**Benefit Coverage**
This clinical medical policy addresses coverage of Botulinum Toxin Type A and B for all Lines of Business, excluding Extended Family Planning (EFP).

**Description**
This clinical medical policy addresses coverage of Botulinum Toxin Type A and B for all Lines of Business, excluding Extended Family Planning (EFP).
Botulinum neurotoxin is a microbial protein that exists in seven serotypes, designated A through G. Although the individual serotypes are immunologically distinct, all members of the group possess similar subunit structures, act on the same target organs, and produce similar functional outcomes. Two serotypes (A and B) are Food and Drug Administration (FDA) approved or clinical use in the United States. Botox (onabotulinumtoxin A) is approved for the treatment of strabismus, blepharospasm, cervical dystonia and axillary hyperhidrosis and Myobloc (rimabotuliumtoxinB) is approved for cervical dystonia. Dysport (AbobotulinumtoxinA) is approved for cervical dystonia and Xeomin (IncobotulinumtoxinA) is approved for blepharospasm and cervical dystonia.

**Coverage Determination**
Neighborhood Health Plan of Rhode Island (Neighborhood) covers Botulinum Toxin Type A and B as a clinical option when recommended by the member’s primary care physician, neurologist, urologist or plastic surgeon and determined medically necessary by the Medical Management Department. Botulinum Toxin A and B will only be covered for the listed diagnoses. No other indications will be considered medically necessary as there is insufficient data supporting the effectiveness of the procedure and drug for other conditions. Cosmetic indications are not a covered benefit.

Retroactive requests for procedures already performed may not be covered.

Requests with incomplete information will be returned for completion prior to review.

**Criteria**
**General Criteria:**
For all requests the following is required.

1. Clinical documentation including history and physical examination documenting the severity of the condition, the previous treatment for the condition if applicable, and laboratory results or diagnostic evidence for the indication for which the botulinum toxin is requested.
2. If the request is for continuation of treatment, documentation of the positive response to treatment and the expected length and frequency of treatment is required.
3. The approved frequency of repeat administration irrespective of diagnosis is not less than every twelve weeks. Some retreatment schedules are longer than every twelve weeks and will be indicated below.
Specific Criteria

Blepharospasm Criteria
- Onabotulinumtoxin A - initial dose 1.25 - 2.5U each site. Cumulative dose not more than 200U in a 30 day period
- Incobotulinumtoxin A – if dose of Botox is not known, starting dose is 1.25 to 2.5U per injection site. Highest dose permitted in clinical trials is 35U per eye. Total dosing no more than 35U/eye or 70 U/both eyes every 12 weeks.

Cervical Dystonia criteria
- Sustained head torsion and/or tilt with limited range of motion in the neck and pain and
- Recurrent involuntary contraction of one or more muscles in the neck and
- Duration for more than six months and
- Alternative causes of member’s symptoms have been considered and ruled out.
- Onabotulinumtoxin A – mean dose 236U divided among affected muscles (25th to 75th percentile range 198-300U). Maximum of 50U/site. Initial dose in previously untreated patients should be lower. Sequential dosing should be based on the patient’s head and neck position, localization of pain, muscle hypertrophy, patient response and previous adverse reactions. Total dose injected in sternocleidomastoid muscles should be less than 100U to decrease the occurrence of dysphagia.
- Incobotulinumtoxin A – 120U per session with a total of 2-10 injections into treated muscles
- Abobotulinumtoxin A – 500U divided among affected muscles. Adjust dosage in 250U increments depending on patient’s response.
- Rimabotulinumtoxin B – If previously treated, 2500 – 5000U divided among affected muscles. If previously untreated, the initial dose should be lower.

Chronic Migraine criteria
- Diagnosis of migraine headaches
- More than 15 headaches per month lasting more than 4 hours and
- Has been evaluated for medication overuse (rebound) headaches and
- Has trialed 2 or more migraine headache prophylaxis medications from different drug classes of adequate dose and duration (at least 2 months)
- Onabotulinumtoxin A – 5U/0.1ml per site. Recommended total dose is 155 U equally divided and administered bilaterally into 31 total sites every 12 weeks.
- If members do not respond to a course of treatment, it should be discontinued. Positive response to treatment is considered to be, reduction in migraine headache frequency of at least 7 days per month or reduction in headache duration of at least 100 hours per month by the end of initial trial.

Hyperhidrosis criteria
- Diagnosis of severe axillary hyperhidrosis for at least six months duration without apparent cause and
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Botulinum Toxin Type A and B

- Has had a trial of aluminum chloride and at least one oral anticholinergic (e.g. glycopyrrolate) of adequate dose and duration and has been unresponsive, failed to achieve adequate clinical outcome or has had a significant side effect (such as severe rash from topical medication) and
- Unable to perform clinically documented age-appropriate daily activities in professional and/or social life and
- Severity of level 3 or 4 on the hyperhidrosis disease severity scale
- onabotulinumtoxin A – 50U/axilla evenly distributed into multiple sites. Can be given every 4 months.

Limb Spasticity criteria

- Diagnosis of cerebral palsy, multiple sclerosis or other demyelinating disease of the central nervous system, hereditary spastic paraplegia, other injury, disease or tumor of brain/spinal cord and spasticity following stroke
- Documentation that abnormal muscle tone is either interfering with functional ability or is expected to result in joint contracture with growth and
- Failure of standard medical treatment and
- Surgical intervention would be the next option
- onabotulinumtoxin A – up to a total dose of 360U (from clinical trials used to support FDA approved labeling)

Strabismus Criteria

- For deviations less than 50 prism diopters, onabotulinumtoxin A from 1.25 to 5U IM in any one muscle. Maximum recommended single injection dose for any muscle is 25 U
- Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

Overactive Bladder Criteria

- Diagnosis is either detrusor overactivity associated with neurologic condition or overactive bladder and
- More than 8 urinations in 24 hours and at least 2 urinary incontinence episodes per 24 hours and
- Documented failure of behavioral therapy and
- Documented failure/intolerance to at least three antimuscarinics of appropriate dose and duration (with at least one being an extended release agent) and
- Patient willingness to self-catheterize and
- Patient is prone to frequent urinary tract infections.
- Detrusor overactivity: onabotulinumtoxin A – 30 injections of 1ml for a total dose of 200U/30ml. Median time to retreatment is reported as 42 to 48 weeks
• Overactive bladder: onabotulinumtoxin A – 20 injections of 0.5ml for a total of 100U/10ml. Median time to retreatment is 24 weeks, but should be no sooner than 12 weeks.

Exclusions
Botulinum toxin is considered not medically necessary for the following conditions:
• Any of the above conditions when the criteria have not been met
• Glabellar lines, lateral canthus lines or other cosmetic indications
• Any other condition other that what is listed.

Table I: Botulinum Toxins

<table>
<thead>
<tr>
<th>Description</th>
<th>ICD-9 Diagnosis Codes</th>
<th>ICD-9 Procedure Codes</th>
<th>CPT Code</th>
<th>HCPCS</th>
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CMP Number: CMP-067
CMP Cross Reference:

References:


Clinical Medical Policy
Botulinum Toxin Type A and B


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