## Botulinum Toxin A and B

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<td>12/10/2012</td>
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<tr>
<td>UnitedHealthcare National Pharmacy &amp; Therapeutics Committee</td>
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**IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY**

*You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Community Plan reimbursement policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS) or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.*

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general reference resource regarding UnitedHealthcare Community Plan’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Community Plan may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Community Plan enrollees.

**Other factors affecting reimbursement supplement, modify or, in some cases, supersede this policy. These factors include, but are not limited to: federal &/or state regulatory requirements, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents.**

Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Community Plan due to programming or other constraints; however, UnitedHealthcare Community Plan strives to minimize these variations.

UnitedHealthcare Community Plan may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

UnitedHealthcare Community Plan uses a customized version of the Ingenix Claims Editing System known as iCES Clearinghouse to process claims in accordance with UnitedHealthcare Community Plan reimbursement policies.

*CPT® is a registered trademark of the American Medical Association*
### Application

This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians and other health care professionals. This includes non-network authorized and percent of charge contract physicians and other health care professionals.

**Payment Policies for Medicare & Retirement, Employer & Individual, Florida Medicaid and Rhode Island Medicaid please use this link.**

### Policy

**Overview**

This policy provides information about Botulinum toxin type A [onabotulinumtoxinA (Botox®), abobotulinumtoxinA (Dysport™), incobotulinumtoxinA (Xeomin®)] and Botulinum toxin type B [rimabotulinumtoxinB (Myobloc®)], and their recommended uses. Botulinum toxins are neurotoxins that inhibit acetylcholine release at the neuromuscular junction. They are used in the treatment of a variety of neuromuscular conditions. Botulinum toxin type A and B are cosmetic when used to improve appearance, or in the absence of physiological functional impairment that would be improved by their use. UnitedHealthcare Community Plan health plans exclude benefit coverage for cosmetic services. Botulinum toxin type A and B are U.S. Food and Drug Administration (FDA) approved for the following non-cosmetic uses:

**Botulinum toxin type A (Botox®, Dysport™, Xeomin®)**

- Botox – axillary hyperhidrosis, cervical dystonia, chronic migraine, strabismus and blepharospasm associated with dystonia, upper limb spasticity
- Dysport – cervical dystonia
- Xeomin – blepharospasm, cervical dystonia

**Botulinum toxin type B (Myobloc®)** – cervical dystonia

Scientific evidence in the literature also supports their use for other, un-labeled indications.

For details on clinical evidence, see link above to policies for Employer & Individual.

### Reimbursement

Botulinum toxin type A [onabotulinumtoxinA (Botox®), abobotulinumtoxinA (Dysport™)] is proven in the treatment of the following non-cosmetic conditions:

1) **Achalasia**¹³,¹⁵
2) Anal fissures, chronic\textsuperscript{11,12,14}  
3) Cervical dystonia (spasmotic torticollis)\textsuperscript{1,21}  
4) Detrusor-sphincter dyssynergia due to spinal cord injury or disease\textsuperscript{19,27,29}  
5) Hand dystonia (writer's, musician's or typist's cramp)\textsuperscript{31}  
6) Hand tremor\textsuperscript{8,31}  
7) Hemifacial spasm (seventh cranial nerve disorders)\textsuperscript{22,31}  
8) Hyperhidrosis\textsuperscript{1,29} including gustatory sweating (Frey's Syndrome)\textsuperscript{16,20,29,33}  
9) Neurogenic detrusor hyperreflexia\textsuperscript{17,26,29,30,36}  
10) Oromandibular dystonia\textsuperscript{4,5,7}  
11) Piriformis syndrome\textsuperscript{24,35}  
12) Sialorrhea\textsuperscript{18,25,29}  
13) Spasmodic dysphonia (laryngeal dystonia)\textsuperscript{4,6,31}  
14) Spasticity associated with cerebral palsy; multiple sclerosis; stroke; or other injury, disease, or tumor of the brain or spinal cord\textsuperscript{1,10,23,34}  
15) Strabismus and blepharospasm associated with dystonia\textsuperscript{1,31}  
16) Tongue dystonia\textsuperscript{4,5,7,28}  
17) Torsion dystonia\textsuperscript{3,4,5}  
18) Voice tremor\textsuperscript{6,8,32}  

Botulinum toxin type A [onabotulinumtoxinA (Botox\textsuperscript{\textregistered})] is proven in the treatment of chronic migraine headache\textsuperscript{1} - OnabotulinumtoxinA (Botox\textsuperscript{\textregistered}) is FDA approved for the prophylaxis of headaches in adult patients with chronic migraine (\geq 15 days per month with headache lasting 4 hours a day or longer).

**Additional information to support medical necessity review where applicable:**
The International Headache Society defines the following criteria for chronic migraine:\textsuperscript{41}

A. Headache (tension-type and/or migraine) on \geq 15 days per month for at least 3 months  
B. Occurring in a patient who has had at least five attacks fulfilling criteria for migraine without aura  
C. On \geq 8 days per month for at least 3 months headache has fulfilled C1 and/or C2 below, that is, has fulfilled criteria for pain and associated symptoms of migraine without aura  
1) Has at least two of the following  
   a) unilateral location  
   b) pulsating quality  
   c) moderate or severe pain intensity  
   d) aggravation by or causing avoidance of routine physical activity  
      (e.g. walking or climbing stairs) AND  
2) Has at least one of the following  
   a) nausea and/or vomiting  
   b) photophobia and phonophobia  
3) Treated and relieved by triptan(s) or ergot before the expected development of C1 above
D. No medication overuse and not attributed to another causative disorder

OnabotulinumtoxinA should be reserved for patients who have failed trials of preventative anti-migraine medications from two of the following classes: beta-blockers, calcium channel blockers, anticonvulsants, and/or antidepressants\(^{42}\) (with or without concomitant behavioral and/or physical therapies) after titration to maximum tolerated doses.

