Policy Title:	Botox (onabotulinumtoxinA) Myobloc (rimabotulinumtoxinB) Dysport (abobotulinumtoxinA) Xeomin (incobotulinumtoxinA)		
		Department:	PHA
Effective Date:	12/2009, 1/1/2020		
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Purpose: To support safe, effective and appropriate use of Botox (onabotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA), and Xeomin (incobotulinumtoxinA).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Botox (onabotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA), and Xeomin (incobotulinumtoxinA) are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.
Patients that are currently on target drug treatment can remain on treatment.

Procedure:

Coverage of Botox (onabotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA), and Xeomin (incobotulinumtoxinA) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria for Botox (onabotulinumtoxinA):

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Blepharospasms:

- Patient is at least 12 years of age

Cervical Dystonia:

- Patient is at least 16 years of age; AND

- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; AND patient has sustained head tilt OR patient has abnormal posturing with limited range of motion in the neck.

Strabismus:

- Patient is at least 12 years of age

Upper & Lower limb spasticity:

- Patient has upper and/or lower limb spasticity due to one of the following:
    - Brain Injury, MS, Spinal cord injury, stroke OR
    - Cerebral Palsy in pediatric patients 2 years of age and older

Chronic Migraine:

- Member must have diagnosis of migraine headaches. (All non-migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage); AND
- The prescriber is a neurologist or headache specialist or the prescription is being written for the member in consultation with a neurologist or headache specialist; AND
- The member is ≥ 18 years of age; AND
- The member has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer; AND
- The member has had an inadequate response to a trial of at least THREE (3) different prophylactic migraine medications each with different mechanisms of action (a total of 3 required trials) that have each been tried for at least 60 days in duration within the past 3 years.
    - Acceptable trials include:
        - Antiepileptic agents: divalproex sodium, valproate, topiramate
        - Beta-blockers: metoprolol, propranolol, timolol, atenolol, or nadolol
        - Antidepressants: amitriptyline, venlafaxine

Severe Primary Axillary Hyperhidrosis:

- Patient has failed with topical agents; AND
- Patient has a history of medical complications such as skin infections or significant functional impairments OR patient has had a significant impact to activities of daily living due to condition

Incontinence due to detrusor over activity:

- Patient has failed a 1 month or longer trial of two medications from either the antimuscarinic or beta-adrenergic classes

Overactive Bladder (OAB):

- Patient has symptoms of urge urinary incontinence, urgency, and frequency;

- Patient has failed a 1 month or longer trial of two medications from either the antimuscarinic or beta-adrenergic classes

Continuation of Therapy Criteriafor Botox (onabotulinumtoxinA):

- Patient meets all initial criteria; AND
- Patient is tolerating treatment; AND

Blepharospasms:

- Improvement of severity and/or frequency of eyelid spasms

Cervical dystonia:

- Improvement in the severity and frequency of pain; AND
- Improvement of abnormal head positioning

Strabismus:

- Improvement in alignment of prism diopters compared to pre-treatment baseline

Upper/Lower Limb Spasticity:

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Severe primary axillary hyperhidrosis:

- Significant reduction in spontaneous axillary sweat production; AND
- Patient has a significant improvement in activities of daily living

Prophylaxis for chronic migraines:

- Significant decrease in the number, frequency, and/or intensity of headaches; AND
- Improvement in function; AND
- Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.)

Incontinence due to detrusor over activity:

- Significant improvements in weekly frequency of incontinence episodes; AND
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Overactive Bladder (OAB):

- Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; AND
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Coverage durations for Botox (onabotulinumtoxinA):

- Initial coverage: 6 months for migraine headaches & hyperhidrosis

- Initial coverage: 3 months for all other diagnoses
- Renewal coverage: 12 months

Initial criteria for Dysport (abobotulinumtoxinA):

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Cervical Dystonia:

- Patient is at least 18 years of age; AND
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; AND
- Patient has sustained head tilt OR patient has abnormal posturing with limited range of motion in the neck

Spastic Conditions:

- Upper/Lower Limb Spasticity in adult patients (such as, spasticity post-stroke, traumatic brain or spinal cord injuries); OR
- Lower Limb spasticity in patients 2 years of age or older.

Continuation of Therapy Criteria for Dysport (*abobotulinumtoxinA*):

- Patient meets all initial criteria; AND
- Patient is tolerating treatment; AND

Cervical dystonia:

- Improvement in the severity and frequency of pain; AND
- Improvement of abnormal head positioning

Spastic conditions:

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Coverage durations Dysport (*abobotulinumtoxinA*):

- Initial coverage: 3 months
- Renewal coverage: 12 months

Initial criteria for Myobloc (rimabotulinumtoxinB):

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Cervical Dystonia:

- Patient is at least 18 years of age; AND
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; AND patient has sustained head tilt OR patient has abnormal posturing with limited range of motion in the neck.

