

Medical Coverage Policy | Botulinum Toxin Injection, PREAUTH



EFFECTIVE DATE: 09/17/2007
POLICY LAST UPDATED: 006/18/2013

OVERVIEW

Botulinum toxin is produced by the anaerobic clostridium botulinum. Botulinum toxin type A BOTOX® (OnabotulinumtoxinA) is useful in reducing the excessive, abnormal contractions associated with blepharospasm and hyperhidrosis. BOTOX® has been FDA-approved for strabismus, blepharospasm associated with dystonia, including benign essential blepharospasm, or nerve disorders in patients over 12 years of age and cervical dystonia in adults.

Botulinum Type B is limited to conditions such as spasticity related to stroke or spinal cord injury/other forms of upper motor neuron spasticity.

PRIOR AUTHORIZATION

Preauthorization is required for BlueCHiP for Medicare members and recommended for all other BCBSRI products for the Botulinum Toxin A, for the treatment of migraines or hyperhidrosis.

POLICY STATEMENT

Botulinum toxin A is medically necessary when the criteria has been met for the treatment of migraines and hyperhidrosis

Botulinum toxin A is covered for the following indications when filed with the appropriate diagnosis code.

ICD-9-CM, FDA-labeled indications of

- (374.03) Spastic Entropion
- (374.13) Spastic Ectropion
- (378.00-378.08) Strabismus
- (378.10) Exotropia unspecified
- (378.11) Monocular exotropia
- (378.12) Monocular exotropia with a pattern
- (378.13) Monocular exotropia with V pattern
- (378.14) Monocular exotropia with other noncomitancies
- (378.15) Alternating exotropia
- (378.16) Alternating exotropia with A pattern
- (378.17) Alternating exotropia with V pattern
- (378.18) Alternating exotropia with other noncomitancies
- (378.20) Intermittent heterotropia unspecified
- (378.21) Intermittent esotropia monocular
- (378.22) Intermittent esotropia alternating
- (378.23) Intermittent exotropia monocular
- (378.24) Intermittent exotropia alternating
- (378.30) Heterotropia unspecified
- (378.31) Hypertropia
- (378.32) Hypotropia
- 378.33) Cyclotropia (
- (378.34) Monofixation syndrome
- (378.35) Accommodative component in esotropia

- (378.40) Heterophoria unspecified
- (378.41) Esophoria
- (378.42) Exophoria
- (378.43) Vertical heterophoria
- (378.44) Cyclophoria
- (378.45) Alternating hyperphoria
- (378.50) Paralytic strabismus unspecified
- (378.51) Third or oculomotor nerve palsy partial
- (378.52) Third or oculomotor nerve palsy total
- (378.53) Fourth or trochlear nerve palsy
- (378.54) Sixth or abducens nerve palsy
- (378.55) External ophthalmoplegia
- (378.56) Total ophthalmoplegia
- (378.60) Mechanical strabismus unspecified
- (378.61) Brown's (tendon) sheath syndrome
- (378.62) Mechanical strabismus from other muscularfascial disorders
- (378.63) Limited duction associated with other conditions
- (378.71) Duane's syndrome
- (378.72) Progressive external ophthalmoplegia
- (378.73) Strabismus in other neuromuscular disorders
- (378.81) Palsy of conjugate gaze
- (378.82) Spasm of conjugate gaze
- (378.83) Convergence insufficiency or palsy
- (378.84) Convergence excess or spasm
- (378.85) Anomalies of divergence
- (378.86) Internuclear ophthalmoplegia
- (378.87) Other dissociated deviation of eye movements
- (378.9) Unspecified disorder of eye movement
- (333.81) Blepharospasm
- (351.8) Facial nerve VII disorders
- (333.83) Spasmodic torticollis
- (527.7) Sialorrhea, (drooling) associated with Parkinson disease
- (344.61) Cauda Equina syndrome with neurogenic bladder
- (596.51) Hypertonicity Of Bladder
- (596.52) Low Bladder Compliance
- (596.54) Neurogenic bladder NOS
- (596.55) Detrusor Sphincter Dyssynergia
- (705.21) Severe primary axillary hyperhidrosis
- (705.21) Primary focal hyperhidrosis
- (705.22) Secondary focal hyperhidrosis
- (788.31) Urinary incontinence, urge incontinence
- (788.33) Urinary incontinence; mixed incontinence (female) (male)

Off-label indications, for consideration as medically necessary for the treatment of spasticity or dystonia resulting in significant functional impairment and/or pain with any of the following:

- (333.6) Torsion dystonia (idiopathic and symptomatic)
- (333.7) Symptomatic torsion dystonia
- (333.82) Orofacial dyskinesia
- (351.8) Other facial nerve disorders
- (333.6) Genetic torsion dystonia
- (333.71) Athetoid cerebral palsy
- (333.79) Other acquired torsion dystonia

