APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. Note: Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

OnabotulinumtoxinA (Botox) injections have been found to be effective in individuals with a variety of medical conditions. Four types of botulinum toxin have received U.S. Food and Drug Administration (FDA) approval. Various botulinum toxin types are used for a range of off-label indications.

POSITION STATEMENT

Applicable To:
- [ ] Medicaid
- [x] Medicare

Botulinum toxin is considered medically necessary when the member has one of the following diagnoses and meets the corresponding criteria. Coverage duration is 12 weeks.

1. **Chronic Migraines**

   Botulinum Toxin for the treatment of headaches is a covered benefit and medically necessary when the following criteria are met:

   **OnabotulinumtoxinA (Botox Brand of Botulinum Toxin Type A)**

   Member must meet the following criteria pertinent to their medical condition

   1. **Migraines** for prevention of chronic (15 days or more per month with headaches lasting 4 hours a day or longer) migraine headaches (see appendix for diagnostic criteria) in adults who have tried and failed trials of at least 3 classes of migraine headache prophylaxis medications of at least 2 months (60 days) duration for each medication:

      a. Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (e.g., losartan, valsartan, lisinopril);
      b. Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortriptiline, protriptyline);
      c. Anti-epileptic drugs (e.g., gabapentin, topiramate, valproic acid);
      d. Beta blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol);
      e. Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil);
      f. Alpha agonist (e.g., clonidine, guanfacine);
      g. Antihistamine (e.g., cyproheptadine).

   AND,

   2. Member is 18 years of age or older.

   AND,
3. Dose of OnabotulinumtoxinA does not exceed 155 units administered intramuscularly divided over 31 injection sites every 12 weeks.

**Continued Treatment**

Continued treatment for ongoing prophylaxis when the member experiences a beneficial response to one of the following:

- Migraine headache frequency was reduced by 7 days per month or more (when compared to pre-treatment average) by the end of the initial trial; OR,
- Migraine headache duration was reduced by 100 total hours per month or more (when compared to pre-treatment average) by the end of the month.

2. **Upper Limb Spasticity.** Documented history of treatment failure or intolerable side effects from treatment with two (2) of the preferred medications: baclofen and cyclobenzaprine.

3. **Cervical dystonia.** Documented history of treatment failure or intolerable side effects from treatment with 1 of the preferred medications from 2 different classes of medications: anticholinergic agents (trihexyphenidyl or benztropine) and skeletal muscle relaxants (chlorzoxazone, methocarbamol, cyclobenzaprine or carisoprodol).

4. **Primary Axillary hyperhidrosis.** Documented history of treatment failure or intolerable side effects from treatment with Aluminum Chloride antiperspirant.

5. **Detrusor Overactivity.** Documented history of trial and failure or intolerable side effects with 2 of the preferred medications: oxybutynin or trospium.  

6. **Blepharospasm or strabismus.** Documented diagnosis of blepharospasm or strabismus

**Age Restrictions**

- 18 years or older (chronic migraine, upper limb spasticity, primary axillary hyperhidrosis, or detrusor)
- 16 years or greater (cervical dystonia)
- 12 years or greater (blepharospasm and strabismus)

**Experimental / Investigational Indications**

Botulinum toxin is considered experimental and investigational for diagnoses that do not meet the above-listed criteria. This includes use of botulinum toxin for cosmetic purposes as well as for the treatment of episodic migraines (those occurring 14 days or fewer per month), chronic daily headaches and tension headaches.

AbobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), and rimabotulinumtoxinB (Myobloc) are considered experimental and investigational for the treatment of chronic migraine headache.
CODING

CPT© Codes – No applicable codes.

HCPCS® Codes

J0585 Injection, Onabotulinumtoxin A, 1 unit
J0586 Injection, Abobotulinumtoxin A, 5 units
J0587 Injection, Rimabotulinumtoxin B, 100 units
J0588 Injection, Incobotulinumtoxin A, 1 unit

Covered ICD-9-CM Diagnosis Codes

333.6 Genetic torsion dystonia
333.81 Blepharospasm
333.83 Spasmodic torticollis
346.00-346.93 Migraine
378.00-378.90 Strabismus and other disorders of binocular eye movements
596.55 Detrusor sphincter dyssynergia
728.85 Spasm of muscle
780.8 Generalized hyperhidrosis

Covered DRAFT ICD-10-CM Diagnosis Codes

G24.1 Genetic torsion dystonia
G24.3 Spasmodic torticollis
G24.5 Blepharospasm
G43 Migraine
H50.00-H50.9 Other strabismus
H51.0-H51.9 Other disorders of binocular movement
M62.411-M62.419 Contracture of muscle, shoulder
M62.421-M62.429 Contracture of muscle, upper arm
M62.431-M62.439 Contracture of muscle, forearm
M62.441-M62.449 Contracture of muscle, hand
N36.44 Muscular disorders of urethra
R61 Generalized hyperhidrosis


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<th>Date</th>
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<tbody>
<tr>
<td>9/17/2015</td>
<td>Approved by MPC. Expanded indications for coverage.</td>
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<tr>
<td>11/6/2014</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>11/7/2013</td>
<td>Approved by MPC. New.</td>
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Original Effective Date: 11/7/2013 - Revised: 11/6/2014, 9/17/2015