Pharmacy Management Drug Policy

SUBJECT: Botulinum Toxin (Botox, Dysport, Myobloc, Xeomin) – For Medicaid Managed Care and Child Health Plus
POLICY NUMBER: PHARMACY-77
ANNUAL REVIEW DATE: 11/21/2020
EFFECTIVE DATE: 12/2019
LAST REVIEW DATE: 3/30/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Botulinum toxins are acetylcholine release inhibitors and neuromuscular blocking agents produced by an anaerobic bacterium: C. botulinum. Of the seven immunologically distinct botulinum toxins, only three have been linked to cases of botulism in humans, and only serotypes A and B are available for clinical use. When administered intramuscularly, these toxins reduce muscle tone by interference with the release of acetylcholine from nerve endings.

As a consequence of the chemistry of the neurotoxins and the manufacturing process used, different botulinum toxin biologicals are not interchangeable. Each biological has distinct pharmacological and clinical profiles specified in the product insert. Dosing patterns are also specific to each biological product and are very different between and within serotypes.

The effects of all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults, particularly in those patients who have an underlying condition that would predispose them to these symptoms

The following products are included within this policy and coverage is provided under the medical benefit. Please refer to the specific product below for approved indications and policy criteria: OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), RimabotulinumtoxinB (Myobloc).
Dosing information is provided for guidance; however, the FDA approved labeling (or compendia or primary literature for off-label indications) should be referenced for detailed dosage information.

Refer to Corporate Medical Protocol 7.01.11 regarding Cosmetic and Reconstructive Procedures.

POLICY:

I. Botox (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor or intradermal use

Based upon our criteria and review of the peer-reviewed literature Botox therapy has been medically proven effective and therefore may be considered **medically appropriate** for the following conditions when the appropriate criteria are met.

Indication	**Policy Criteria** (must meet all including age and dosing restrictions)
	FDA approved indications
Cervical Dystonia (spasmodic torticollis) to reduce the severity of abnormal head position and neck pain • Most common isolated focal dystonia • Affects muscles of neck and shoulders • It may appear as horizontal turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis). • Overlying spasms may give rise to a head tremor that is distinguished from essential tremor by the directional preponderance of the movement • Adult-onset (usually after age 30) • Rarely becomes generalized.	Initial Request: 1. Diagnosis of cervical dystonia **and** 2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and** 3. Experiencing involuntary contractions of the neck and shoulder muscles (e.g.: splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulder or head **and** 4. Contractions are causing pain and functional impairment **and** 5. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 16 years; Dosing guidelines: a. Dose does not exceed 400 units per treatment session. b. Dose based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum toxin naïve patients c. Average dose: 198 to 300 units divided among affected muscles; up to 50 units per site. d. Average duration of effect: 4 - 6 weeks to 3 months. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection and 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 400 units per treatment session.
Blepharospasm *(a focal dystonia)* or Strabismus associated with dystonia, including benign essential blepharospasm or VII nerve disorders	Initial request 1. Diagnosis of: a. Blepharospasm (i.e., abnormal contraction of eyelid muscles) **or** b. Strabismus (i.e. misalignment of the eyes) **and** 2. Prescribed by or in consultation with a neurologist or ophthalmologist **and**

	3. Member has significant disability in daily functional activities due to interference with vision **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit. Age restriction: ≥ 12 years Dosing guidelines: Blepharospasm a. Dose does not exceed 5 units per site per treatment session (maximum of 200 units total in a 30-day period) b. Average dose: 1.25 – 2.5 units per site c. Average duration of effect: 12.5 weeks. d. Time to retreat: 3 months Strabismus a. The dose is based on prism diopter correction or previous response to treatment with Botox. b. Dose does not exceed 25 units per treatment session c. Average dose 12.5 – 5 units per muscle (max 25 units) d. Average duration of effect: 6-8 weeks to 6-12 months Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection and 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed for Blepharospasm: 5 units per site per treatment session (maximum of 200 units total in a 30-day period) and for Strabismus: 25 units per muscle per treatment session
Upper Limb Spasticity in patients ≥ 2 years to decrease the severity of increased muscle tone in elbow, wrist, finger and thumb flexors, that ARE NOT due to Cerebral Palsy (Please see Off-Label indications below for treatment of spasticity due to cerebral palsy in pediatric patients)	Initial request: 1. Diagnosis of upper limb spasticity **and** 2. Focal increased muscle tone causing functional impairment, **and** 3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and** 4. Failure of an age appropriate, adequate trial of baclofen, tizanidine or dantrolene unless contraindicated, not age appropriate or not clinically appropriate for diagnosis **and** 5. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 2 years Dosing guidelines: Adults ≥18 years of age: a. Dose does not exceed 400 units per treatment session b. Average dose