Botulinum toxin type A [incobotulinumtoxinA (Xeomin\(^\text{®}\))] is proven in the treatment of the following conditions:

1) Cervical dystonia (spasmodic torticollis)\(^{42}\)
2) Blepharospasm associated with dystonia\(^{42}\)
3) Spasticity associated with cerebral palsy; multiple sclerosis; stroke; or other injury, disease, or tumor of the brain or spinal cord\(^{39-40}\)

Botulinum toxin type B [rimabotulinumtoxinB (Myobloc\(^\text{®}\))] is proven in the treatment of the following conditions:

1) Cervical dystonia (spasmodic torticollis)\(^{2}\)
2) Sialorrhea\(^{29,37-8}\)
3) Neurogenic detrusor hyperreflexia\(^{29,30}\)

AbobotulinumtoxinA (Dysport\(^\text{TM}\)), incobotulinumtoxinA (Xeomin\(^\text{®}\)), and rimabotulinumtoxinB (Myobloc\(^\text{®}\)) are unproven in the treatment of chronic migraine headache.

Botulinum toxin types A and B are unproven in the treatment of the following conditions:

1) Acquired nystagmus\(^{18-20,172-3}\)
2) Anismus (pelvic floor dyssynergia)\(^{51,78,139,140}\)
3) Benign prostatic hyperplasia\(^{109,130,146,285}\)
4) Brachial plexus palsy\(^{69,70,237-8}\)
5) Chronic daily headache\(^{133-135,138,179,188}\)
6) Chronic low back pain\(^{90,138}\)
7) Chronic prostatic pain\(^{53,146}\)
8) Cricopharyngeal dysphagia\(^{42,64-5,148-64}\)
9) Epiphora following salivary gland transplantation\(^{77}\)
10) Esophageal spasm\(^{74,190}\)
11) Gastroparesis (including diabetic gastroparesis)\(^{89,90,98,145,270-7,290}\)
12) Gustatory epiphora (Crocodile tears)\(^{48,77,193-5}\)
13) Head tremor\(^{14-15}\)
14) Lateral epicondylitis (tennis elbow)\(^{95,248-51}\)
15) Lichen simplex\(^{84}\)
16) Lower urinary tract (voiding) dysfunction\(^{71,88,122-3,146}\)
17) Motor tics\(^{62,189}\)
18) Myofascial pain syndrome\(^{69,75,96,226-36}\)
19) Nasal hypersecretion\(^{83,247,284}\)
20) Pain and/or wound healing after hemorrhoidectomy\(^{125,265-6}\)
21) Pancreas divisum\(^{72}\)
22) Pelvic floor spasticity (and associated pain conditions)\(^{146,291}\)
23) Postparotidectomy sialoceles\(^{88}\)
24) Post-thoracotomy pseudoangina
25) Proctalgia fugax
26) Severe bruxism
27) Severe paradoxical vocal cord movement
28) Sphincter of Oddi dysfunction
29) Stiff-person syndrome
30) Temporomandibular disorders
31) Tension headache
32) Thyroid associated ophthalmopathy
33) Tourette's syndrome
34) Traumatic sixth nerve palsy
35) Trigeminal neuralgia
36) Trismus and stridor in amyotrophic lateral sclerosis

Botulinum toxin type A and B may be approved for uses other than the proven conditions noted above, as per specific state requirements.

**Centers for Medicare and Medicaid Services (CMS):**
Medicare does not have a National Coverage Determination (NCD) for botulinum toxins. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, Section 50 Drugs and Biologicals at [http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf](http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf).

Local Coverage Determinations (LCDs) for Botulinum Toxins which address the four (4) botulinum toxin products, Botox (onabotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA) and Xeomin (incobotulinumtoxinA) exist. Compliance with these policies is required where applicable. These LCDs are available at [Botulinum Toxin](#) and [Botulinum Toxins Type A and B](#) and [Drugs and Biologicals Botulinum Toxin](#) and [Serotypes A and B Botulinum Toxin Products](#)

(Accessed May 21, 2012)

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Approved Diagnosis List for Botulinum toxin type A and B and incobotulinumtoxinA

Resources

Individual state Medicaid regulations, manuals & fee schedules


Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

References


### History

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| 1/1/2013   | Annual Policy Version Change  
State Exception Section: added AZ information  
Clinical evidence and references updated. Added Cochrane review on low back pain. Added Hayes Medical Technology Directory on tension-type headache. |
| 12/10/12   | Annual renewal of policy approved                                           |
| 2/12/2012  | Policy Update: added information about Xeomin  
Policy List Update: added code J0588                                          |
| 1/1/2012   | Annual Version Change                                                        |
| 11/14/2011 | Policy posted by UnitedHealthcare Community & State                          |

### 2013A United Healthcare Community Plan Botulinum Policy Allowable Diagnosis List

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