| MEDICAL POLICY STATEMENT | | |
|---|---|---|
| **Original Effective Date** | **Next Annual Review Date** | **Last Review / Revision Date** |
| **06/15/2011** | **10/17/2017** | **10/19/2016** |
| **Policy Name** | | **Policy Number** |
| **Botulinum Toxin Injection** | | **SRx-0016** |
| **Policy Type** | | |
| ☒ **Medical** | ☐ **Administrative** | ☐ **Payment** |

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

## A. SUBJECT

**Botulinum Toxin Injection**

- OnabotulinumtoxinA (Botox)
- AbobotulinumtoxinA (Dysport)
- IncobotulinumtoxinA (Xeomin)
- RimabotulinumtoxinB (Myobloc)

## B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Botulinum Toxin Injection Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

## C. DEFINITIONS

N/A

## D. POLICY

I. CareSource will approve the use of botulinum toxin and consider its use as medically necessary when the following criteria have been met for:
   A. **OnabotulinumtoxinA (Botox)** may be indicated for **1 (one) or more** of the following:
      1. **Achalasia**, as indicated by **ALL** of the following:

1.1 Achalasia confirmed by esophageal manometry
1.2 No response to pharmacologic treatment (eg, long-acting nitrates, calcium channel antagonists)
1.3 Other causes of dysphagia (eg, peptic stricture, carcinoma, lower esophageal ring or extrinsic compression) ruled out by upper gastrointestinal endoscopy
1.4 Patient not candidate for pneumatic dilation or surgical myotomy
1.5 Progressive dysphagia for liquids and solids

3. **Blepharospasm,** as indicated by **ALL** of the following:
   3.1 Age 12 years or older
   3.2 Blepharospasm, as indicated by **1 (one) or more** of the following:
      a. Benign essential blepharospasm
      b. Blepharospasm associated with dystonia
      c. Blepharospasm associated with facial nerve (cranial nerve VII) disorders such as Bell palsy
      d. No infection at proposed injection site
   3.3 No neuromuscular disease (eg, myasthenia gravis)
4. **Cervical dystonia (spasmodic torticollis),** as indicated by **ALL** of the following
   4.1 Age 16 years or older
   4.2 Cervical dystonia (spasmodic torticollis)
   4.3 Neck pain or abnormal head position causing adverse effect on daily functioning
   4.4 No fixed contractures causing decreased neck range of motion
   4.5 No infection at proposed injection site
   4.6 No neuromuscular disease (eg, myasthenia gravis)
   4.7 No prior surgical treatment
7. **Hyperhidrosis**, as indicated by **ALL** of the following:
   **(Excluded for Marketplace members (OH, KY, IN & WV JUST4ME)**
   7.1 Age 18 years or older
   7.2 Axillary hyperhidrosis, with resting sweat production of 50 mg per axilla measured over 5 minutes at room temperature
   7.3 Failed conservative treatment using topical agents
   7.4 Secondary causes of hyperhidrosis (eg, hyperthyroidism) have been evaluated and, if necessary, treated
   7.5 Significant effect of hyperhidrosis upon daily activities

9. **Migraine headache prophylaxis** needed, as indicated by **ALL** of the following:
   9.1 Age 18 years or older
   9.2 Migraine headache, as indicated by 5 (five) or more attacks with **ALL** of the following:
      a. Headache symptoms, as indicated by **2 (two) or more** of the following:
         (1) Aggravation by or causing avoidance of routine physical activity
         (2) Moderate or severe pain intensity
         (3) Pulsating quality
         (4) Unilateral location
      b. Migraine associated symptoms, as indicated by **1 (one) or more** of the following:
         (1) Nausea or vomiting
         (2) Photophobia and phonophobia
   9.3 Migraine headache frequency occurring 15 (fifteen) or more days per month lasting ≥ 4 hours/day
   9.4 No medication-overuse headaches
   9.5 No neuromuscular disease (e.g., myasthenia gravis)
   9.6 Other prophylactic therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by **2 (two) or more** of the following:
      a. beta-blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications
   9.7 Abortive therapeutic options have been ineffective or not tolerated for trial of

at least 3 months, as indicated by **1 (one) or more** of the following:
   a. Use of ergotamine, triptans, or combination analgesics for 10 or more days per month
   b. Use of simple analgesics or any combination of ergotamine, triptans, analgesics, and opioids for 15 or more days per month

11. **Neurogenic urinary incontinence, neurogenic detrusor over activity, or detrusor sphincter dyssynergia**, as indicated by **ALL** of the following:
    11.1 Age 18 years or older
    11.2 Condition secondary to spinal cord injury or neurologic disease, including but not limited to multiple sclerosis
    11.3 No acute urinary tract infection
    11.4 No acute urinary retention unless patient receiving regular clean intermittent catheterization
    11.5 Surgical treatment or balloon sphincter dilatation is not indicated, has been refused, or has failed
    11.6 Unresponsive or intolerant to pharmacologic therapy including anticholinergic medication
12. **Overactive bladder with urge urinary incontinence**, as indicated by **ALL** of the following:
    12.1 Age 18 years or older
    12.2 Failure of or intolerance to a 30 day trial of 2 or more anticholinergic medications.
    12.3 No acute urinary retention
    12.4 No acute urinary tract infection
    12.5 Urge urinary incontinence demonstrated on urodynamic testing
14. **Spasticity**, as indicated by **1 (one) or more** of the following:
    14.1 Child with cerebral palsy receiving rehabilitation
    14.2 Upper extremity spasticity in adult due to stroke
15. **Strabismus**, as indicated by **ALL** of the following:
    15.1 Age 12 years or older
    15.2 Deviation of 50 prism diopters or less
    15.3 Strabismus not due primarily to Duane syndrome with lateral rectus weakness
    15.4 Strabismus not due primarily to restrictive strabismus
    15.5 Strabismus not due primarily to secondary strabismus caused by prior surgical over-recession of antagonist muscle
16. **Upper extremity focal dystonia (eg, writer's cramp),** as indicated by **ALL** of the following:
    16.1 Age 16 years or older
    16.2 Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning
    16.3 No prior surgical treatment
17. **Lower Limb Spasticity,** as indicated by **ALL** of the following:
    17.1 Age 18 years or older
    17.2 Decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