	Upper Limb Spasticity: 12.5 up to 50 units in one site (75 – 400 units divided among selected muscles) c. Average duration of effect / time to retreat: 12 weeks Children 2 - 17 years of age: a) Dose does not exceed 6 units/kg or 200 units per session. b) 3 units/kg to 6 units/kg divided among the affected muscles per treatment session; initiate with lowest dose; c) Dosage may be repeated no sooner than 12 weeks after the previous injection; d) Maximum cumulative dosage should not exceed the lower of 8 units/kg body weight or 300 units in a 3-month interval (When treating both the upper and lower limbs in combination, the total dose should not exceed the lower of 10 units/kg or 340 units, in a 3-month interval) Limitations: Safety and effectiveness of BOTOX has not been established for the treatment of the upper limb muscle groups other than those specified in the FDA approved labeling or for the treatment of upper limb spasticity in pediatric patients under 2 years of age. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than: a) Adults ≥ 18 years of age: 400 units over the last 3 months, b) Children 2-17 years of age: 300 units over the last 3 months **and** 3. It has been 12 weeks (3 months) since the last injection **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** Requests for dose increase must not exceed 400 units per treatment session for Adults ≥ 18 years of age, and 300 units per treatment session for Children 2-17 years of age
Lower Limb Spasticity In patients ≥ 2 years to decrease the severity of increased muscle tone in ankle and toe flexors, that ARE NOT due to Cerebral Palsy (Please see Off-Label indications below for treatment of spasticity due to cerebral palsy in pediatric patients)	Initial request: 1. Diagnosis of lower limb spasticity **and** 2. Focal increased muscle tone causing functional impairment, **and** 3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and** 4. Failure of an age appropriate, adequate trial of baclofen, tizanidine or dantrolene unless contraindicated, not age appropriate or not clinically appropriate for diagnosis **and** 5. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 2 years Dosing guidelines: Adults ≥18 years of age:

(Note: The safety and effectiveness of Botox have not been established for treatment of upper **or** lower limb spasticity in pediatric patients under the age of 2)	a) Dose does not exceed 400 units per treatment session b) Average dose: Lower Limb Spasticity: 25 units in one site (300 units – 400 units divided among 5 muscles) c) Average duration of effect / time to retreat: 12 weeks Children 2 - 17 years of age: a) Dose does not exceed 8 units/kg or 300 units, whichever is lower b) to 8 units/kg IM divided among the affected muscles c) Dosage may be repeated no sooner than 12 weeks after the previous injection; d) d) Maximum cumulative dosage should not exceed the lower of 8 units/kg or 300 units (When treating both lower limbs or the upper and lower limbs in combination, the total dose should not exceed the lower of 10 units/kg or 340 units, in a 3-month interval Limitations: Safety and effectiveness of BOTOX has not been established for the treatment of the lower limb muscle groups other than those specified in the FDA approved labeling or for the treatment of lower limb spasticity in pediatric patients under 2 years of age. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than: a) Adults ≥ 18 years of age: 400 units over the last 3 months, b) Children 2-17 years of age: 300 units over the last 3 months (340 units when treating both lower limbs or the upper and lower limbs in combination), **and** 3. It has been 12 weeks (3 months) since the last injection **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 5. Requests for dose increase must not exceed 400 units per treatment session for Adults ≥ 18 years of age, and 300 units (340 units when treating both lower limbs or the upper and lower limbs in combination), per treatment session for Children 2-17 years of age
Chronic Migraine	Initial Approval 1. Diagnosis of chronic migraine, defined by **all** of the following a) headache that occurs ≥ 15 days per month **and** b) at least 8 days per month has the features of migraine **and** c) Headaches lasting 4 hours a day or longer (that are not occurring due to medication overuse) **and** d) Have experienced the above symptoms over a period of at least 3 months. 2. Prescribed by or in consultation with a neurologist or pain specialist a**nd** 3. The provider must attest that the patient has had serious side effects

	or drug failure, at an effective dose, to at least 3 months of THREE preventative oral medications from THREE different classes including, but not limited to: a) Anti-Depressants b) Serotonin-Norepinephrine Reuptake Inhibitors c) Beta-Blockers d) Anti-Convulsant If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required. 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in <u>each muscle site</u>, anticipated frequency of injection, and total dose per visit (Requests submitted without a detailed treatment plan will not be approved regardless of meeting other policy criteria); <u>Age Restrictions:</u> Botox for Chronic Migraine headaches will only be approved for use in those who are ≥ 18 years of age. Botox will not be approved for Chronic Migraine under any circumstances for those under 18 years of age. <u>Dosing guidelines:</u> a. Dose does not exceed 200 units per treatment session. b. Recommended dose is 155 units given as 5 units into each of 31 sites across 7 specific head/neck muscle areas c. Average duration of effect: 3 – 4 months. <u>Limitations</u>: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. Micromedex Class III (not recommended) for episodic migraine. Initial approval of Botox therapy for chronic migraines will consist of a maximum quantity of two (2) treatments in a 6-month period (one (1) treatment every 90 days) Botox will NOT be approved for use in combination with large molecule or Intravenous (IV) Calcitonin Gene-Related Peptide (CGRP) antagonists, which are indicated for the prevention of migraine headaches. (Small molecule CGRP antagonists [gepants] used for the acute treatment of migraine are permissible). Initiation of a large molecule, or IV CGRP antagonist during Botox therapy will automatically void any current authorization. The provider must attest that any existing large molecule or IV CGRP therapy will be discontinued before Botox will be approved. <u>Recertification</u> – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. At least 30% reduction in monthly migraine headache frequency from baseline (after at least 2 treatment sessions) to be documented via a “Headache Journal” or other detailed form of documentation. On a case by case scenario, a reduction in monthly migraine days or

