Texas Children's	Botulinum Toxin Guidelines	
Guideline # 6175	***Categories*** Clinical →Care Management CM, TCHP Guidelines, Utilization Management UM	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Bhavana Babber

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of botulinum toxin injections when billed outside of the guidance documented in the Texas Medicaid Provider Procedure Manual Outpatient Drug Services Handbook

Definitions:

OnabotulinumtoxinA (Botox brand of botulinum toxin type A), abobotulinumtoxinA (Dysport brand of botulinum toxin type A), incobotulinumtoxin A (Xeomin brand of botulinum toxin type A), and rimabotulinumtoxinB (Myobloc brand of botulinum toxin type B) are benefits of Texas Medicaid.

Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonias, spasms, and twitches. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated. Two of the seven naturally occurring serotypes of botulinum toxin have been approved by the FDA for human use in the United States- type A and type B. Due to the unique manufacturing process of each toxin, botulinum toxins are chemically, clinically, and pharmacologically distinct; as a consequence, these products are not interchangeable. The units of biological activity of one botulinum toxin product cannot be compared to, nor converted into, units of any other botulinum toxin product. The established drug names of the botulinum products emphasize the differing dose-to-potency ratios of these products

PRIOR AUTHORIZATION GUIDELINES

1. All requests for prior authorization for botulinum toxin injections are received online, via fax, phone or mail by the Utilization Management Department and processed during normal business hours.

2. To request prior authorization for medically necessary botulinum toxin injections when billed outside the guidance of the Texas Medicaid Provider Procedure Manual Outpatient Drug Services Handbook., the following documentation must be provided:

2.1 Support for the medical necessity of the botulinum toxin injection

2.2 Dosage and frequency of the injections

2.1.1. Requests for Botulinum toxins administered more frequently than every 12 weeks must include documentation of medical necessity stating the need of an interval less than 12 weeks

3 The use of botulinum toxin may be considered **medically necessary** for:

3.1 Strabismus

3.2 The treatment of the following disorders if associated with spasticity or dystonia:

3.2.1 Blepharospasm

3.2.2 Cerebral palsy

3.2.3 Facial nerve (VII) dystonia

3.2.4 Hemifacial spasm

3.2.5 Hereditary spastic paraparesis

3.2.6 Idiopathic torsion dystonia

3.2.7 Multiple sclerosis

3.2.8 Neuromyelitis optica

3.2.9 Organic writer's cramp

3.2.10 Orofacial dyskinesia (i.e., jaw closure dystonia)

3.2.11 Schilder's disease

3.2.12 Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking)

3.2.13 Spastic hemiplegia

3.2.14 Spasticity related to stroke, spinal cord injury, or traumatic brain injury

3.2.15 Symptomatic torsion dystonia

3.2.16 Other forms of upper motor neuron spasticity

3.2.16.1 The treatment of essential tremor

3.2.16.2 The treatment of achalasia

3.2.16.3 The treatment of anal fissures

3.2.16.4 The treatment of significant drooling in individuals who are unable to tolerate scopolamine

3.2.16.5 The treatment of neurogenic overactive bladder (also referred to as detrusor over-activity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy.

3.2.16.6 The treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy.

3.2.16.7 The treatment of functional obstruction caused by the inability of the internal anal sphincter to relax in individuals with Hirschsprung disease who have undergone prior surgical treatment.

3.2.16.8 The treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity

3.2.16.8.1 For initial treatment when all of the following criteria are met:

3.2.16.8.1.1 History of recurrent clonic or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius or posterior cervical muscles; **And**

3.2.16.8.1.2 Sustained head tilt or abnormal posturing with limited range of motion in the neck; **And**

3.2.16.8.1.3 The duration of the condition is greater than 6 months.

3.2.16.8.2 Subsequent injections of botulinum toxin for the treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity are considered medically necessary when:

3.2.16.8.2.1 There is a response to the initial treatment documented in the medical records; **And**

3.2.16.8.2.2 The individual still meets the medically necessary criteria above.

3.2.16.9 The prevention of chronic migraine headaches

3.2.16.9.16 An initial 6 month trial of botulinum toxin is considered medically necessary when all of the following are met:

3.2.16.9.16.1 Adult individual diagnosed with chronic migraine headache; **And**

3.2.16.9.16.2 Fifteen (15) or more headache-days per month with headache lasting 4 hours or longer; **And**

3.2.16.9.16.3 First episode at least 6 months ago; **And**

3.2.16.9.16.4 Symptoms persist despite trials of at least 1 agent in any 2 of the following classes of medications used to prevent migraines or reduce migraine frequency:

3.2.16.9.16.4.1 Antidepressants (for example, amitriptyline, nortriptyline, doxepin); **Or**

3.2.16.9.16.4.2 Beta blocker (for example, propranolol, timolol, metoprolol extended-release); **Or**

3.2.16.9.16.4.3 Antiepileptics (for example, valproate, topiramate, gabapentin).

3.2.16.9.17 Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary for individuals who have previously met criteria above and completed an initial 6 month trial when:

3.2.16.9.18 Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial; **Or**

3.2.16.9.19 Migraine headache duration was reduced by at least 100 total hours per month (when compared to the pre-treatment average) by the end of the initial trial.

4 Botulinum toxin is considered ***cosmetic and not medically necessary*** as a treatment of skin wrinkles or other cosmetic indications.

5 Botulinum toxin is considered ***investigational and not medically necessary***:

5.1 For the treatment of headache other than chronic migraine meeting the criteria above, including but not limited to tension, episodic migraine (14 migraine days per month or less), or chronic daily headaches.

5.2 For the treatment of individuals with Hirschsprung disease when the criteria above are not met.

5.3 The use of botulinum toxin, whether the same or a different product, following ***failure*** of an initial trial for the treatment of a medically necessary condition (as listed above) is considered investigational and not medically necessary. *Note: when the initial product was stopped due to a product specific intolerance or allergic reaction (rather than clinical failure), this investigational and not medically necessary statement does not apply.*

5.4 As a treatment for conditions listed above when criteria are not met and for all other conditions not addressed above, including, but not limited to, the following:

5.4.1 Anismus (pelvic floor dyssynergia)

5.4.2 Behcet's syndrome

5.4.3 Benign prostatic hyperplasia

5.4.4 Brachial plexus palsy

5.4.5 Carpal tunnel syndrome

5.4.6 Chronic motor tic disorder

5.4.7 Disorders of the esophagus (except as listed above in the medically necessary section)

5.4.8 Epicondylitis

5.4.9 Fibromyalgia/fibromyositis

5.4.10 Gastroparesis

5.4.11 Low back pain

5.4.12 Myofascial pain syndrome

5.4.13 Neck pain not related to conditions mentioned above

5.4.14 Acquired Nystagmus

5.4.15 Parkinson's disease

5.4.16 Post-mastectomy reconstruction syndrome

5.4.17 Reynaud's syndrome

5.4.18 Sphincter of Oddi dysfunction

5.4.19 Stuttering

5.4.20 Tics associated with Tourette's Syndrome

5.4.21 Tinnitus

5.4.22 Tourette's Syndrome

5.4.23 Tremors

5.4.24 Urinary and anal sphincter dysfunction (except as listed above in the medically necessary section)

5.4.25 Vaginismus

5.4.26 Whiplash-related disorders

5.4.27 Zygomatic fractures

6 Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy may be followed.

7 Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only

to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

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