

## Medical Coverage Policy | Botulinum Toxin Injection



**EFFECTIVE DATE:** 09/17/2007

**POLICY LAST UPDATED:** 07/15/2014

### OVERVIEW

Botulinum toxin is produced by the anaerobic clostridium botulinum. Botulinum toxin type A is useful in reducing the excessive, abnormal contractions associated with blepharospasm and hyperhidrosis. Botulinum Toxin A has been approved for the treatment of migraines, hyperhidrosis, 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

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products for the Botulinum Toxin A, for the treatment of migraines or hyperhidrosis.

### POLICY STATEMENT

#### **BlueCHiP for Medicare and Commercial:**

Botulinum toxin A for the treatment of migraines and hyperhidrosis is medically necessary when the below criteria has been met and prior authorization has been obtained.

Botulinum toxin A, for other indications is covered only when filed with one of the diagnosis listed in the attachment below (diagnosis code Type A edit no auth), all other indications are not medically necessary as their is insufficient peer reviewed scientific literature that demonstrates that the procedure service is effective. For the treatment of wrinkles or any other cosmetic indications, it is not a covered benefit.

Botulinum Type B is covered when filed with one of the indications listed in the attachment below( Botox B, ICD9 edits).

Use of Botulinum toxin B, for any diagnoses not listed in the attachments below is not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

### MEDICAL CRITERIA

Hyperhidrosis: J0585 Injection, Onabolulinumtoxina1 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:

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

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.

Migraines (J0585 Injection, Onabotulinumtoxin A, 1 unit A)

### **Blue CHiP for Medicare**

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
  - 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.

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

- 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 is medically necessary when all of the criteria below is met:

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 is medically necessary when one of the criteria below is met :

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

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 includes:

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/](http://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**

BlueCHIP for Medicare and Commercial Botulinum Toxin type A

- J0585 Injection, Onabotulinumtoxin A, 1 unit (A)
- J0586 Injection, Abobotulinumtoxin A, 5 units (A)
- J0588 Injection, Incobotulinumtoxin A, 1 unit

The HCPC codes above require pre-authorization for hyperhidrosis and migraines, (dx codes as in attachment below).

The HCPC codes listed above are covered for other diagnosis as listed in the attachment below:

Botulinum Toxin type B

J0587 Injection, rimabotulinumtoxin B100 units (B):

The HCPC code listed above for Botulinum type B is covered for conditions as listed in the attachment below, such as spasticity related to stroke or spinal cord injury or other forms of upper motor neuron spasticity.

The procedure codes listed below are covered when submitted with one of the diagnosis codes attached and one of the following HCPC codes, (J0585, J0586 and J0588), and meets our medical criteria.

- 31513**
- 31570**
- 31571**
- 43201**
- 43236**

46505  
52287  
64611  
64612  
64613 Deleted 12/31/13  
64614 Deleted 12/31/13  
64615  
64616  
64617  
64642  
64643  
64644  
64645  
64646  
64647  
64650  
64653  
67345  
95873  
95874  
S2340  
S2341

Botulinum toxin A, (**J0585, J0586 and J0588**) for the treatment of migraines and hyperhidrosis, is covered for the following indications when filed with the appropriate diagnosis codes listed in the attachment below:



ICD9 Migraine  
hyperhidrosis.pdf

Botulinum toxin A, (**J0585, J0586, J0588**), is covered for the following indications when filed with the appropriate diagnosis codes listed in the attachment below:



ICD9 dx code edits  
Type A no auth.pdf

Botulinum B (**J0587**), is covered for the following indications when filed with the appropriate diagnosis codes listed in the attachment below:



Botox B, ICD9  
edits.pdf

## RELATED POLICIES

Not applicable

## PUBLISHED

Provider Update	Sept 2014
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Provider Update	Jun 2013
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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

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