	hours will be considered (see explanation below) **and** 3. It has been 12 weeks (3 months) since the last injection **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in <u>each muscle site</u>, anticipated frequency of injection, and total dose per visit (Requests submitted without a detailed treatment plan will not be approved regardless of meeting other policy criteria) **and** 5. Request for dose increase does not exceed 200 units per treatment session Note: On a case by case basis, continuation of therapy after at least 2 treatment sessions is considered medically necessary when: • Migraine headache frequency was reduced by at least 7 days per month (compared to pre-treatment average) or • Migraine headache duration was reduced by at least 100 total hours per month (compared to pre-treatment average) 6. Requests for recertification will not be approved if Botox has been used in combination with a large molecule or IV CGRP antagonist during the previously approved treatment period. Initiation of a large molecule or IV CGRP antagonist after an approval of Botox therapy for Migraine will automatically void any current authorization for Botox. This will be verified via a review of the member's pharmacy and /or medical records.
<u>Primary Axillary Hyperhidrosis</u>	<u>Initial request:</u> 1. Diagnosis of severe primary axillary hyperhidrosis (e.g., resulting in medical complications such as skin maceration and infection or significant disruption of professional/social life) that is inadequately managed by topical agents **and** 2. Prescribed by / in consultation with a neurologist or dermatologist **and** 3. Failure of a 6-month trial of topical aluminum chloride, unless contraindicated or serious side effects are experienced **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit <u>Age restriction</u>: ≥ 18 years <u>Dosing guidelines:</u> a. Dose does not exceed 50 units per axilla per treatment session (maximum of 100 units total). b. Average duration of effect: 4-12 months c. Time to retreat: 8 - 12 weeks <u>Limitations</u>: The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. <u>Recertification</u> – previously approved by plan or has met initial approval criteria:

	1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the past 3 months, **and** it has been at least 8 - 12 weeks (2 - 3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 50 units per axilla per treatment session.
Overactive Bladder with symptoms of urge urinary incontinence, urgency and frequency in adults who have experienced serious side effects, drug failure or contraindications to anticholinergic medication and Urinary Incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have experienced serious side effects, drug failure or contraindications to anticholinergic medication	Initial request: 1. Diagnosis of: a. Overactive Bladder **or** b. Urinary Incontinence (Detrusor Overactivity) associated with a neurologic condition (e.g., spinal cord injury, MS) **and** 2. Prescribed by / in consultation with a neurologist or urologist **and** 3. Failure of a trial of at least TWO anticholinergic agents and ONE oral beta-3 agonist medication (e.g., oxybutynin chloride, tolterodine tartrate, mirabegron), each used for at least 30 days, unless contraindicated or serious side effects are experienced **and** 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 18 years Dosing guidelines: 1. Overactive Bladder a. Dose does not exceed 100 units per treatment session as 0.5mL (5 Units) injections across 20 sites into the detrusor. b. Average duration of effect: 12 weeks c. Time to retreat: no sooner than 12 weeks. 2. Urinary Incontinence (Detrusor Overactivity): a. Dose does not exceed 200 units per treatment session as 1 mL (~6.7 units) injections across 30 sites into the detrusor b. Average duration of effect: 8 – 12 months c. Time to retreat: no sooner than 12 weeks. Limitations: BOTOX is contraindicated in patients with overactive bladder who have a urinary tract infection or with detrusor overactivity associated with a neurologic condition who have urinary retention. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed for Overactive Bladder 100 units per treatment session and for Urinary Incontinence 200 units per treatment session.

