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OVERVIEW

Botulinum toxin is produced by the anaerobic clostridium botulinum. Four formulations of botulinum toxin have been approved by the U.S. Food and Drug Administration (FDA). Labeled indications of these agents differ; however, all are FDA approved for treating cervical dystonia in adults. Botulinum toxin products are also used for a range of off-label indications

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section

MEDICAL CRITERIA

BlueCHiP for Medicare

Hyperhidrosis

Severe Primary Axillary Hyperhidrosis

Treatment is considered medically necessary with any of the following criteria:

- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical therapy.
- Focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least 2 of the following characteristics:
 - Bilateral and relatively symmetric significant impairment in daily activities
 - Age of onset less than 25 years
 - Positive family history
 - Cessation of focal Hyperhidrosis

Migraines

Headache/migraine coverage is medically necessary for those patients who meet the criteria for chronic daily headaches or chronic migraine headache.

1. Chronic daily headaches including tension-type headache – Headache disorders occurring greater than 15 days a month, in many cases daily with a duration of 4 or more hours for a period of at least 3 months who have significant disability due to the headaches and have been refractory to standard and usual conventional therapy.

2. Chronic migraine (CM) – CM is characterized by headache on greater than 15 days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment.

Continuing therapy is medically necessary when both of the criteria below are met:

- Demonstrate a significant decrease in the number and frequency of headaches; and
- Improvement in function upon receiving botulinum toxin.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare for Botulinum Toxin, for the treatment of migraine or hyperhidrosis.

POLICY STATEMENT

BlueCHiP for Medicare

The use of botulinum toxin may be considered medically necessary for the treatment of migraines and hyperhidrosis when the criteria is met:

The use of botulinum toxin is considered **medically necessary** for the following indications:

- Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury)
- Strabismus*
- Blepharospasm or facial nerve (VII) disorders (including hemifacial spasm)*
- Upper limb spasticity*
- Dystonia/spasticity resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain
- Organic writer's cramp

Focal dystonias:

- Focal upper limb dystonia (e.g., organic writer's cramp)
- Oromandibular dystonia (orofacial dyskinesia, Meige syndrome)
- Laryngeal dystonia (adductor spasmodic dysphonia)
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia

Spastic conditions:

- Cerebral palsy
- Spasticity related to stroke
- Acquired spinal cord or brain injury
- Hereditary spastic paraparesis
- Spastic hemiplegia
- Neuromyelitis optica
- Multiple sclerosis or Schilder disease
- Esophageal achalasia in patients who have not responded to dilation therapy or who are considered poor surgical candidates
- Sialorrhea (drooling) associated with Parkinson disease
- Chronic anal fissure
- Urinary incontinence due to detrusor overactivity associated with neurogenic causes (e.g., spinal cord injury, multiple sclerosis) in patients unresponsive to or intolerant of anticholinergics*
- Overactive bladder in adults unresponsive to or intolerant of anticholinergics*

Other conditions:

- Chronic anal fissures

Use of botulinum toxin for all other indications is not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure service is effective.

The use of assays to detect antibodies to botulinum toxin is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician office injection coverage/benefits.

BACKGROUND

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. The clinical indications for Botulinum toxins have increased exponentially since first used two decades ago. They are used in the treatment of overactive skeletal muscles (e.g. hemifacial spasm, dystonia, spasticity), smooth muscles (e.g. detrusor overactivity and achalasia), glands (e.g. sialorrhoea and hyperhidrosis) and additional conditions that are being investigated.

There are currently four Botulinum toxin products commercially available in the United States: Botox® (onabotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), Dysport™ (abobotulinumtoxinA), and Xeomin® (incobotulinumtoxinA). Each preparation has distinct pharmacological and clinical profiles specified on the product insert. Dosing patterns are also specific to the preparation of neurotoxin and are very different between different serotypes. Failure to recognize the unique characteristics of each formulation of Botulinum toxin can lead to undesired patient outcomes. It is expected that physicians will be familiar with and experienced in the use of these agents, and utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient condition. Physicians may decide which agent to use in beneficiary care except as noted below. Although Botulinum toxins have only been FDA-approved for limited uses, they are frequently used off-label as well. A patient who is not responsive or who ceases to respond to one serotype may respond to the other.

