 1-17, provider must attest that they are aware of the increased risk for severe myositis associated with these mutations 2. Documentation of ambulatory status in the medical records AND as evidenced by North Star Ambulatory Assessment (NSAA) score of ≥1 (or equivalent on another recognized scale). 3. Documentation of anti-AAVrh74 total antibody titers <1:400 using a Total Binding Antibody enzyme linked immunosorbent assay (ELISA) 4. Documentation of baseline liver function tests, platelet counts, left ventricular ejection fraction (LVEF) and troponin I levels. Elevidys administration should be postponed until acute liver disease has resolved or been controlled. 5. Documentation that the member does not have any signs or symptoms of infection 6. Concurrent use corticosteroids (prednisone, prednisolone, deflazacort (Emflaza™), vamorolone (Agamree™) etc.) at a stable dose for at least 12 weeks, unless contraindicated or intolerant Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals.
Age Restriction	Ages 4-5 years old only
Prescriber Restriction	Prescribed by, or under supervision and monitoring of a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy
Coverage Duration	Once per lifetime
Other Requirements & Information	Requests for use in members over the age of 5 or who are considered non-ambulatory: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

	Prescriber must attest or otherwise document member will receive prophylactic prednisolone (or glucocorticoid equivalent) (in addition to baseline corticosteroid dose) one day prior to Elevidys™ infusion and for 60 days following therapy to monitor liver function.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

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

Requirements for Collagenase Clostridium Histolyticum CCH (Xiaflex™)

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

PA Criteria	Criteria Details
Covered Uses	1) Treatment of adults with Dupuytren's contracture with a palpable cord. 2) Treatment of adults with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy
Exclusion Criteria	Treatment of Peyronie plaques that involve the penile urethra
Required Medical Information	<u>Information requested for each indication:</u> 1) Clinic notes from specialist to confirm the diagnosis submitted and severity of disease (limited to FDA approved indications, found in the manufacturer's package labeling). 2) Treatment plan. 3) Anticipated duration of treatment (if applicable). 4) Prescriber has completed the required Xiaflex training program -Risk Evaluation and Mitigation Strategy (REMS) due to Boxed warning: Corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease (Xiaflex). <u>For Dupuytren's contracture:</u> 1) Palpable cord. 2) Evidence of discomfort/functional impairment of hand interferes with ADLs. 3) Physical findings of either contracture at MCP joint greater than 30 degrees flexion or contracture at PIP joint greater than 20 degrees flexion. 4) Surgical interventions (percutaneous, open, or needle fasciectomy) option has been addressed are not preferred. <u>For Peyronie's disease:</u> 1) Palpable plaque. 2) Evidence of penile pain, nodule/plaque, indentation, curvature, deformity, functional impairment which interferes with ADLs such as Sexual Health Inventory for Men (SHIM) score. 3) Physical findings of curvature deformity of at least 30 degrees. 4) Surgical options (tunical shortening (eg, plication), tunical lengthening (eg, grafting), or implantation of penile prostheses) for stable disease have been addressed. 5) Patient has stable disease, defined as nonprogression of deformity and stable symptoms for at least three months prior to requesting treatment with Xiaflex.
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with healthcare provider experienced in injection procedures of the hand for the treatment of Dupuytren's contracture. Prescribed by or in consultation with a urologist experienced in injection procedures for the treatment of Peyronie's disease
Coverage Duration	Dupuytren's contracture: TBD per number of palpable cords 6-month duration

Requirements for Collagenase Clostridium Histolyticum CCH (Xiaflex™)

	Peyronie's disease: 4 injections 6-month duration

Other Requirements & Information	For Peyronie's disease: Renewal: If more than 2 cycles (2 injections per cycle): Continued penile curvature >15 degrees and confirmed penile modeling or penile traction therapy for four to six weeks after CCH injections. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

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

Requirements for IV Ustekinumab (Stelara™) and biosimilars Ustekinumab-auub (Wezlana™), -ttwe (Pyzchiva™), -aekn (Selarsdi™) (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).
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated). 2) Treatment plan (Note: the single induction dose is recommended to be followed by 90 mg subcutaneous dose 8 weeks after induction dose, and every 8 weeks thereafter). 3) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease. 4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test).
Age Restriction	18 years and older
Prescriber Restriction	Prescribed or in consultation with a gastroenterologist
Coverage Duration	Single fill/date of service. FDA indicated dosing is for a single IV dose for induction, followed by subcutaneous dosing thereafter.
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for IV Ustekinumab (Stelara™) and biosimilars Ustekinumab-auub (Wezlana™), -ttwe (Pyzchiva™), -aekn (Selarsdi™) (IV products only)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J3358</td><td>Ustekinumab, for IV injections, 1 mg (only indicated for Crohn’s or UC induction)</td><td rowspan="4">
<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>
With transition to subcutaneous dosing after the initial IV induction dose
</td></tr>
<tr><td>Q5138</td><td>Injection, ustekinumab-auub (Wezlana), biosimilar, intravenous, 1 mg (only indicated for Crohn’s or UC induction)</td></tr>
<tr><td>Q9997</td><td>Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg (only indicated for Crohn’s or UC induction)</td></tr>
<tr><td>Q9998</td><td>Injection, ustekinumab-aekn (Selarsdi), 1 mg (only indicated for Crohn’s or UC induction)</td></tr>
</table>

