GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

Botulinum toxins type A and type B
Botox *(onabotulinumtoxin A)*
Daxxify *(daxibotulinumtoxinA-lanm)*
Dysport *(abobotulinumtoxin A)*
Myobloc *(rimabotulinumtoxin B)*
Xeomin *(incobotulinumtoxin A)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Coverage is limited to the spastic conditions listed under "Codes that Support Medical Necessity" of the Billing and Coding: Botulinum Toxin Type A & Type B (A57185) article.
Exclusion Criteria	None.
Required Medical Information	Medical records supporting the request must be provided, including documentation of a covered diagnosis, dose and frequency of injections, clinical effectiveness of the injections, and specific site(s) injected.
Other Criteria	Must follow the Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L35170. Meet the following criteria based on the supported indication for the drug requested. Note that supported indications for individual botulinum toxin type A and toxin type B differ. The indications below do not indicate the requested drug is supported for the indication. It is the responsibility of providers to use each drug in accordance with the supported indications. 1. **Chronic anal fissures:** Treatment with toxin injections will be considered reasonable and necessary when meeting the following requirements: (1) anal fissure has been present for more than 6 weeks; AND (2) conservative treatment has been tried for eliminating constipation and reducing anal sphincter spasm. 2. **Chronic migraines:** Initial BTIs for chronic migraine prophylaxis will be considered reasonable and necessary when the following requirements are met: (1) The BTI is being used only for the indication of chronic migraine prophylaxis, AND (2) The monthly headache days have occurred ≥15 headaches days per month, AND (3) The monthly migraine headache days have occurred ≥ 8 migraine headache days per month, AND (4) The migraine headaches are documented to be lasting for a duration ≥4 hours on a migraine day, AND (5) The chronic headaches have been present for a period of at least 3 months, AND (6) The beneficiary has had a trial of and inadequate response to a 2-month trial of at least 1 agent in any 2 of the following classes or has contraindication to the following medications; AND a. Antidepressant class: amitriptyline, venlafaxine, nortriptyline, duloxetine; OR b. Beta blocker class: metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; OR c. Calcium channel blocker class: verapamil; OR d. Antiepileptic class: valproate sodium, divalproex sodium, topiramate, gabapentin. (7) The 2-month trial of the oral pharmacologic classes above for chronic migraine prophylaxis must have been at the target dose of the usual effective dose or an intolerance to the 2 agents in each class, AND (8) If the beneficiary is also currently using a calcitonin gene-related peptide (CGRP) agent for chronic migraine prophylaxis and is going to be using CGRP and botulinum toxin together the following must apply: a. The beneficiary had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with CGRP use, but still has chronic migraines requiring additional therapy for chronic migraine prevention; AND