<table>
<tr><th colspan="2">Off-label indications</th></tr>
<tr><td colspan="2">Based upon our criteria and review of the peer-reviewed literature, Botox has been medically proven effective and is considered medically appropriate for the following off label indications when other treatments or interventions have been unsuccessful or are contraindicated:</td></tr>
<tr><td>Indication</td><td>Policy Criteria (must meet all including age and dosing restrictions)</td></tr>
<tr><td>Anal Fissure, chronic
(off-label)</td><td>Initial request:
1. Diagnosis of chronic anal fissure and
2. Prescribed in consultation with a gastroenterologist or colorectal surgeon and
3. Must have failure of an adequate trial of nitroglycerin 0.2% to 0.4% ointment or topical calcium channel blocker (such as nifedipine or diltiazem) in addition to supportive measures (fiber, sitz bath, topical analgesic, stool softeners/laxatives) unless contraindicated or serious side effects experienced.
Age restriction: ≥ 18 years
Dosing guidelines:
a. Dose does not exceed 100 units total
b. Average dose: 5 to 100 units
c. Reinjection for recurrence: at least 12 weeks
Recertification – previously approved by plan or has met initial approval criteria:
1. Documentation to support a positive response to treatment and
2. Member has not received more than 100 units over the past 3 months, and it has been 12 weeks (3 months) since the last injection and
3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit and
4. Requests for dose increase must not exceed 100 units per treatment session.</td></tr>
<tr><td>Other Dystonias (off-label)
• Dystonia is a movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements, postures, or both
• Dystonic movements are typically patterned, twisting, and may be tremulous
• Dystonia is often initiated or worsened</td><td>Initial request:
1. Diagnosis of dystonia and
2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist and
3. Documentation detailing diagnosis, symptoms and functional impairment due to dystonia and
4. Failure of a trial of carbidopa/levodopa, trihexyphenidyl or tetrabenazine (or other anticholinergic or dopamine receptor blocker if the use of carbidopa/levodopa, trihexyphenidyl or tetrabenazine is not clinically appropriate) unless contraindicated or serious side effects are experienced and
5. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit
Dosing guidelines:
a. Dose does not exceed 400 units per single treatment with the following exceptions:
Oromandibular dystonia: Generally, 25 units per muscle per</td></tr>
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by voluntary action and associated with overflow muscle activation Botox therapy will be considered for dystonia including the following: -focal dystonia: writer's cramp and segmental dystonia -focal upper limb dystonia -Frey's Syndrome (auriculotemporal syndrome) -hemifacial spasm -idiopathic and symptomatic torsion dystonia -limb dystonia -Oromandibular dystonia -Meige syndrome (craniocervial dystonia) -orofacial dyskinesia (jaw closure dystonia) -spasmodic dysphonia/laryngeal dystonia -writer's cramp	treatment session; Laryngeal dystonia (spasmodic dysphonia): generally, 1.25 to 5 units per treatment session. a. Average duration of effect / time to retreat: 12 weeks <u>Recertification</u> – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 400 units per treatment session.
<u>Esophageal Achalasia</u> (e.g., Nutcracker esophagus) (off-label) • Achalasia is characterized by a failure in relaxation of the lower esophageal sphincter with swallowing and by a lack of esophageal peristalsis in the distal esophagus • Treatment of idiopathic, chagastic, previously untreated achalasia and pseudoachalasia. • Improve symptoms of dysphagia, chest pain and regurgitation in	<u>Initial request:</u> 1. Diagnosis of esophageal achalasia based on symptoms and diagnostic testing (upper endoscopy, esophageal manometry, barium swallow, endoscopic ultrasound): • Dysphagia to solids and foods • Heartburn unresponsive to a trial of at least 4 weeks of proton pump inhibitor therapy • Retained food in esophagus on upper endoscopy • Unusually increased resistance to passage of an endoscope through the esophagogastric junction **and** 2. Must be prescribed by or in consultation with a gastroenterologist **and** 3. Member is not a candidate for graded pneumatic dilation or surgical myotomy (high surgical risk due to age or comorbidities) <u>Age restriction</u>: ≥ 18 years of age <u>Dosing guidelines:</u> a. Dose does not exceed 100 units b. Average dose of 20 to 25 units into each of four quadrants of lower esophageal sphincter. c. Time to retreat: at least 12 weeks

idiopathic achalasia	Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 100 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 100 units per treatment session.
Hirschsprung's Disease and Internal Anal Sphincter Achalasia (off-label)	Initial request: 1. Must have diagnosis of either a, b or c: (a) Hirschsprung's Disease (a congenital motor disorder of the gut caused by failure of nerve cells to migrate during intestinal development where by the colon is unable to relax causing functional obstruction; diagnosis occurs during neonatal period or childhood) • Obstructive symptoms (including constipation) after surgery may respond to Botox when there is no mechanical obstruction and repeat biopsy is normal **or** (b) ultra-short segment Hirschsprung disease (USSHD) established by biopsy **or** (c) Internal Anal Sphincter (IAS) Achalasia • lack of rectoanal inhibitory reflex on anal manometry • rectal biopsy demonstrates the presence of ganglion cells thus excluding Hirschsprung disease • clinical presentation similar to functional constipation **and** 2. Prescribed by or in consultation with a gastroenterologist **and** 3. Must have had an adequate trial of stool softeners and laxatives that have been ineffective, or member has become medication dependent Dosing guidelines: a. Dose does not exceed 100 units b. Time to retreat if needed: 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 100 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 100 units per treatment session.

