

## Botulinum Toxin Policy Number: C8755-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
03/2016	01/2019	01/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
J0585, J0586, J0587, J0588	RxPA	Q1 2019

**PRODUCTS AFFECTED:** Botox/Botox Cosmetic (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB) and Xeomin (incobotulinumtoxinA)

**DRUG CLASS:**

Neuromuscular Blocking Agent

**ROUTE OF ADMINISTRATION:**

Intramuscular

**PLACE OF SERVICE:**

Specialty Pharmacy, Buy and Bill

**AVAILABLE DOSAGE FORMS:**

Dysport 300Unit, Dysport 500Unit, Botox 100Unit, Botox 200Unit, Myobloc 2500Unit/0.5ML, Myobloc 500Unit/ML, Myobloc 1000Unit/2ML, Xeomin 50Unit, Xeomin 100Unit, Xeomin 200Unit

**FDA-APPROVED USES:** *Botox (onabotulinumtoxinA)*: Bladder muscle dysfunction - overactive, Refractory to or intolerant of anticholinergic medication, Blepharospasm, Associated with dystonia, Cervical dystonia, Prophylaxis of chronic migraine headache, Hyperhidrosis of axilla (Severe), Primary disease inadequately managed by topical agents, Incontinence due to detrusor instability, Associated with a neurologic condition, upper and lower limb spasticity, Strabismus

*Dysport (abobotulinumtoxinA)*: cervical dystonia

*Xeomin (incobotulinumtoxinA)*: cervical dystonia, blepharospasm in adults who were previously treated with onabotulinumtoxin A (Botox)

*Myobloc (rimabotulinumtoxinB)*

**COMPENDIAL APPROVED OFF-LABELED USES:** Hemifacial spasm, Facial spasm, Jaw-closing oromandibular dystonia, Spasmodic dysphonia (laryngeal dystonia, lingual dystonia, laryngeal spasm), Focal task-specific dystonia, Head and neck tremor, Dynamic muscle contractions in pediatric cerebral palsy, Limb spasticity, including: Heredity spastic paraplegia; Limb spasticity due to multiplesclerosis or other demyelinating diseases of the central nervous system; Spastic hemiplegia; Infantile cerebral palsy, Frey's Syndrome (gustatory sweating) secondary to parotid surgery, Sialorrhea in Parkinson's Disease, Detrusor sphincter dyssynergia (lower urinary tract dysfunction)

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:** FDA approved or compendia approved off-label uses above

**REQUIRED MEDICAL INFORMATION:**

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**A. CHRONIC MIGRAINE HEADACHE:**

1. Documented diagnosis of chronic migraines that meets international Classification of Headache Disorders (ICHD-3) diagnostic criteria for chronic migraine headache (see appendix)  
AND
2. The patient has a persistent history of chronic, debilitating migraine headaches with frequent attacks on 15 or more days per month for longer than 3 months  
AND
3. There is documentation of significant functional disability (e.g., work absenteeism, multiple emergency department visits)  
AND
4. The member has failed or had a clinically significant adverse reaction to abortive treatment with different therapy classes, including at least three (3) of the following classes: Triptans [Imitrex® (sumatriptan), Maxalt (rizatriptan), Zomig (zolmitriptan), AmERGE® (naratriptan), Axert® (almotriptan), Frova® (frovatriptan), Relpax® (eletriptan)], ergot derivatives [Cafergot® (ergotamine/caffeine), D.H.E.-45® (dihydroergotamine)], analgesics [Aspirin, acetaminophen, opioids (morphine, oxycodone)], opioid combinations [APAP/codeine, APAP hydrocodone], non-steroidal anti-inflammatory agents (NSAIDs) [Motrin® (ibuprofen), Naprosyn® (naproxen), Relafen® (nabumetone), Voltaren® (diclofenac), Orudis® (ketoprofen), Clinoril® (sulindac), Toradol® (ketorolac)], and combination products [Midrin® (isometheptene/APAP), Fiorinal® (butalbital/aspirin), Fioricet® (butalbital/APAP)]  
AND
5. Documentation of trial and ineffectiveness/failure after 2 months or clinical intolerance or contraindication to THREE of the following therapeutic classes: beta blockers (propranolol, timolol, atenolol, metoprolol, nadolol), antiepileptics (divalproex sodium, topiramate), antidepressants (amitriptyline, nortriptyline, venlafaxine, duloxetine), antihypertensive (verapamil, lisinopril, candesartan)

**B. GASTROINTESTINAL DISORDERS:**

1. (a) Member has a diagnosis of esophageal schalasia and ONE of the following: High risk for complications associated with pneumatic dilation or surgical myotomy; or Failure of a prior dilation or myotomy; or Previous perforation due to pneumatic dilation; or Epiphrenic diverticulum or hiatal hernia; or Esophageal varices  
OR  
(b) Member has documentation of anal fissure refractory to conventional nonsurgical medical therapy (e.g., sitz baths, stool softeners, bulk agents, diet modifications)  
AND
2. Documentation of a trial/failure or absolute contraindication to topical nifedipine or topical nitroglycerin

**C. HYPERHIDROSIS:**

1. Member has a documented diagnosis of Primary focal hyperhidrosis  
AND
2. Failure of (trial period of  $\geq 1$  month), intolerance to or unable to receive conventional medical therapy for hyperhidrosis (e.g., anti-cholinergics, anti-inflammatories)  
AND
3. Documentation of failure of (trial period of  $\geq 1$  month) or intolerance to Drysol (aluminum chloride)  
AND
4. Presence of medical complications of hyperhidrosis, including skin maceration with secondary infection or significant functional impairment

**D. MOVEMENT DISORDERS:**

1. Diagnosis of a movement or focal spastic disorder or excessive muscular contractions, including at least one of the following: Genetic torsion dystonia, Acquired torsion dystonia, Fragments of torsion dystonia, Hereditary spastic paraplegia, Multiple sclerosis or Other demyelinating diseases of central nervous system, Spastic hemiplegia, Infantile cerebral palsy, Quadriplegia and quadriplegia, Paraplegia, Diplegia of upper limbs, Monoplegia of upper and/or lower limb, Unspecified monoplegia, Trigeminal nerve disorder, Facial nerve disorder(s), Spastic entropion, Spastic ectropion, and other disorders of binocular eye movements including blepharospasm, Hemiplegia/hemiparesis, Paralysis of vocal cords or larynx, unilateral or bilateral, partial, Laryngeal spasm, Torticollis, unspecified (including cervical dystonia), Spasm of muscle (including upper and lower limb spasticity), Other musculoskeletal symptoms referable to limbs, Certain congenital musculoskeletal deformities of sternocleidomastoid muscle, Abnormal involuntary movements, Voice and resonance disorder, unspecified, Dysphonia, OR Other voice and resonance disorders  
AND
2. Member has a documented failure of, intolerance to or unable to receive conventional medical therapy (e.g., physical therapy, medication)

**E. SIALORRHEA:**

1. Member has a documented disability from sialorrhea due to conditions such as Parkinson's disease or motor neuron disease  
AND
2. Failure of, intolerance to or unable to receive a trial of conventional medical therapy, including but not limited to, anticholinergics and speech therapy

**F. URINARY INCONTINENCE:**

1. Documented diagnosis of urinary incontinence due to neurogenic detrusor over activity or overactive bladder  
AND
2. Documented inadequate response to or clinically significant adverse reaction to at least two anticholinergic agents (oxybutynin immediate and extended release tabs, Oxytrol patch, Gelnique gel, tolterodine immediate and extended release, Toviaz, Enblex, Vesicare, trospium immediate and extended release)  
AND
3. No evidence of current urinary tract infection