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	b. The headaches are causing an objective significant functional disability, AND (9) The headaches are moderate to severe intensity with typical migraine headache characteristics; AND (10) The botulinum toxin serotype is approved by the FDA for chronic migraine prophylaxis. 3. **Strabismus:** Initial BTIs for strabismus will be considered reasonable and necessary when the following requirements are met: (1) Objective documentation of the clinical features consistent with the diagnosis of strabismus; AND (2) Moderate to severe strabismus; AND (3) The clinical objective treatment goals are documented. 4. **Hyperhidrosis:** Initial BTIs for primary axillary hyperhidrosis will be considered reasonable and necessary when the following requirements are met: (1) Beneficiary has a diagnosis of primary or secondary axillary hyperhidrosis; AND (2) Excessive sweating in the axilla lasting 6 months or more; AND (3) Bilateral symmetric sweating in the axilla; AND (4) Cessation of focal sweating while asleep; AND (5) The failure of a 6-month trial to respond to other noninvasive conservative management for axillary hyperhidrosis (systemic anticholinergics, tranquilizers, topical dermatologics such as aluminum chloride, tannic acid, or glutaraldehyde, or non-steroid anti-inflammatory drugs); AND (6) Severe chronic hyperhidrosis measured on objective clinical scale*; AND (7) There is severe chronic axillary hyperhidrosis manifested by medical complications or skin maceration with secondary infection; AND (8) There is severe chronic axillary hyperhidrosis associated with and impairment of daily activities; AND (9) Significant functional impairment due to the hyperhidrosis. *Retreatment no greater than once every 6 months.* 5. **Sialorrhea:** Initial BTIs for sialorrhea will be considered reasonable and necessary when the following requirements are met: (1) The documentation supports a diagnosis of sialorrhea; AND (2) The etiology of the impairment which is causing the sialorrhea is documented; AND (3) There is moderate to severe sialorrhea assessed by an objective scale; AND (4) The condition has failed conservative measures such as observation, positioning, behavioral therapies, speech therapy and pharmacological therapy. 6. **Overactive Bladder (OAB)/Urinary Incontinence (UI):** Initial BTIs for OAB will be considered reasonable and necessary when the following requirements are met: (1) The documentation supports a diagnosis of refractory overactive bladder; AND (2) The OAB has been diagnosed by a history and physical exam and a urine analysis to rule out infection or blood in the urine; AND (3) There is moderate to severe OAB assessed by an objective scale; AND (4) Conservative treatment for OAB has been tried but the OAB symptoms are refractory to a minimum of 12 weeks of standard of care treatment. Conservative management which may consist of education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy; AND pharmacological therapy: anticholinergic or beta-3 adrenergic agonists (in absence of absolute contraindication to the medications). 7. **Achalasia:** (1) Objective documentation of the clinical features consistent with the diagnosis of achalasia; AND (2) Chronic achalasia measured on objective clinical scale; AND (3) Medically high-risk patients diagnosed with achalasia who cannot undergo other invasive treatments (peroral endoscopic myotomy (POEM), Heller myotomy, pneumatic dilation [PD]) – OR (4) As a bridge for those patients diagnosed with achalasia awaiting more effective treatments such as Heller myotomy, PDs or POEM – OR (5) During work-up and treatment planning of definitive treatments for achalasia. *Subsequent dose of up to 100 units of toxin given 30 days after initial dose.*

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	8. **Blepharospasm:** (1) objective documentation of clinical features consistent with the diagnosis of blepharospasm; AND (2) Chronic blepharospasm of at least 30 days duration measured using an objective clinical scale; Botulinum toxin injections are considered first line treatment in patients with blepharospasm. 9. **Blepharospasm Associated with Orofacial Dystonia:** (1) Objective documentation of the clinical features consistent with the diagnosis of blepharospasm associated with orofacial dystonia; AND (2) Moderate to severe chronic blepharospasm associated with orofacial dystonia measured on objective clinical scale; OnabotulinumtoxinA injection therapy is accepted first line treatment for patients with blepharospasm associated with orofacial dystonia. 10. **Cervical Dystonia (CD):** Initial BTIs for CD will be considered reasonable and necessary when the following requirements are met: (1) The documentation supports a diagnosis of CD; AND (2) The etiology of the central nervous system impairment which is causing the CD is documented, AND (3) the beneficiary has a history of recurrent clonic or tonic involuntary contractions of 1 or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles; AND (4) There is moderate to severe CD assessed by an objective scale; AND (5) There are objective measurements of abnormal posturing, with limited range of motion in the neck, or sustained head tilt; AND (6) The duration of the CD is greater than 6 months; AND (7) The initial toxin dose is based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum toxin naïve patients. 11. **Focal Hand Dystonia (FHD):** BTI therapy is an accepted FDA off-label use first line treatment for patients with FHDs. In the management of FHD, BTI is considered reasonable and necessary consisting of focal injections of the toxin into the muscles responsible for the abnormal postures, and initial BTIs for FHD will be considered reasonable and necessary when the following requirements are met: (1) Objective documentation of the clinical features consistent with the diagnosis of FHD; AND (2) Moderate to severe chronic FHDs measured on objective clinical scale*; AND (3) The injections are used with guidance either by ultrasound or by electromyography (EMG) with or without electrostimulation. 12. **Hemifacial Spasm(HFS)/Facial Dystonia:** Initial BTIs for HFS will be considered reasonable and necessary when all the following requirements are met: (1) BTI therapy is accepted as first line treatment for patients with primary or secondary HFS; AND (2) Objective documentation of the clinical features consistent with the diagnosis of primary or secondary HFS; AND (3) Moderate to severe primary or secondary HFS measured on objective clinical scale to measure severity, complexity and psychosocial aspects of HFS. 13. **Laryngeal Dystonia (Spasmodic Dysphonia):** Initial BTIs for LD will be considered reasonable and necessary when the following requirements are met: (1) Objective documentation of the clinical features consistent with the diagnosis of Adductor Spasmodic Dysphonia (ADSD); AND (2) Objective assessment and documentation to rule out non-organic voice disorders; AND (3) Moderate to severe chronic ADSD measured on objective clinical scale; AND (4) BTI therapy is an accepted FDA off-label use first line treatment for patients with ADSD. *Subsequent injections are usually given 12-week intervals.* 14. **Upper and Lower Spasticity:** Spasticity is a subset of dystonia; Initial botulinum toxin injections for spasticity will be considered reasonable and necessary when the following requirements are met: (1) Objective documentation of the clinical features consistent with the diagnosis of spasticity; AND (2) Moderate to severe chronic spasticity; AND (3) The clinical treatment goals are documented; AND (4) Electromyography, electrical stimulation, and/or ultrasonography, rather than site pain or tenderness, is required to determine injection site(s) for botulinum toxin especially for spastic conditions of the face, neck and upper extremity.