Sialorrhea / excessive salivation associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy)	Initial request: 1. Diagnosis of sialorrhea, excessive salivation or excessive drooling associated with Parkinson's Disease, cerebral palsy or other neurologic disorder that has been present for at least 3 months and 2. Prescribed by or in consultation with neurologist or otolaryngologist and 3. Failure of an adequate trial of anticholinergic agent such as glycopyrrolate, trihexyphenidyl, scopolamine, atropine or amitriptyline to control symptoms and 4. Persistence of medically significant complications due to excessive drooling such as chronic skin maceration or bacterial / fungal skin infections despite standard topical treatments. Age restriction: ≥ 4 years Dosing guidelines: a. Dose does not exceed 100units b. Dose calculated based on patient weight and rate of salivation Recommended dosage ranges from 1 to 5.5 units per kg distributed into 2 to 4 glands. Alternative dosing: 15 units/gland (body weight less than 15 kg), 20 units/gland (body weight 15 to 25 kg), or 25 units/gland (body weight greater than 25 kg) c. Average duration of effect = 3 to 6 months; Time to retreat: 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 100 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 100 units per treatment session.
Spasticity Associated with Cerebral Palsy (off-label)	Initial request: 1. Diagnosis of spasticity associated with cerebral palsy (CP) **and,** 2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and,** 3. Indicated in patients who have increased muscle tone that interferes with function or is likely to lead to joint contracture with growth **and**, 4. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: Age ≥ 2 years Dosing guidelines: a. Dose does not exceed 400 units per treatment session. b. Dosing depends on the muscles injected, body weight, muscle bulk, the number of muscles being injected simultaneously, and the patient's response to previous therapy

	c. Average duration of effect / time to retreat: 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 400 units per treatment session.
Auriculotemporal syndrome / Frey's syndrome: • a rare neurological disorder resulting from damage to or near the parotid glands responsible for making saliva, and from damage to the auriculotemporal nerve often from surgery (i.e., parotidectomy)	Initial request: 1. Diagnosis of auriculotemporal syndrome / Frey's syndrome and 2. Symptoms of undesirable facial flushing or profuse sweating occurring on the cheek, temple or behind the ears after eating certain foods, which are severe and accompanied by significant disruption in daily activities Age restriction: ≥ 18 years Dosing guidelines: a. Average dose = 15 to 75 units b. Average duration of effect / time to retreat: 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Botox to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 400 units per treatment session.
Excluded diagnoses/indications for which coverage will NOT be authorized:	
Non-FDA approved indications which are not addressed in the policy above, unless the Off-Label Use of FDA Approved Drugs Policy criteria have been met.	
Episodic migraine prophylaxis	Safety and effectiveness of Botox have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.
Spasticity (any upper or lower limb muscle groups other than elbow, wrist, finger, thumb, ankle and toe flexors.)	Safety and effectiveness of Botox have not been established for the treatment of other upper or lower limb muscle groups. Safety and effectiveness of Botox have not been established for the treatment of spasticity in pediatric patients under age 18 years. Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture. Treatment with Botox is not intended to substitute for usual standard of care rehabilitation regimens.
Hyperhidrosis	Safety and effectiveness of Botox have not been established for the treatment of hyperhidrosis in body areas other than axillary.
Cosmetic indications	Treatment of wrinkles {such as wrinkles of the upper face including

	glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet)} is considered a cosmetic use and is excluded from coverage due to a lack of functional deficit.

II. Dysport (abobotulinumtoxinA) for injection, for intramuscular use

Based upon our criteria and review of the peer-reviewed literature Dysport therapy has been medically proven effective and therefore may be considered **medically appropriate** for the following conditions when the appropriate criteria are met.	
Indication	**Policy Criteria** (must meet all including age and dosing restrictions)
FDA approved indications	
Cervical Dystonia (spasmodic torticollis) to reduce the severity of abnormal head position and neck pain • Most common isolated focal dystonia • Affects muscles of neck and shoulders • It may appear as horizontal turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis). • Overlying spasms may give rise to a head tremor that is distinguished from essential tremor by the directional preponderance of the movement • Adult-onset (usually after age 30) • Rarely becomes generalized.	Initial Request: 1. Diagnosis of cervical dystonia, **and** 2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist, **and** 3. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, posterior cervical) resulting in abnormal postures or movements of the neck, shoulder or head, **and** 4. Contractions are causing pain and functional impairment **and** 5. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 18 years Dosing guidelines: a. Dose does not exceed 1000 units per treatment session b. Initial dose 500 units divided among affected muscles; titrate in 250-unit steps according to patient response c. Average dose: 250 to 1000 units divided among affected muscles d. Peak clinical effect expected between 2 to 4 weeks after injection e. Retreatment if needed should not occur in intervals of less than 12 weeks. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 1000 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 1000 units per treatment session.
Lower limb spasticity in pediatric patients 2 years of age and older - to decrease the severity of increased muscle tone in	Initial request: 1. Diagnosis of lower limb spasticity, **and** 2. Focal increased muscle tone causing functional impairment or is likely to lead to joint contracture with growth, **and** 3. Prescribed by or in consultation with a neurologist, **and**