B. **AbobotulinumtoxinA (Dysport)** may be indicated for **1 (one) or more** of the following
   1. **Blepharospasm,** as indicated by **ALL** of the following:
      1.1 Age 18 years or older
      1.2 Diagnosis of benign essential blepharospasm
      1.3 No infection at proposed injection site
      1.4 No neuromuscular disease (eg, myasthenia gravis)
   2. **Cervical dystonia (spasmodic torticollis),** as indicated by **ALL** of the following:
      2.1 Age 16 years or older
      2.2 Neck pain or abnormal head position causing adverse effect on daily

functioning
2.3 No fixed contractures causing decreased neck range of motion
2.4 No infection at proposed injection site
2.5 No neuromuscular disease (eg, myasthenia gravis)
2.6 No prior surgical treatment

6. **Spasticity**, as indicated by **1 (one) or more** of the following:
   6.1 Child with cerebral palsy receiving rehabilitation
   6.2 Upper extremity spasticity in adult due to stroke
7. **Upper extremity dystonia (eg, writer's cramp),** as indicated by **ALL** of the following:
   7.1 Age 16 years or older
   7.2 Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning
   7.3 No injection at proposed injection site
   7.4 No prior surgical treatment
8. **Lower Limb spasticity**
   8.1 Diagnosed with lower limb spasticity due to cerebral palsy
   8.2 Age 2 years of age an older
   8.2. Patient is at least 10kg
   8.3. If already being treated with Dysport, it has been at least 12 weeks since last dose.

C. **RimabotulinumtoxinB (Myobloc)** may be indicated when **1 (one) or more** of the following are present:
   1. **Cervical dystonia (spasmodic torticollis)** and **ALL** of the following:
      1.1 Age 16 years or older
      1.2 Neck pain or abnormal head position causing adverse effect on daily functioning
      1.3 No fixed contractures causing decreased neck range of motion
      1.4 No infection at proposed injection site
      1.5 No neuromuscular disease (eg, myasthenia gravis)
      1.6 Have a history of a positive response to botulinum toxin type A

D. **IncobotulinumtoxinA (Xeomin)** may be indicated when **1 (one) or more** of the following are present:
   1. **Cervical dystonia (spasmodic torticollis)** and **ALL** of the following:
      1.1 Age 18 years or older
      1.2 Neck pain or abnormal head position causing adverse effect on daily functioning
      1.3 No fixed contractures causing decreased neck range of motion
      1.4 No neuromuscular disease (eg, myasthenia gravis)
   2. **Blepharospasm,** as indicated by **ALL** of the following:
      1.1 Age 18 years or older
      1.2 No neuromuscular disease (eg, myasthenia gravis)
      1.3 Blepharospasm, as indicated by **1 (one) or more** of the following:
         a. Benign essential blepharospasm
         b. Blepharospasm associated with dystonia
         c. Blepharospasm associated with facial nerve (cranial nerve VII) disorders such as Bell palsy
         d. Prior treatment failure with onabotulinumtoxinA (Botox)
   3. **Upper limb Spasticity**
      a. Age 18 years or older
      b. Focal spasticity with equal or more than 2 points on the Ashworth scale in the wrist flexors

**NOTE:** Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

**Conditions of Coverage**

**HCPCS** J0585 OnabotulinumtoxinA (Botox)
J0586 AbobotulinumtoxinA (Dysport)
J0587 RimabotulinumtoxinB (Myobloc)
J0588 IncobotulinumtoxinA (Xeomin)

**CPT**

**Place of Service**

Office, Outpatient

**Preferred place of service is in the office or outpatient setting.

**Note:** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

**Authorization Period**

Approved initial authorizations are valid for 6 (six) months. Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

## E. RELATED POLICIES/RULES

## F. REVIEW/REVISION HISTORY

| | |
|---|---|
| Date Issued: | 06/15/2011 |
| Date Reviewed: | 06/15/2011, 02/20/2013, 12/31/2014 |
| Date Revised: | 02/20/2013 – Removed approvable off-label indications and safety section, beta blockers and CCB's removed from prophylactic treatment of chronic migraine, added overactive bladder to Botox indications, added Neurologist to Blepharospasm.<br>12/31/2014 – Revision to clarify exclusions.<br>11/17/2015 – Revision adding preventive therapy criteria to migraine<br>10/19/2016- Removed off-label indications from Botox. Added and removed indications for Dysport. dded criteria to Myobloc. Added an indication to Xeomin. |

## G. REFERENCES


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**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**

Independent medical review – April 2013