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	15. **Neurogenic Bladder:** Initial BTIs for neurogenic detrusor overactivity will be considered reasonable and necessary when the following requirements are met: (1) The documentation supports a diagnosis of neurogenic detrusor overactivity; AND (2) The etiology of the central nervous system impairment which is causing the neurogenic detrusor overactivity is documented; AND (3) There is moderate to severe neurogenic detrusor overactivity and/or detrusor sphincter dyssynergia assessed by an objective diagnostic testing; AND (4) The voiding dysfunction has failed or become refractory to conservative measures such as lifestyle interventions, bladder training, intermittent catheterizations, pelvic floor muscle exercises and anticholinergic drugs or beta-3 adrenergic agonists (in absence of absolute contraindication to the medications) for a minimum of 12 weeks. 16. Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS): Initial BTIs for IC will be considered reasonable and necessary when the following requirements are met: (1) Diagnosis of IC/BPS established based on symptoms, frequency and cystoscopic findings consistent with IC/BPS. (2) IC/BPS are refractory or failed all other management options for a minimum of 6 months including: a. Conservative management/standard of care which may consist of education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy AND b. Pharmacological therapy (at least 1 agent) AND c. Bladder instillations AND d. Hydrodistention
Age Restriction	None.
Prescriber Restrictions	None.
Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. It is usually considered NOT medically necessary to give injections for spastic conditions more frequently than every 12 weeks.

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Other Criteria/Information	

HCPCS	Description	Billing Units/How Supplied
J0585	Botox (onabotulinumtoxinA)	**Billing unit: 1 unit** 100-unit, 200-unit SDV
J0589	Daxxify (daxibotulinumtoxinA)	**Billing unit: 1 unit** 100-unit SDV
J0586	Dysport (abobotulinumtoxin A)	**Billing unit: 5 units** 300-unit, 500-unit SDV
J0587	Myobloc (rimabotulinumtoxinB)	**Billing unit: 100 units** 2500 unit/0.5 mL, 5000 unit/mL, 10,000 unit/2 mL SDV
J0588	Xeomin (incobotulinumtoxin A)	**Billing unit: 1 unit** 50-unit, 100-unit, 200-unit SDV

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025
Updated (new CMS LCD)	3/3/26	3/3/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A