ankle flexors, that ARE NOT due to Cerebral Palsy (Please see Off-Label indications below for treatment of spasticity due to cerebral palsy in pediatric patients)	4. Provider submits treatment plan detailing the quantity (in units of Dysport to be injected into each muscle site, anticipated frequency of injection and total dose per visit. Age restriction: ≥ 2 years Dosing guidelines: a. Prescribed dose does not exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral injections or 1000 units, whichever is lower. b. Average dose is 10 to 15 units/kg per limb divided between the spastic muscles of the lower limb (gastrocnemius and or soleus). c. Retreatment based on return of clinical symptoms should not occur at intervals less than 12 weeks. Limitations: The safety and effectiveness of Dysport in the treatment of lower limb spasticity in pediatric patients of less than 2 years of age and injection into the proximal muscles of the lower limb for spasticity in pediatric patients has not been evaluated. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 1000 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection and 3. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 1000 units per treatment session.
Upper limb spasticity in pediatric patients 2 years of age and older - to decrease the severity of increased muscle tone in ankle flexors, that ARE NOT due to Cerebral Palsy (Please see Off-Label indications below for treatment of spasticity due to cerebral palsy in pediatric patients)	Initial request: 1. Diagnosis of upper limb spasticity, **and** 2. Focal increased muscle tone causing functional impairment or is likely to lead to joint contracture with growth, **and** 3. Prescribed by or in consultation with a neurologist, **and** 4. Provider submits treatment plan detailing the quantity (in units of Dysport to be injected into each muscle site, anticipated frequency of injection and total dose per visit Age restriction: ≥ 2 years Dosing guidelines: a. 2 years and older and weighing at least 10 kg b. Prescribed dose is not to exceed 16 units/kg or 640 units, whichever is lower, total dose in upper limbs; no more than 0.5 mL should generally be administered at any single injection site c. Average dose is 8 units/kg or 16 units/kg divided among the

	affected muscles per treatment session (Biceps brachii, 3 to 6 units/kg divided up to 2 sites; brachialis, 3 to 6 units/kg divided up to 2 sites; brachioradialis, 1.5 to 3 units/kg in 1 site; pronator teres, 1 to 2 units/kg in 1 site; pronator quadratus, 0.5 to 1 units/kg in 1 site; flexor carpi radialis, 2 to 4 units/kg divided up to 2 sites; flexor carpi ulnaris, 1.5 to 3 units/kg in 1 site; flexor digitorum profundus, 1 to 2 units/kg in 1 site; flexor digitorum superficialis, 1.5 to 3 units/kg divided up to 4 sites) Retreatment based on return of clinical symptoms should not occur at intervals less than 16 weeks Limitations: The safety and effectiveness of Dysport in the treatment of upper limb spasticity in pediatric patients under the age of 2, has not been evaluated. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 640 units over the last 16 weeks, **and** it has been 16 weeks since the last injection and 3. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** Requests for dose increase must not exceed 640 units per treatment session
Excluded diagnoses/indications for which coverage will NOT be authorized:	
Non-FDA approved indications which are not addressed in the policy above, unless the Off-Label Use of FDA Approved Drugs Policy criteria have been met.	
Cosmetic indications	Treatment of wrinkles is considered a cosmetic use and is excluded from coverage due to a lack of functional deficit – includes treatment of moderate to severe glabellar lines associated with procerus and corrugator muscle activity.

III. Myobloc (rimabotulinumtoxinB) for injection, for intramuscular use.

Based upon our criteria and review of the peer-reviewed literature Myobloc therapy has been medically proven effective and therefore may be considered **medically appropriate** for the following conditions when the appropriate criteria are met.	
Indication	**Policy Criteria** (must meet all including age and dosing restrictions)
FDA approved indications	
Cervical Dystonia (spasmodic torticollis) to reduce the severity of abnormal head position and neck pain • Most common	Initial Request: 1. Diagnosis of cervical dystonia **and** 2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and** 3. Experiencing involuntary contractions of the neck and shoulder muscles (e.g.: splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or

