Botox (onabotulinumtoxinA)
Dysport (abobotulinumtoxinA)
Xeomin (incobotulinumtoxinA)
Myobloc (rimabotulinumtoxinB)

Line(s) of Business:
HMO; PPO; QUEST Integration
Akamai Advantage

Original Effective Date:
03/14/2006

Current Effective Date:
08/01/2017 10/01/2015

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a
covered benefit provided that all the approval criteria are met and the member has no exclusions to
the prescribed therapy.

FDA-Approved Indications
Botox
• Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in
adults who have an inadequate response to or are intolerant of an anticholinergic medication
• Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g.,
spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are
intolerant of an anticholinergic medication
• Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with
headache lasting 4 hours a day or longer)
• Upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in
elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris) and finger
flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor
pollicis and flexor pollicis longus)
• Lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle
and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor
digitorum longus)
• Cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain
associated with cervical dystonia
• Severe primary axillary hyperhidrosis that is inadequately managed with topical agents
• Strabismus and blepharospasm associated with dystonia, including benign essential
blepharospasm or VII nerve disorders in patients 12 years of age and above

Dysport
• Cervical dystonia to reduce the severity of abnormal head position and neck pain in both
botulinum toxin-naïve and previously treated adults' patients
Botulinum toxins

- Upper limb spasticity in adults to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors
- Lower limb spasticity in pediatric patients 2 years of age and older

Xeomin
- Upper limb spasticity in adults
- Cervical dystonia in adults to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naive and previously treated patients
- Blepharospasm in adults who were previously treated with onabotulinumtoxinA (Botox)

Myobloc
- Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

Compendial Uses (applicable to Botox only)

**Botox**
- Achalasia
- Chronic anal fissures
- Dysphagia
- Detrusor sphincter dyssynergia (DSD) associated with spinal cord injury
- Excessive salivation secondary to advanced Parkinson’s disease
- Hemifacial spasm
- Sphincter of Oddi dysfunction
- Oromandibular dystonia
- Spasmodic dysphonia (laryngeal dystonia)

**Dysport**
- Blepharospasm

B. REQUIRED DOCUMENTATION
The following documentation from the medical record is necessary to initiate the prior authorization review:
- Chronic migraine prophylaxis (initial therapy): documentation (e.g., chart notes) of all previous preventative oral migraine medication trials (including length of each treatment)

C. EXCLUSIONS
- Prescribed for cosmetic purposes (e.g., treatment of wrinkles)

D. INITIAL CRITERIA FOR APPROVAL

1. Cervical dystonia (e.g., torticollis)
   Authorization of 12 months may be granted to members who are prescribed Botox, Xeomin, Dysport, or Myobloc for the treatment of cervical dystonia.

2. Blepharospasm
Authorization of 12 months may be granted to members who are prescribed Botox, Dysport or Xeomin for the treatment of blepharospasm.

3. **Chronic migraine prophylaxis**
   Authorization of 24 weeks (2 injection cycles) may be granted to members who are prescribed Botox when ALL of the following criteria are met:
   a. Prior to initiating therapy, the member experiences headaches 15 days per month or more
   b. The member has completed an adequate trial (at least 8 weeks) of oral preventative therapy from at least two different drug classes listed below:
      - **Antiepileptic drugs:**
        i. Divalproex sodium (Depakote, Depakote ER)
        ii. Topiramate (Topamax)
        iii. Gabapentin (Neurontin)
      - **Antidepressants:**
        i. Amitriptyline (Elavil)
        ii. Venlafaxine (Effexor)
      - **Beta-blockers:**
        i. Atenolol
        ii. Metoprolol
        iii. Propranolol
        iv. Timolol
        v. Nadolol
      - **Calcium channel blockers**
        i. Nimodipine
        ii. Verapamil

4. **Primary axillary hyperhidrosis**
   Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of primary axillary hyperhidrosis.

5. **Spasticity**
   Authorization of 12 months may be granted to members who are prescribed Botox, Dysport or Xeomin for the treatment of upper limb spasticity.
   Authorization for 12 months may be granted to members who are prescribed Botox or Dysport for the treatment of lower limb spasticity.

6. **Urinary incontinence**
   Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of 1) urinary incontinence associated with a neurologic condition (eg, spinal cord injury, multiple sclerosis) OR 2) overactive bladder with urinary incontinence when ONE of the following criteria is met:
   a. Member has had an inadequate response to an anticholinergic medication
   b. Member is intolerant of anticholinergic medication

7. **Achalasia**
   Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of achalasia.
8. **Chronic anal fissures**
   Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of chronic anal fissures.


9. **Detrusor sphincter dyssynergia**
   Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of detrusor sphincter dyssynergia due to a spinal cord injury.

10. **Dysphagia**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of dysphagia.

11. **Excessive salivation secondary to Parkinson’s disease**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of excessive salivation secondary to Parkinson’s disease.

12. **Hemifacial spasm**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of hemifacial spasm.

13. **Sphincter of Oddi dysfunction**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of sphincter of Oddi dysfunction.

14. **Strabismus**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of strabismus.

15. **Oromandibular dystonia**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of oromandibular dystonia.

16. **Spasmodic dysphonia (laryngeal dystonia)**
    Authorization of 12 months may be granted to members who are prescribed Botox for the treatment of spasmodic dysphonia (laryngeal dystonia).

E. **CONTINUATION OF THERAPY**

1. **Chronic migraine prophylaxis**
   Authorization of 12 additional months may be granted to members prescribed Botox for chronic migraine prophylaxis who were previously authorized by HMSA or who meet ALL initial criteria for approval AND the member has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy.

2. **All other indications**
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. **DOSAGE AND ADMINISTRATION**
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
G. PROGRAM EXCEPTION – AKAMAI ADVANTAGE
For Akamai Advantage members, the following Local Coverage Determination (LCD) applies:
• Botulinum Toxin Types A and B Policy (L35170).

H. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

I. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. REFERENCES
### Document History

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<tr>
<td>10/26/2016</td>
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