



Description

CPT Code J0585, Injection, OnabotulinumtoxinA, 1 unit

Botulinum toxin injections are commonly used to treat a wide variety of conditions in which the main therapeutic effect is to decrease undesired or excessive contraction of striated or smooth (involuntary) muscle. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical-denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively.

Medical Necessity

Documentation must support compliance with Medicare rules and regulations such as: diagnoses; appropriate orders and signatures; administration/frequency/deliverance of the service; as well as correct coding and billing of the drug, per medical necessity.

Accepted Dosage and Administration

Condition	Dosage
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	Overactive Bladder: Recommended total dose 100 Units, as 0.5 mL (5 Units) injections across 20 sites into the detrusor
Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication	Detrusor Overactivity associated with a Neurologic Condition: Recommended total dose 200 Units, as 1 mL (~6.7 Units) injections across 30 sites into the detrusor
Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)	Chronic Migraine: Recommended total dose 155 Units, as 0.1 mL (5 Units) injections per each site divided across 7 head/neck muscles
Treatment of spasticity in adult patients	<ul style="list-style-type: none">Upper Limb Spasticity: Select dose based on muscles affected, severity of muscle activity, prior response to treatment, and adverse event history; Electromyographic guidance recommendedLower Limb Spasticity: Recommended total dose 300 Units to 400 Units divided across ankle and toe muscles
Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain	Cervical Dystonia: Base dosing on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum toxin naïve patients
Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients	Axillary Hyperhidrosis: 50 Units per axilla
Treatment of blepharospasm associated with dystonia in patients ≥12 years of age	Blepharospasm: 1.25 Units-2.5 Units into each of 3 sites per affected eye
Treatment of strabismus in patients ≥12 years of age	Strabismus: The dose is based on prism diopter correction or previous response to treatment with BOTOX
Prophylaxis of episodic migraine (14 headache days or fewer per month)	
Treatment of upper or lower limb spasticity in pediatric patients	
Treatment of hyperhidrosis in body areas other than axillary	

This Fact Sheet is for informational purposes only and is not intended to guarantee payment for services, all services submitted to Medicare must meet Medical Necessity guidelines. The definition of "medically necessary" for Medicare purposes can be found in Section 1862(a)(1)(A) of the Social Security Act – Medical Necessity (http://www.ssa.gov/OP_Home/ssact/title18/1862.htm).

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Coding

- All services/procedures performed on the same day for the same beneficiary by the physician/provider should be billed on the same claim.
- The relevant anatomic modifier, or the modifier 59 (distinct procedural services) should be reported as applicable. Please indicate the left (LT) or right (RT) modifier.
- Bilateral services must be reported on separate lines using an RT and LT modifier (bilateral modifier (50) should not be used).
- When HCPCS code J0585 is denied, the related injection code(s) will also be subject to denial.
- Due to the short life span of the drug once it is reconstituted, Medicare will reimburse the unused portions of Botulinum toxins. When modifier –JW is used to report that a portion of the drug is discarded, the medical record must clearly show the amount administered and the amount discarded.
- Dose and frequency should be in accordance with the FDA label. When services are performed in excess of established parameters, they may be subject to review for medical necessity.
- Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts

Supporting Documentation

Documentation of Administration

- If applicable, an ABN should be present in the record.
- Signed order must be present for the drug by the approved specialty provider. In addition, a purchase order with the name of the drug and information on single dose vial or multi dose vial should be included.
- Documentation of the medical necessity for this treatment. For spastic conditions other than upper or lower limb spasticity, blepharospasm, hemifacial spasm, cervical dystonia or other focal dystonias, documentation should include a statement that the spastic condition has been unresponsive to conventional treatment
- Covered diagnosis.
- Dosage(s), site(s) and frequency(ies) of injection
- Documentation of the medical necessity for associated electromyography when used; and
- Description of the effectiveness of this treatment.

The following administration details must be documented within the record:

- Name of the drug
- Date of Service
- Patient consent
- Documentation to support drug was administered to the correct beneficiary
- Amount of the drug administered per the order
- Documentation to support route drug was administered
- Amount of the drug wasted, signature of person wasting, and appropriate modifier (JW) if applicable

Off-Label indications for onabotulinumtoxin (Botox®) may be considered medically reasonable and necessary in patients for the following conditions:

- Esophageal achalasia in adults who are considered poor surgical candidates
- Chronic anal fissure for patients with inadequate response to conservative or pharmacologic treatment
- Essential hand tremor for patients with a high amplitude tremor that disrupts activities of daily living and have had inadequate response to oral pharmacotherapy such as propranolol and primidone
- Focal limb dystonia
- Hemifacial spasm in adults (cranial nerve VII disorder)
- Isolated oromandibular dystonia in adults
- Laryngeal dystonia (spastic dysphonia) for adductor type (ADSD)
- Botherome simple motor tics in adolescents and adults when the benefits of treatment outweigh the risks
- Severely disabling or aggressive vocal tics in older adolescents and adults when the benefits of treatment outweigh the risks



Appropriate Signatures

- Signature and credentials of person performing the service must meet CMS requirements
- Amendments/corrections/delayed entries are properly identified

For more information regarding signature requirements, please view the following resources:

- CGS Administrators, LLC, J15 Part B Medical Review
 - <https://www.cgsmedicare.com/partb/mr/signatures.html>
 - <https://www.cgsmedicare.com/partb/cert/signatures.pdf>
- CMS MLN Fact Sheet, Complying with Medicare Signature Requirements.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/signature_requirements_fact_sheet_icn905364.pdf
- CMS IOM Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4, Signature Requirements.
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf>

References

- IOM 100-02, Chapter 15 – Covered Medical and Other Health Services
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>
- IOM 100-04, Chapter 17 – Drugs and Biologicals
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>
- Article - Billing and Coding: Botulinum Toxins (A56472)
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56472&ver=20&LCDId=33949&ContrlD=239&ContrVer=1&CntrctrSelected=239*1&Cntrctr=239&DocType=2&bc=AAAAgACAIAAA&=
- LCD - Botulinum Toxins (L33949)
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33949&ver=25&ContrlD=239&ContrVer=1&CntrctrSelected=239*1&Cntrctr=239&DocType=2&bc=AAAAgACAAAAA&=
- BOTOX (onabotulinumtoxinA) for injection, for intramuscular
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf