

# Review Criteria

**Review Area:** OUTPATIENT SURGERY

**Date Implemented:** 05/24/2019  
**Last Review Date:** 05/24/2019

**Specific Item/Procedure/Service: Botox Injections**

**Approved Criteria Set:**

- InterQual
- LMP
- LMP as an internal IQ edit
- BMS Criteria (based on Policy Manual)
- BMS Approved Criteria

**Local Medical Policy: Developed Criteria Specific**

**Applicable HCPCS/CPT Codes:** J0585, J0586, J0587, J0588

**Applicable ICD10 Codes: (if diagnosis specific restricted) See tables below for diagnostic restrictions.**

**Definition:**

**Botox®** OnabotulinumtoxinA: is an acetylcholine release inhibitor and neuromuscular blocking agent. While Botox has a number of FDA-approved indications, this criteria document applies **ONLY** to the prophylaxis of headaches in adult patients with chronic migraine\* (≥15 days/month with headache lasting ≥4 hrs/day).

**Criteria:**

Initiation of botulinum toxin **meets the definition of medical necessity** when administered for the treatment of indications listed in Table 1.

[table 1.pdf](#)

For J0585 coverage only, refer to Table 2.

[table 2.pdf](#)

For the list of Chemodenervation Codes, refer to Table 3.

[table 3.pdf](#)

**For prevention of chronic migraine headaches, administration of botulinum toxin meets the definition of medical necessity when all of the following criteria is met:**

1. Diagnosis limited to the following:
  - G43.011 Migraine without aura, intractable, with status migrainosus
  - G43.019 Migraine without aura, intractable, without status migrainosus
  - G43.111 Migraine with aura, intractable, with status migrainosus
  - G43.119 Migraine with aura, intractable, without status migrainosus
  - G43.411 Hemiplegic migraine, intractable, with status migrainosus
  - G43.419 Hemiplegic migraine, intractable, without status migrainosus
  - G43.511 Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
  - G43.519 Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
  - G43.611 Persistent migraine aura with cerebral infarction, intractable, with status migrainosus
  - G43.619 Persistent migraine aura with cerebral infarction, intractable, without status migrainosus
  - G43.711 Chronic migraine without aura, intractable, with status migrainosus
  - G43.719 Chronic migraine without aura, intractable, without status migrainosus
2. The patient is within the age range as recommended by the FDA label; **AND**
3. Prescriber must be a neurologist or similar specialist, **AND**
4. Patient is experiencing at least fifteen (15) days per month with headache lasting four (4) hours a day or longer, **AND**
5. Claims data must indicate the use of acute therapy as well as at least one 90-day trial of prophylaxis therapy (see below) within the most recent 12 months prior to the initial request. **The use of samples shall not be considered**; **AND**
6. **Patient has failed to achieve therapeutic goals after using one of the listed agents from each of the following classes of preventative medications\***. Individual trials may be waived when evidence is presented indicating the presence of a direct contraindication due to a clinically significant allergy, drug interaction or adverse effect. Listed are the doses at which efficacy has generally been observed:
  - **Beta blockers** - metoprolol (50 – 200 mg daily), propranolol (40-160 mg daily), timolol (10-30 mg daily), nadolol (20-240 mg daily), atenolol (25-100 mg daily)
  - **Anti-depressants** - amitriptyline (20-50 mg qHS), venlafaxine (75-150 mg daily)
  - **Anti-epileptic drugs** - valproate (500-1500 mg daily), topiramate (100 mg daily)

\*Agents may be used alone or in combination, but records indicate that the patient was compliant on each of the agents for at least 90 consecutive days, and one of these trials must have occurred within the last 12 months prior to the request.

7. Additional therapy may be approved only with clinical documentation showing a 50% reduction in either number of headache days per month or the overall symptom severity (as measured by MIDAS of HIT-6) compared to baseline.

**Botulinum toxin is considered experimental and investigational for migraines that do not meet the above-listed criteria.**

*Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.*

**References: WV Bureau of Medical Services Manual: Drug Code List Version 11.2 Revised 9/11/17**  
[http://dhhr.wv.gov/bms/HCPCS/Documents/NDC%20drug%20codes/2017/Copy%20of%20NDC\\_DRUG%20CODE%20LIST\\_v%20%2011.2\\_091117.pdf](http://dhhr.wv.gov/bms/HCPCS/Documents/NDC%20drug%20codes/2017/Copy%20of%20NDC_DRUG%20CODE%20LIST_v%20%2011.2_091117.pdf) (Accessed 10/26/2017)

[http://dhhr.wv.gov/bms/HCPCS/Documents/Other%20J%20codes/J0585\\_J0586\\_J0587\\_J0588\\_MAID\\_COVERAGE\\_Rev%203.pdf](http://dhhr.wv.gov/bms/HCPCS/Documents/Other%20J%20codes/J0585_J0586_J0587_J0588_MAID_COVERAGE_Rev%203.pdf) (Accessed 10/26/2017)

WV Bureau of Medical Services, Chapter 518.1.5  
[http://dhhr.wv.gov/bms/Provider/Documents/Manuals/Policy/Policy\\_518.1\\_Physician\\_Administered\\_Drugs.pdf](http://dhhr.wv.gov/bms/Provider/Documents/Manuals/Policy/Policy_518.1_Physician_Administered_Drugs.pdf) (Accessed 10/26/2017)

Botox [package insert]. Irvine, CA. Allergan Inc. April 2017

LexiComp monograph on Botox (reviewed 03/26/2019)

Preventative treatment in migraine and the new US guidelines. Neuropsychiatr Dis Treat. 2013; 9: 709-720.

American Academy of Neurology 2012 Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults

<https://securecms.highmark.com/content/medpolicy/en/highmark/wv/commercial/policies/Injections/I-11/I-11-034.html> (Accessed 3/1/19)

[https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/botulinum\\_toxin\\_injection.pdf](https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/botulinum_toxin_injection.pdf) (Accessed 3/1/19)

[http://www.aetna.com/cpb/medical/data/100\\_199/0113.html](http://www.aetna.com/cpb/medical/data/100_199/0113.html) (Accessed 3/1/19)

<https://www.wellmark.com/Provider/MedicalDentalPharm/Pharmacy/docs/NeuromuscularBlockingAgents.pdf> (Accessed 3/1/19)

Review Date	Approving Authority/Responsible Party	Date Approved:
11/15/2017	Sherri Young, DO, FAAFP, Medical Director, WV KEPRO	

04/24/2019	Paul Kuryla, MD Medical Director, WV KEPRO	04/24/2019
05/24/2019	Brian Thompson, PharmD BMS	05/24/2019