**DURATION OF APPROVAL:** Initial authorization: 24 weeks, Continuation of Therapy: 24 weeks.

**QUANTITY:** Blepharospasm: 5 Units per site, Strabismus: 5 Units per muscle (maximum 25 units total), Cervical dystonia: 300 Units total, divided among affected muscles, Overactive bladder: 100 Units total, at least 12 weeks apart between treatments, Axillary hyperhidrosis: 50 Units per axilla, Migraines: 155 total Units (5 to 40 Units per site), Neurogenic bladder: 200 Units total, given in multiple sites, Upper Limb Spasticity: 50 Units in one site, Lower Limb Spasticity: 400 Units divided across 5 muscles, Oromandibular dystonia: 50 Units per masseter muscle and 40 Units per temporalis, Spasmodic dysphonia: 10 Units per vocal cord and 30 Units in abductor muscle, Spastic muscle contracture of pediatric cerebral palsy: 12 Units/Kg and 220 Units divided among affected muscles, Childhood myoclonus following failure of Baclofen, benzodiazepines, and antiseizure medications: 80 Units/Kg, Chronic anal fissure: 20 Units both sides, Gustatory sweating (Frey's syndrome): 75 Units per injection, Internal anal sphincter (IAS) achalasia: 25 Units in each quadrant or 50 Units on either side of IAS, Plantar/palmar hyperhidrosis: 165 Units per palm

prescribed dose for any indication can NOT exceed 400 Units total per treatment, divided among affected muscles and can NOT be administered more frequently than every 12 weeks

**PRESCRIBER REQUIREMENTS:** Chronic migraines: Prescribed by a board eligible or board certified neurologist, ophthalmologist, pain management specialist or by a physician certified in headache medicine

**AGE RESTRICTIONS:** No requirements

**GENDER:**

Male and female

**CONTINUATION OF THERAPY:**

A. ALL INDICATIONS:

1. Member must continue to meet initial criteria for approvable conditions other than chronic migraine  
AND
2. For chronic migraine prophylaxis: member has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:** All other uses of botulinum toxins are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

Botulinum toxins prescribed for Treatment of brow furrows, wrinkles, forehead creases or other skin lines is considered cosmetic and not eligible for reimbursement.

**OTHER SPECIAL CONSIDERATIONS:** botulinum toxin products are not interchangeable, and dosing units of one product cannot be converted or compared with dosing units of another botulinum toxin product. When treating one or more indications, the maximum cumulative dose of onabotulinumtoxinA should generally not exceed 400 units in a 3-month interval

**BACKGROUND:**

Botulinum neurotoxins produced by *Clostridium botulinum*, a gram-positive anaerobic bacterium, can prevent the release of acetylcholine, carrying chemical denervation and blockage of neuromuscular transmission. Botulinum toxins produce a presynaptic neuromuscular blockage by preventing release of acetylcholine from motor nerve terminals. The resulting chemical denervation of muscle induces local paresis or paralysis and individual muscles can be weakened selectively. Botulinum toxins have the advantage of being potent neuromuscular blocking agents with good selectivity, long duration of action and few side effects. Of seven known distinct neurotoxins (A-G), onabotulinumtoxinA (Botox® /Botox Cosmetic), abobotulinumtoxinA (Dysport™), rimabotulinumtoxinB (Myobloc® ) and incobotulinumtoxinA (Xeomin® ) have been approved by the U.S. Food and Drug Administration for clinical use.

**APPENDIX:**

*International Headache Society Criteria for Migraine Diagnosis (ICHD-3)*

- A. Headache (tension-type-like and/or migraine-like) on  $\geq 15$  days per month for  $> 3$  months and fulfilling criteria B and C;  
OR

- B. Occurring in a patient who has had at least five attacks fulfilling criteria B-D for 1.1 Migraine without aura and/or criteria B and C for 1.2 migraine with aura;  
OR
  - C. On  $\geq 8$  days per month for  $> 3$  months, fulfilling any of the following: 1. Criteria C and D for 1.1 Migraine without aura; or 2. Criteria B and C for 1.2 Migraine with aura; or 3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative;  
OR
  - D. Not better accounted for by another ICHD-3 diagnosis.
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