- (333.84) Organic writer's cramp
- (333.89) Other fragments of torsion dystonia
- (334.1) Hereditary spastic paraplegia
- (340) Multiple sclerosis
- (341.0) Neuromyelitis optica
- (341.1);Schilder's disease
- (341.22)Idiopathic transverse myelitis
- (341.8) Other demyelinating diseases of central nervous system
- (341.9) Demyelinating disease of central nervous system, unspecified
- (342.10)Spastic hemiplegia affecting unspecified side
- (342.11)Spastic hemiplegia
- (342.12)Spastic Hemiplegia and hemiparesis affecting nondominant side
- (343.0-343.9);Infantile cerebral palsy
- (344.00-344.09)Quadriplegia unspecified
- (344.1)Paraplegia
- (344.2) Siplegia of upper limbs
- (344.30-344.32) Monoplegia of lower limb
- (344.40-344.42) Monoplegia of upper limb
- (344.5) Unspecified monoplegia
- (438.20) Hemiplegia affecting unspecified side
- (438.21) Hemipleia affecting dominant side
- (438.22)Hemiplegia affecting nondominant side
- (438.30) Monoplegia of upper limb affecting unspecified side
- (438.31) Monoplegia of upper limb affecting dominant side
- (438.32) Monoplegia of upper limb affecting nondominant side
- (438.50)Other paralytic syndrome affecting unspecified side
- (438.51)Other paralytic syndrome affecting dominant side
- (438.52)Other paralytic syndrome affecting nondominant side
- (438.53) Other paralytic syndrome bilateral
- (478.75, 478.79) Laryngeal spasm
- (530.0);Achalasia of lower esophageal sphincter (only if poor surgical candidate or non-responsive to dilation therapy)
- (564.6);Anal spasm
- (565.0) Anal fissure
- (723.5) Torticollis, unspecified
- (728.85) Muscle spasm
- (729.89) Other musculoskeletal symptoms referable to limbs
- (784.40-784.41, 784.49) Voice disturbance
- (342.10, 342.11, 343.12) Upper limb spasticity
- (736.72) Equinus foot, if related to cerebral palsy
- (342.1, 342.10, 342.11, 342.12) Spasticity related to stroke or spinal cord injury/Other forms of upper motor neuron spasticity

Botulinum Type B is limited to conditions such as spasticity related to stroke or spinal cord injury/Other forms of upper motor neuron spasticity

- (333.83)Cervical dystonia
- (754.1).Congenital musculoskeletal deformities of sternocleidomastoid muscle

Use of botulinum toxin A and B, for any indication not listed above is not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Botox used as a treatment for wrinkles or any other cosmetic indication is not a covered benefit.

MEDICAL CRITERIA

Hyperhidrosis: J0585 Injection, OnabotulinumtoxinA 1 unit (A).

Blue CHiP for Medicare

Primary Focal Hyperhidrosis (Primary Axillary Hyperhidrosis)

Treatment of primary focal hyperhidrosis 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 sweating during sleep

Commercial

Primary Focal Hyperhidrosis

Treatment of primary focal hyperhidrosis is considered medically necessary with any of the following complications:

1. acrocyanosis of the hands;
2. history of recurrent skin maceration with bacterial or fungal infections;
3. history of recurrent secondary infections;
4. history of persistent eczematous dermatitis in spite of medical treatments with topical dermatological or systemic anticholinergic agents.
5. inadequately managed with topical agents for the following
 - a. axillary focal region
 - b. palmar focal region (botulinum toxin A)
 - c. axillary focal region:

Hyperhidrosis Disease Severity Scale

Using the hyperhidrosis disease severity scale, patients rate the severity of symptoms on a scale of 1-4:

1. My underarm sweating is never noticeable and never interferes with my daily activities.
2. My underarm sweating is tolerable but sometimes interferes with my daily activities.
3. My underarm sweating is barely tolerable and frequently interferes with my daily activities.
4. My underarm sweating is intolerable and always interferes with my daily activities.

The severity level for treatment of hyperhidrosis must be level 3 or 4 on the severity scale

Migraines (J0585 Injection, OnabotulinumtoxinA, 1 unit A)

Blue CHiP for Medicare

Headache/Migraine Coverage is medically necessary for those patients with

1. chronic daily headaches including tension-type headache
 - a. 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.
2. chronic migraine (CM).
 - a. 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.
 3. For continuing Botulinum toxin therapy the patients must
 - a. demonstrate a significant decrease in the number and frequency of headaches and
 - b. improvement in function upon receiving Botulinum toxin.