Requirements for IV Ustekinumab (Stelara™) and biosimilars Ustekinumab-auub (Wezlana™), -ttwe (Pyzchiva™), -aekn (Selarsdi™) (IV products only)

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Requirements for Eculizumab (Soliris™) and Eculizumab-aeeb (Bkemv™)

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

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy. 2) Generalized myasthenia gravis (gMS) in adults who are anti-acetylcholine receptor antibody-positive (AChR+). 3) Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive. 4) Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Exclusion Criteria	• Unresolved serious *Neisseria meningitidis* infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Use along with ravulizumab (Ultomiris™) or efgartigimodum alfa-fcab (Vyvgart™) • NMOSD negative AQP4-IgG
Required Medical Information	1) Requirements for atypical hemolytic uremic syndrome (all of the following, a-e): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Weight (kg, lb) d. Documentation that Shiga toxin has been ruled out e. Trial and failure with ravulizumab (Ultomiris™) 2) Requirements for paroxysmal nocturnal hemoglobinuria (all of the following, a-e): a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Weight (kg, lb) d. Documentation of trial and failure or reasons why iptacopan (Fabhalta™) OR pegcetacoplan (Empaveli™) cannot be used e. Trial and failure with ravulizumab (Ultomiris™) 3) Requirement for AChR antibody-related myasthenia gravis (all of the following, a-f): a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies. b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta-blockers, hydroxychloroquine, gabapentin, lithium. d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline. e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV

Requirements for Eculizumab (Soliris™) and Eculizumab-aeeb (Bkemv™)

	f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following (i-vi): i. Pyridostigmine ii. Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose iii. Oral glucocorticoid sparing immunomodulatory, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate iv. Zilucoplan (Zilbrysq™) v. Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™) vi. Ravulizumab (Ultomiris™) 4) Requirements for Neuromyelitis optica spectrum disorder (NMOSD) (all of the following a-d): a. At least one of the following: i. Optic neuritis Acute myelitis ii. Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting iii. Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) iv. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions v. Symptomatic cerebral syndrome with NMOSD-typical brain lesions b. Seropositive for AQP4-IgG antibodies c. Documentation of trial and failure or contraindication to Satralizumab (Enspryng™) OR Inebilizumab-cdon (Uplizna™) d. Documentation of trial and failure or contraindication to ravulizumab (Ultomiris)
Age Restriction	aHUS: 2 months of age and older gMS, NMOSD, PNH: 18 years and older
Prescriber Restriction	• PNH: Hematologist • aHUS: Nephrologist, Hematologist • gMS: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial TAR for loading dose: Approved for 1 to 4 loading doses, depending on indication and weight of the patient (if relevant) Initial TAR for maintenance dose: 6 months Renewal TAR: Approved for 1 dose per fill for up to 6 months.
Other Requirements & Renewal Information	Renewal Requests: • Clinical notes with current: o MG-ADL o MGFA classification Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Eculizumab (Soliris™) and Eculizumab-aeeb (Bkemv™)

Medical Billing:

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

Dose limits & billing requirements (approved TAR is required)

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J1300</td><td>Injection, Eculizumab, 10 mg</td><td>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):
<table>
<tr><th>Weight</th><th>Induction dose (qwk)</th><th>Maintenance dose</th></tr>
<tr><td>≥ 40 kg</td><td>900 mg x 4</td><td>1,200 mg at week 5, then q2wks</td></tr>
<tr><td>30 -39 kg</td><td>600 mg x 2</td><td>30 -39 kg 600 mg x2 900 mg at week 3, then q2wks</td></tr>
<tr><td>0 – 29 kg</td><td>600 mg x 2</td><td>600 mg at week 3, then q2wks</td></tr>
<tr><td>10 – 19 kg</td><td>600 mg x 1</td><td>300 mg at week 2, then q2wks</td></tr>
<tr><td>5 - 9 kg</td><td>300 mg x 1</td><td>300 mg at week 2 then q3wks</td></tr>
</table></td></tr>
<tr><td>Q5139</td><td>Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg</td><td>PNH:
600 mg IV qwk x 4 doses, then 900 mg for the 5th dose on week 5, then 900 mg q2wks thereafter.</td></tr>
</table>