Continuation of Therapy Criteria for Myobloc (rimabotulinumtoxinB):

- Patient meets all initial criteria; AND
- Patient is tolerating treatment; AND

  Cervical dystonia:
  - Improvement in the severity and frequency of pain; AND
  - Improvement of abnormal head positioning

Coverage durations for Myobloc (rimabotulinumtoxinB):

- Initial coverage: 3 months
- Renewal coverage: 12 months

Initial criteria for Xeomin* (incobotulinumtoxinA)*:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Blepharospasms:

- Patient is at least 18 years of age

Cervical Dystonia:

- Patient is at least 18 years of age; AND
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; AND patient has sustained head tilt OR patient has abnormal posturing with limited range of motion in the neck

Upper Limb Spasticity:

- Patient is at least 18 years of age

Sialorrhea:

- Patient is at least 18 years of age; AND
- Patient has had condition for 3 months or more; AND

- Patient has had failure, intolerance or contraindication to oral therapy AND the patient has Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury

Continuation of Therapy Criteria for Xeomin (incobotulinumtoxinA):

- Patient meets all initial criteria; AND
- Patient is tolerating treatment; AND

Cervical dystonia:

- Improvement in the severity and frequency of pain; AND
- Improvement of abnormal head positioning

Upper Limb Spasticity:

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Sialorrhea:

- Significant decrease in saliva production

Coverage durations *Xeomin (incobotulinumtoxinA)*:

- Initial coverage: 3 months
- Renewal coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Billable Units:

Drug	Billable Units
Botox (onabotulinumtoxinA)	1 billable unit = 1 unit
Myobloc (rimabotulinumtoxinB)	1 billable unit = 100 units
Dysport (abobotulinumtoxinA)	1 billable unit = 5 units
Xeomin (incobotulinumtoxinA)	1 billable unit = 1 unit

Dosing and Maximum Units:
Botox:**

Indication	Dosing	Maximum Billable Units	Per number of days
Blepharospasm	1.25-2.5 Units (0.05—0.1 ml per site) injected into each of 3 sites per affected eye every three months. There appears to be little benefit obtainable from injecting more than 5 Units per site. The effect of	200	84

	treatment lasts an average of 12 weeks. Cumulative dose in 30 days should not exceed 200 units		
Cervical Dystonia	198 Units to 300 Units divided among the affected muscles. No more than 50 Units per site. May re-treat in 12 weeks.	300	84
Strabismus	Based on muscle(s) affected, 1.25-2.5 Units in any one muscle initially. Subsequent doses may be increased up to two-fold compared to previously administered dose. No more than 25 Units in any one muscle for recurrent cases. The effect of treatment usually lasts about 12 weeks	100	84
Upper Limb Spasticity	Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history.	400	84
Lower Limb Spasticity	300 to 400 Units divided among 5 muscle groups (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus), no sooner than every 12 weeks	400	84
Chronic Migraine	155 Units administered intramuscularly (IM) as 0.1 mL (5 Units) injections per each site. Injections should be divided across 7 specific head/neck muscle areas. The recommended re-treatment schedule is every 12 weeks	200	84
Severe Primary Axillary Hyperhidrosis	50 Units intradermally per axilla every 16 weeks	100	112
Sialorrhea	15-40 Units in the parotid gland injected in two places and 10-15 Units in the submandibular glands (total dose from 50-100 Units per patient/administration), repeated in 3 months (12 weeks), if needed	100	84
Neurogenic Bladder/Detrusor Overactivity	200 Units per treatment injected into the detrusor muscle using 30 injections (6.7 units each). Re-inject no sooner than 12 weeks from the prior bladder injection.	200	84
Overactive Bladder	100 Units per treatment injected into the detrusor muscle using 20 injections (5 units each). Re-inject no sooner than 12 weeks from the prior bladder injection.	100	84

****Allowed for up to 600 Billable Units****

Myobloc:

Indication	Dosing	Maximum Billable Units	Per number of days
Cervical Dystonia	Initial dose: 2,500 – 5,000 units divided among the affected muscles. Re-treatment: 2,500-10,000 units every 12 -16 weeks or longer, as necessary Initial dose: 2,500 – 5,000 units divided among the affected	1000	84

	muscles. Re-treatment: 2,500-10,000 units every 12 - 16 weeks or longer, as necessary		

Dysport:

Indication	Dosing	Maximum Billable Units	Per number of days
Cervical Dystonia	Initial dose: 500 units divided among the affected muscles. Re-treatment: 250-1000 units every 12 -16 weeks or longer as necessary	200	84
Upper Limb Spasticity	Initial dose: 500 – 1000 units based on muscles affected, severity of muscle spasticity, prior response and adverse reaction history Re-treatment: 500 – 1000 units every 12 – 16 weeks or longer, as necessary	200	84
Lower Limb Spasticity	Adults Up to 1500 units divided among the affected muscles every 12 weeks	300	84
Lower Limb Spasticity (pediatric)	Pediatrics Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks. Maximum dose per treatment session is 1000 units, total.	200	84

Xeomin:

Indication	Dosing	Maximum Billable Units	Per number of days
Blepharospasm	1.25 – 5.6 units per injection site, not to exceed 35 units per eye, every 12 weeks or longer, as necessary	100	84
Cervical Dystonia	120 units divided among the affected muscles every 12 weeks or longer, as necessary	400	84
Upper Limb Spasticity	Up to 400 units total no sooner than every 12 weeks	400	84
Sialorrhea	100 units via intra-salivary gland injection divided as follows, May repeat treatment after no fewer than 16 weeks	100	112

Investigational Use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes: Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes

from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, onabotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
46505	Chemodenervation of internal anal sphincter
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscle(s)
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscle(s) (list separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscle(s)
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle

References:

1. Xeomin package insert. Raleigh, NC ; Merz Group Services GmbH; September 2018.
2. Botox package insert. Madison, NJ: Allergan, Inc.; September 2018.
3. Dysport package insert. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc. November 2017.
4. Myobloc package insert. South San Francisco, CA: Solstice Neurosciences, Inc.; October 2018