isolated focal dystonia • Affects muscles of neck and shoulders • It may appear as horizontal turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis). • Overlying spasms may give rise to a head tremor that is distinguished from essential tremor by the directional preponderance of the movement • Adult-onset (usually after age 30) • Rarely becomes generalized.	movements of the neck, shoulder or head **and** 4. Contractions are causing pain and functional impairment **and** 5. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 18 years; Dosing guidelines: a. Dose does not exceed 10,000 units total. b. Dose based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history and optimized according to the patient's individual response. c. Average dose: • The recommended initial dose of rimabotulinumtoxinB for patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 units divided among affected muscles • Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose. d. Average duration of effect: 12 to 16 weeks at doses of 5000 units to 10,000 units e. Time to retreat: at least 12 weeks. Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 10,000 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection and 3. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 10,000 units per treatment session.
Sialorrhea / excessive salivation associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy)	Initial request: 1. Diagnosis of chronic sialorrhea, excessive salivation or excessive drooling associated with Parkinson's disease, atypical parkinsonism, stroke or traumatic brain injury that has been present for at least 3 months **and** 2. Prescribed by or in consultation with neurologist or otolaryngologist **and** 3. Failure of an adequate trial of anticholinergic agent such as glycopyrrolate, trihexyphenidyl, scopolamine, atropine or amitriptyline to control symptoms (unless contraindicated or not clinically appropriate) **and** 4. Persistence of medically significant complications due to excessive drooling such as chronic skin maceration or bacterial / fungal skin infections despite standard topical treatments. Age restriction: ≥ 18 years

	Dosing Guidelines: a) Dose is not to exceed 3500 units per treatment session b) Initial, 1500 to 3500 units divided among the parotid and submandibular glands as 500 to 1500 units into each parotid gland and 250 units into each submandibular gland c) Average duration of effect = 3 months d) Do not retreat more frequently than every 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 3500 units over the past 3 months, **and** it has been 12 weeks since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 3500 units per treatment session.
Excluded diagnoses/indications for which coverage will NOT be authorized:	
Non-FDA approved indications which are not addressed in the policy above, unless the Off-Label Use of FDA Approved Drugs Policy criteria have been met.	
Cosmetic indications	Treatment of wrinkles is considered a cosmetic use and is excluded from coverage due to a lack of functional deficit – includes treatment of moderate to severe glabellar lines associated with procerus and corrugator muscle activity.

IV. Xeomin (incobotulinumtoxinA) for injection for intramuscular or intra-salivary gland use

Based upon our criteria and review of the peer-reviewed literature Xeomin therapy has been medically proven effective and therefore may be considered **medically appropriate** for the following conditions when the appropriate criteria are met.	
Indication	**Policy Criteria** (must meet all including age and dosing restrictions)
FDA approved indications	
Cervical Dystonia (spasmodic torticollis) to reduce the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients • Most common isolated focal dystonia • Affects muscles of neck and shoulders • It may appear as	Initial Request: 1. Diagnosis of cervical dystonia, **and** 2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist, **and** 3. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, posterior cervical) resulting in abnormal postures or movements of the neck, shoulder or head, **and** 4. Contractions are causing pain and functional impairment **and** 5. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 18 years Dosing guidelines:

horizontal turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis). • Overlying spasms may give rise to a head tremor that is distinguished from essential tremor by the directional preponderance of the movement • Adult-onset (usually after age 30) • Rarely becomes generalized.	a. Dose does not exceed 400 units per treatment session a. Initial dose 120 units per treatment session divided among affected muscles (In a placebo-controlled trial utilizing initial Xeomin doses of 120 Units and 240 Units, no meaningful difference in effectiveness was demonstrated between the doses) b. The dose and number of injection sites in each treated muscle should be individualized based on the number and location of the muscle(s) to be treated, the degree of spasticity/dystonia, muscle mass, body weight, and response to any previous botulinum toxin injections. c. Wait at least 10 weeks after any other botulinum toxin treatment d. Average dose: 120 units divided among affected muscles e. Time to retreat if needed: at least 12 weeks. <u>Recertification</u> – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 400 units over the last 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 400 units per treatment session.
<u>Sialorrhea</u> / excessive salivation associated with neurological disorders - Parkinson's disease, atypical parkinsonism, stroke or traumatic brain injury	<u>Initial request</u>: 1. Diagnosis of chronic sialorrhea, excessive salivation or excessive drooling associated with Parkinson's disease, atypical parkinsonism, stroke or traumatic brain injury that has been present for at least 3 months **and** 2. Prescribed by or in consultation with neurologist or otolaryngologist **and** 3. Failure of an adequate trial of anticholinergic agent such as glycopyrrolate, trihexyphenidyl, scopolamine, atropine or amitriptyline to control symptoms (unless contraindicated or not clinically appropriate) **and** 4. Persistence of medically significant complications due to excessive drooling such as chronic skin maceration or bacterial / fungal skin infections despite standard topical treatments. <u>Age restriction</u>: ≥ 18 years <u>Dosing guidelines:</u> a. Dose does not exceed 100 units b. Recommended dose is 30 units in each parotid gland and 20 units in each submandibular gland for a total of 100 units c. (4 injection sites per treatment session). d. Dose divided with a ratio of 3:2 between parotid and submandibular glands. e. Median first onset of effect within 7 days

	f. Average duration of effect = 3 months g. Time to retreat: 16 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 100 units over the past 4 months, **and** it has been 16 weeks (4 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 100 units per treatment session.
Blepharospasm with onabotulinumtoxinA (Botox) prior treatment	Initial request: 1. Must have a diagnosis of Blepharospasm (i.e., abnormal contraction of eyelid muscles) **and** 2. Prescribed by or in consultation with a neurologist or ophthalmologist **and** 3. Member has significant disability in daily functional activities due to interference with vision **and** 4. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit. Age restriction: ≥ 18 years Dosing guidelines: a. Treatment-naïve patients: Initial, 50 units (25 units per eye)) •Previously treated with onabotuliniumtoxinA (Botox): Consider past dose, response to treatment, duration of effect, and adverse event history. If not known, the recommended starting dose is 2.5 units (1.25 units per injection site) •Maximum dosage: 100 units per treatment session (50 units per eye) •Retreatment: May repeat based on clinical response, but no more frequently than every 12 weeks Recertification – previously approved by plan or has met initial approval criteria: 1. Documentation to support a positive response to treatment **and** 2. Member has not received more than 100 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** 3. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** 4. Requests for dose increase must not exceed 100 units total (50 units per eye) per treatment session.

Upper Limb Spasticity to decrease the severity of increased muscle tone in elbow, fist, wrist, forearm, finger and thumb flexors.	Initial request: 1. Diagnosis of upper limb spasticity **and** 2. Focal increased muscle tone causing functional impairment, **and** 3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **and** 4. Failure of an adequate trial of baclofen, tizanidine or dantrolene unless contraindicated or not clinically appropriate for diagnosis **and** 5. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit Age restriction: ≥ 18 years Dosing guidelines: a. Dose does not exceed 400 units per treatment session b. Initial dose: 5 to 200 units depending on muscles to be treated. c. The optimum dose, frequency, and number of injection sites in the treated muscle(s) should be based on severity and prior treatment response; individualize dosing for each patient d. In spasticity patients not previously treated with botulinum toxins, initial dosing should begin at the low end of the recommended dosing range and titrated as clinically necessary e. Average dose f. Time to retreat: at least 12 weeks (generally 12 – 14 weeks) Recertification – previously approved by plan or has met initial approval criteria: g. Documentation to support a positive response to treatment **and** h. Member has not received more than 400 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **and** i. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **and** j. Requests for dose increase must not exceed 400 units per treatment session.
Excluded diagnoses/indications for which coverage will NOT be authorized:	
Non-FDA approved indications which are not addressed in the policy above, unless the Off-Label Use of FDA Approved Drugs Policy criteria have been met.	
Cosmetic indications	Treatment of wrinkles is considered a cosmetic use and is excluded from coverage due to a lack of functional deficit – includes treatment of moderate to severe glabellar lines associated with procerus and corrugator muscle activity.

POLICY GUIDELINES:

1. Prior-authorization is contract dependent.
2. For treatment of diagnoses not found within this policy – Refer to the Off-label use of FDA Approved Drugs policy for the relevant line of business.
3. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
4. Supportive documentation of previous drug use must be submitted for any criterion that requires the trial of a preferred agent, if the preferred drug is not found in claims history.
5. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

6. Unless otherwise stated below within the individual drug criteria, approval time periods are listed in the table below
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. [Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics or other guideline-supported treatment options)] and the requested dose must continue to meet FDA approved or off-label/guideline supported dosing

Line of Business	Medical Initial approval	Medical Recert
Medicaid Managed Care (MMC) / Child Health Plus (CHP)	Botox for Chronic Migraine: 6 months (2 treatments) All other requests: 12 months	12 months

Experimental/investigational or cosmetic diagnoses:

Diagnoses considered experimental/investigational or cosmetic for all botulinum toxin formulations:
Backache, low back pain Cervicogenic headache Chronic motor tic disorder (other than blepharospasm, hemifacial spasm, Meige syndrome) Congenital esotropia Dysphagia Epicondylitis Essential tremor Excessive tear production Fibromyalgia Granuloma of vocal cords Hemorrhoidectomy – postoperative pain Injury to oculomotor nerve (acute) Larynx closure, adjunct to surgical procedure Migraine – first line management Organic voice tremor Spasm, of pharyngoesophageal segment – total laryngectomy Stuttering Tardive dyskinesia Temporomandibular joint disorder Tension-type headaches Thoracic outlet syndrome Trigeminal neuralgia, idiopathic, refractory Urinary and anal sphincter dysfunction / detrusor, pelvic floor and sphincter dyssynergia Whiplash injury to neck

UPDATES:

Date	Revision
3/30/2020	Revision
2/10/2020	Revision
11/15/2019	Revision
9/23/2019	Revised
09/6/2018	Created

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In addition to the full prescribing information for each individual drug (accessed 11/7/2019), the following references have been utilized in creating drug specific criteria:

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