



Subject: Botulinum Toxin*

Effective Date: December 14, 2004

Department(s): Utilization Management

Policy: Non-cosmetic use of botulinum toxin (**HCPCS J0585, J0586, J0587, J0588**) is reimbursable under Plans administered by QualCare, Inc.

Objective: To assure proper and consistent reimbursement for and to delineate medical necessity of a product that also has cosmetic applications.

Procedure:

1. Medically necessary indications for botulinum toxin injections include, but are not limited to, the following, which are followed by the corresponding CPT codes:

- **Ocular**
Strabismus (**63745**)
Blepharospasm (**64612**)
Sixth nerve palsy, persistent for ≥ 1 month,
with
diplopia or other visual impairment(**63745**)
Gaze palsies causing persistent pain or vision
Impairment(**63745**)
- **Oro-laryngeal**
Laryngeal spasm (**64613**)
Sialorrhea (**64653**)

- Oromandibular dystonia(64612)
- **Neuromuscular/neurologic**
 - Hemifacial spasm (64612)
 - Focal dystonias (including spasmodic torticollis) (64613, 64614)
 - Limb spasticity (64614)
 - Migraine syndrome(chronic) (64612, 64613) for prevention in adults with migraine \geq 15 days/month and failure or contraindication to at least two different classes of prophylaxis medications (anticonvulsant, beta-blockers, antidepressants,ACE inhibitors, alpha agonists, angiotensin receptor blockers)
 - Essential tremor(head, neck, hand, voice) that causes functional impairment(various code per anatomic region)
 - Seventh cranial nerve palsy (Bell's palsy) related synkinesis(64612)
- **Gastrointestinal**
 - Esophageal achalasia (64613)
 - Anal achalasia (46505)
 - Chronic anal fissure (46505)
 - Hirschsprung's disease following colon resection and pull-through reanastomosis (46505)
 - Fistula associated secretions(i.e.parotid gland, Pharyngocutaneous)(64611)
- **Dermatologic**
 - Focal hyperhidrosis (64650, 64653)
 - Gustatory sweating (Frey's syndrome) (64653)
- **Urologic**
 - Overactive bladder, when conservative measures either fail or are contraindicated (52283)

Neurogenic detrusor overactivity (52287)
Interstitial cystitis/bladder pain syndrome
after failure of oral medication, intravesical
treatment and cystoscopy(52287)

2. **Cosmetic uses** of botulinum toxin are not reimbursable, and include, but are not limited to, the following:

- Wrinkles or frown lines
- Aging neck
- Blepharoplasty without visual field defect

3. Experimental/investigational use of botulinum therapy products includes but is not limited to the following-

- Bruxism
- Chronic low back pain
- Headache including cervicogenic, chronic daily(≤ 14 Days/month), episodic migraine, menstrual headache, tension type.
- Hemorrhoid pain
- Myofascial pain
- Sphincter of Oddi dysfunction
- Temporomandibular joint syndrome
- Tics
- Voiding dysfunction associated with benign prostatic hyperplasia
- Lateral epicondylitis

4. All uses of botulinum toxin require medical review.

5. Documentation of medical necessity must include other treatments, if any, that have failed, or the reasons that they are contraindicated.

6. When criteria are met, botulinum therapy is approvable for four treatments in a 12 month period (one treatment every 90 days). If clinical response is documented but the duration of response is less than 90 days, then up to six treatments in a 12 month period can be approved.

7. The following chart indicates which products are approvable by diagnosis when criteria are met- based on FDA approved indications and/or published evidence.

Condition Category	Botox HCPCS J0585	Dysport HCPCS J0586	Myobloc HCPCS J0587	Xeomin HCPCS J0588
Ocular	Strabismus, Blepharospasm, Gaze palsies	Blepharospasm		Blepharospasm
Oro-laryngeal	Laryngeal dystonia, oromandibular dystonia, sialorrhea		Sialorrhea	
Neurologic	Hemifacial spasm, focal dystonias(including spasmodic torticollis), limb spasticity(including cerebral palsy), prevention of chronic migraine, essential tremor, sixth nerve palsy, Bell's palsy	Limb spasticity- upper limb in adults; lower limb in children age 2-17 yrs	Cervical dystonia, including spasmodic torticollis.	Cervical dystonia, including spasmodic torticollis , Upper limb spasticity.
Gastrointestinal	Esophageal and anal achalasia, chronic anal fissure, Hirschprung disease post re-anastamosis surgery, fistula associated secretions(i.e.parotid gland, pharyngocutaneous)	Hirschprung disease post re-anastamosis surgery		
Dermatologic	Focal hyperhidrosis,			

	gustatory sweating			
Urologic	Overactive bladder, detrusor overactivity, interstitial cystitis/bladder pain syndrome			

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.