Commercial

Prevention (treatment) of chronic migraine headache in the following situations:

1. Initial 6-month trial: Adult patients who:
 - a. meet International Headache Classification (ICHD-2) diagnostic criteria for chronic migraine headache (e.g. migraine headaches lasting at least 4 hours on at least 15 days per month; migraine headaches for at least 3 months in the absence of medication overuse); and
2. have symptoms that persist despite adequate trials of at least 2 agents from different classes of medications used in the treatment of chronic migraine headaches, e.g. antidepressants, antihypertensives and antiepileptics. Patients who have contraindications to preventive medications are not required to undergo a trial of these agents.

Continuing treatment beyond 6-months:

1. Migraine headache frequency reduced by at least 7 days per month, or
2. Migraine headache duration reduced at least 100 hours per month.

BACKGROUND

Posterior Botulinum toxin is produced by the anaerobic clostridium botulinum. Only type A and type B preparations are available in this country. The 3 formulations of botulinum toxin type A are currently called onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), and incobotulinumtoxinA (Xeomin). The paralytic mechanism of action that makes botulinum toxin so dangerous also provides the foundation for it to be considered a therapeutic substance. When injected at therapeutic doses, it produces a localized chemical denervation muscle paralysis. Botulinum toxin type A BOTOX® (onabotulinumtoxinA) is useful in reducing the excessive, abnormal contractions associated with blepharospasm. BOTOX® has been FDA-approved for strabismus, blepharospasm associated with dystonia, including benign essential blepharospasm, or nerve disorders in patients over 12 years of age and cervical dystonia in adults.

DYSPORT® (abobotulinumtoxinA), XEOMIN® (incobotulinumtoxinA) and MYOBLOC® (rimabotulinumtoxinB) have been FDA-approved for the treatment of adults with cervical dystonia.

On January 18, 2013 the US Food and Drug Administration (FDA) approved BOTOX® (onabotulinumtoxinA) for the treatment of overactive bladder with symptoms of urge incontinence.

The criteria for treatment of overactive bladder include:

1. symptoms of urge urinary incontinence, and frequency
2. adults who have an inadequate response to or are intolerant of an anticholinergic medication.
3. Urinary incontinence due to neurogenic detrusor overactivity (NDO) commonly occurs in patients with spinal cord injuries (SCI)

4. neurological diseases such as multiple sclerosis (MS)

Other approved indications include: severe primary axillary hyperhidrosis, upper limb spasticity in adult patients, prophylaxis of headaches in adult patients with chronic migraine urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS), and overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

Primary focal hyperhidrosis: Blue CHiP for Medicare

- 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 (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 sweating during sleep

Primary focal hyperhidrosis: Commercial

The consequences of hyperhidrosis are primarily psychosocial in nature. Excessive perspiration may be socially embarrassing (e.g., limiting the ability to shake hands) or interfere with certain professions. For example, palmar hyperhidrosis may preclude artwork, working with electrical components, or playing certain musical instruments. In addition, hyperhidrosis may require several changes of clothing daily and may cause staining of clothing and/or shoes.

Primary focal hyperhidrosis may be defined as excessive sweating, beyond a level required to maintain normal body temperature, in response to health exposure or exercise. It may be classified as either primary or secondary. Primary focal hyperhidrosis is a condition characterized by visible, excessive sweating of at least 6 months duration without apparent cause and with at least 2 of the following features

- Bilateral and relatively symmetric sweating;
- Impairment of daily activities;
- Frequency of at least once per week;
- Age at onset younger than 25 years;
- Positive family history; and
- Cessation of focal sweating during sleep

Secondary hyperhidrosis:

Secondary hyperhidrosis may result from a variety of drugs, such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), or underlying diseases/conditions, such as febrile diseases, diabetes mellitus, or menopause. Secondary hyperhidrosis is usually generalized or craniofacial sweating

Secondary gustatory hyperhidrosis:

Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. This trigeminovascular reflex typically occurs symmetrically on scalp or face and predominately over forehead, lips, and nose.

Qualitative assessment tools include general health surveys and hyperhidrosis-specific surveys. Of these, the Hyperhidrosis Disease Severity Scale (HDSS) has been found to have a good correlation to other assessment tools and to be practical in the clinical setting.

Hyperhidrosis Disease Severity Scale

Using the hyperhidrosis disease severity scale, patients rate the severity of symptoms on a scale of 1-4 :

1. My underarm sweating is never noticeable and never interferes with my daily activities.
2. My underarm sweating is tolerable but sometimes interferes with my daily activities.
3. My underarm sweating is barely tolerable and frequently interferes with my daily activities.
4. My underarm sweating is intolerable and always interferes with my daily activities.

Chronic migraine:

On October 15, 2010, the FDA approved Botox injection for prevention of chronic migraine. Chronic migraine is defined as episodes that otherwise meet criteria for migraine (e.g., at least 4 hours in duration) that occur on at least 15 days per month for more than 3 months, in the absence of medication overuse.