Indications:

Spasticity

Botulinum toxin can be used to reduce spasticity or excessive muscular contractions, to relieve pain, to assist with posture and walking, to improve range of motion, to enhance the effectiveness of physical therapy, and to reduce severe spasm to allow better perineal hygiene in patients with spasticity secondary to spastic hemiplegia and hemiparesis.

Organic writer's cramp is uncommon, and so Botulinum toxin for the treatment of organic writer's cramp should be infrequent.

Botulinum toxin is indicated for disorders associated with spastic conditions as above and dystonia. Please note: covered spastic conditions are listed under "ICD-10-CM Codes that Support Medical Necessity." The wide range of Botulinum toxin dosages used in a treatment session is determined by patient age, degree of spasticity, number of injections made into each muscle and number of muscles treated.

Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck and upper extremity.

Blepharospasm

Botulinum toxin injection therapy is accepted first line treatment for patients with blepharospasm and/or hemifacial spasm. If the upper and lower lid of the same eye and/or adjacent facial muscles, or brow are injected at the same surgery, the procedure is considered to be when both eyes or both sides of the face are injected.

Achalasia

Botulinum toxin for achalasia may be considered for the patient who has not responded satisfactorily to conventional therapy; is at high risk of complication from pneumatic dilation or surgical myotomy; has had treatment failure with pneumatic dilation or surgical myotomy; had perforation from pneumatic dilation; has an epiphrenic diverticulum or hiatal hernia; or has esophageal varices.

Anal Fissure

Botulinum toxin for chronic anal fissure may be considered for the patient who has not responded satisfactorily to conventional therapy.

Hyperhidrosis

OnabotulinumtoxinA has been approved by the Federal Drug Administration (FDA) for treatment of severe primary axillary hyperhidrosis (primary focal hyperhidrosis) that is inadequately managed with topical therapy. Compendia list onabotulinumtoxinA and rimabotulinumtoxinB as acceptable off-label agents for this condition. The definition of primary focal hyperhidrosis is severe sweating, beyond physiological needs; focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least two (2) of the following characteristics: bilateral and relatively symmetric, significant impairment in daily activities, age of onset less than 25 years, positive family history, and cessation of focal sweating during sleep.

Sialorrhea

The treatment of sialorrhea due to conditions such as motor neuron disease or Parkinson's disease in those patients who have failed to respond to a reasonable trial of traditional therapies (eg., anticholinergics and speech therapy) or who have a contraindication to or cannot tolerate anticholinergic therapy, will be allowed for coverage.

Urinary Incontinence

Urinary incontinence due to neurogenic detrusor overactivity (NDO) commonly occurs in patients with spinal cord injuries (SCI) or neurological diseases such as multiple sclerosis (MS). Patients with NDO usually use clean intermittent self catheterization (CIC) to empty the bladder. When incontinence episodes occur between catheterizations, oral anticholinergic agents are used to decrease bladder contractility and improve incontinence.

Effective January 18, 2013, the FDA has approved onabotulinumtoxinA for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Headache/Migraine

Coverage will only be allowed for those patients with chronic daily headaches (headache disorders occurring greater than 15 days a month - in many cases daily with a duration of four or more hours - for a period of at least 3 months) who have significant disability due to the headaches, and have been refractory to standard and usual conventional therapy. The etiology of the chronic daily headache may be chronic tension-type headache or chronic migraine (CM). CM is characterized by headache on > 15 days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment. For continuing Botulinum toxin therapy the patients must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin.

CODING

BlueCHIP for Medicare

Botulinum Toxin: The HCPC codes below require pre-authorization for hyperhidrosis and the treatment of migraines:

- J0585** Injection, Onabotulinumtoxin A, 1 unit (A) (Botox)
- J0586** Injection, Abobotulinumtoxin A, 5 units (A) (Dysport)
- J0588** Injection, Incobotulinumtoxin A, 1 unit (Xeomin)
- J0587** Injection, rimabotulinumtoxin B 100 units (B): (Myobloc)



CMS

Migraine_Hyperhidro:

The following HCPCS codes (J0585, J0586, J0587 and J0588), are covered without authorization when submitted with one of the ICD-10 codes in the attachment below:
(for indications other than Migraine or Hyperhidrosis)



CMS Medically
Necessary Diagnosis.›

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, February 2020
Provider Update, June 2018
Provider Update, June 2016
Provider Update, December 2015
Provider Update, September 2014

REFERENCES

1. Centers for Medicare and Medicaid (CMS): **Local Coverage Determination (LCD): Botulinum Toxins (L33646)**

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