Headache Classification (ICD-2) (ihs-classification.org/en/), diagnostic criteria for migraine without aura are:

1. At least 5 attacks fulfilling criteria B-D
2. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
3. Headache has at least two of the following characteristics:
 - a. unilateral location
 - b. pulsating quality
 - c. moderate or severe pain intensity
 - d. aggravation by or causing avoidance of routine activity (e.g., walking or climbing stairs)
4. During at least one of the following:
 - a. nausea and/or vomiting
 - b. photophobia and phonophobia
5. Not attributed to another disorder

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Member Certificate, Subscriber Agreement, and Benefits Booklet for applicable physician office injection coverage/benefits.

Botulinum toxin is covered under the member's medical benefit for those contracts with no specialty pharmacy benefit and is subject to any applicable copay/coinsurance and/or deductible.

Specialty Pharmacy

Botulinum toxin is available for member purchase at community pharmacies; however physicians may order Botulinum Toxin through the network specialty pharmacy. For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

CODING

The following codes require preauthorization for hyperhidrosis and migraines, and are covered for other diagnosis as listed in the policy:

J0585	Injection, Onabotulinumtoxin A, 1 unit (A)
J0586	Injection, Abobotulinumtoxin A, 5 units (A)
J0587	Injection, rimabotulinumtoxinB100 units (B)
J0588	Injection, Incobotulinumtoxin A, 1 unit

The following codes listed below are covered when administration of the above drug meets our medical criteria:

31570
31571

43201
46505
52287
64611
64612
64613 Delete 12/31/2013
64614 Delete 12/31/2013
64615
64616 Effective 1/1/2014
64617 Effective 1/1/2014
64642 Effective 1/1/2014
64643 Effective 1/1/2014
64644 Effective 1/1/2014
64645 Effective 1/1/2014
64646 Effective 1/1/2014
64647 Effective 1/1/2014
64650
67345
95873
95874
S2340
S2341

The following are diagnosis codes for the treatment of migraines and hyperhidrosis. For all other indications see diagnosis listed in the policy statement.

ICD-9-CM Chronic Migraine

(339.12)	Chronic tension type headache
(346.01)	Migraine with aura, with intractable migraine, so stated, without mention of status migrainosus
(346.03)	Migraine with aura, with intractable migraine, so stated, with status migrainosus
(346.11)	Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
(346.13)	Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
(346.21)	Variants of migraine, not elsewhere classified, with intractable migraine, so stated, without mention of status migrainosus
(346.23)	Variants of migraine, with intractable migraine, so stated, with status migrainosus
(346.31)	Hemiplegic migraine , with intractable migraine, so stated, without mention of status migrainosus
(346.33)	Hemiplegic migraine, with intractable migraine, so stated, with status migrainosus
(346.41)	Menstrual migraine, with intractable migraine, so stated, without mention of status migrainosus
(346.43)	Menstrual migraine, with intractable migraine, with intractable migraine, so stated, without mention of status migrainosus
(346.51)	Persistent migraine aura without cerebral infarction , with intractable migraine, so stated, without mention of status migrainosus
(346.53)	Persistent migraine aura without cerebral infarction , with intractable migraine, so stated, without mention of status migrainosus
(346.61)	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
(346.63)	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
(346.70)	Chronic migraine without aura, without mention of intractable migraine without mention of status migrainosus
(346.71)	Chronic migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
(346.72)	Chronic migraine without aura, without mention of intractable migraine with status migrainosus
(346.73)	Chronic migraine without aura, with intractable migraine, so stated, with status migrainosus
(346.81)	Other forms of migraine, with intractable migraine, so stated, without mention of status migrainosus
(346.83)	Other forms of migraine, with intractable migraine, so stated, with status migrainosus
(346.90)	Migraine, unspecified, without mention of intractable migraine, without mention of status migrainosus
(346.91)	Migraine, unspecified, with intractable migraine, so stated, without mention of status migrainosus
(346.92)	Migraine, unspecified, without mention of intractable migraine with status migrainosus
(346.93)	Migraine, unspecified, with intractable migraine, so stated, with status migrainosus

ICD-9-CM Codes for hyperhidrosis:

(705.2)	Focal hyperhidrosis
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(705.21)	Primary focal hyperhidrosis
(705.22)	Secondary focal hyperhidrosis

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update	Jun 2013
Provider Update	Oct 2012
Provider Update	May 2011
Provider Update	Jan 2011
Provider Update	Feb 2010
Provider Update	Jul 2009
Policy Update	Nov 2006
Policy Update	Oct 2001
Policy Update	May 2001
Policy Update	Nov 2000



Updated list botox
ICD9-10.xlsx

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