Drug Class Prior Authorization Criteria

Botulinum Toxin

Medical Benefit

Line of Business: Medicaid

P & T Approval Date: August 21, 2019 **Effective Date:** October 1, 2019

This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and was approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: Botox (onabotulinum toxin A), **Myobloc** (rimabotulinum toxin B), **Dysport** (abobotulinum toxin A), **Xeomin** (incobotulinum toxin A)

CRITERIA:

BOTOX (ONABOTULINUM TOXIN A)

Covered Uses:	Bladder dysfunction including: overactive bladder or urinary incontinence resulting from a neurologic condition (e.g. multiple sclerosis or spinal cord injury)
Exclusion Criteria:	N/A
Required Medical Information:	Must meet the following requirement: a. Failure or clinically adverse effects to "1" of the following: oxybutynin, tolterodine, darifenacin, trospium, **Toviaz** or **Vesicare**
Age Restrictions:	Must be age of 18 years or older
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

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Covered Uses:	Dystonia or spastic conditions including: a. Cerebral palsy including equines varus deformity b. Cervical dystonia including spasmodic torticollis (e.g. reduction of severity of abnormal head position and neck pain associated with involuntary contraction of the neck muscles resulting in twisting and repetitive movements) c. Demyelinating diseases of the central nervous system (e.g. multiple sclerosis, Schilder's disease, etc.) d. Dysphonia including laryngeal spasm, spasmodic dysphonia e. Focal dystonia including Organic writer's cramp, oromandibular dystonia, orofacial dyskinesia, torsion dystonia f. Lower limb spasticity g. Spastic hemiplegia or paraplegia including hereditary, related to stroke or related to spinal cord injury h. Upper limb spasticity related to stroke, spinal cord injury, traumatic brain injury or related hemiplegia
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Confirmed diagnosis
Age Restrictions:	N/A
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

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Covered Uses:	Facial nerve disorders including blepharospasm, benign essential blepharospasm, VII nerve disorders such as hemifacial spasm and facial nerve VII dystonia
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Confirmed diagnosis
Age Restrictions:	Must be age of 12 years or older

Prescriber Restrictions: N/A

Other Criteria: Quantity Limit: See FDA recommended dosing table

Reauthorization criteria: Must meet the following requirement:
a. Clinical review by IEHP pharmacist

Covered Uses: Prevention of chronic migraine headache

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet all of the following requirements:
a. Documentation of at least 15 days per month with headaches lasting 4 hours a day or longer
b. Failure or clinically significant adverse effects to "1" of the following: sumatriptan, rizatriptan or rizatriptan ODT
c. Failure or clinically significant adverse effects to at least "2" different drug classes below:
    i. Beta blockers: propranolol, atenolol, metoprolol
    ii. Antidepressants: amitriptyline, nortriptyline, doxepin
    iii. ACE/ARB inhibitors: lisinopril, losartan, valsartan
    iv. Calcium channel blockers: diltiazem, nifedipine, verapamil
    v. Anticonvulsants: gabapentin, topiramate, valproic acid

Age Restrictions: Must be age of 18 years or older

Prescriber Restrictions: N/A

Other Criteria: Quantity Limit: See FDA recommended dosing table

Reauthorization criteria: Must meet the following requirement:
a. Clinical review by IEHP pharmacist

Covered Uses: Strabismus

Exclusion Criteria: CCS eligible

Required Medical Information: Confirmed diagnosis

Age Restrictions:	Must be age of 12 years or older
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

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DYSPORT (ABOBOTULINUM TOXIN A)

Coverage Uses:	Dystonia or spastic conditions including: a. Cerebral palsy including equines varus deformity b. Cervical dystonia in adult patient including spasmodic torticollis (e.g. reduction of severity of abnormal head position and neck pain associated with involuntary contraction of the neck muscles resulting in twisting and repetitive movements) c. Demyelinating diseases of the central nervous system (e.g. multiple sclerosis, Schilder's disease, etc.) d. Dysphonia including laryngeal spasm, spasmodic dysphonia e. Focal dystonia including Organic writer's cramp, oromandibular dystonia, orofacial dyskinesia, torsion dystonia f. Lower limb spasticity g. Spastic hemiplegia or paraplegia including hereditary, related to a stroke or related to a spinal cord injury h. Upper limb spasticity related to stroke, spinal cord injury, traumatic brain injury or related hemiplegia
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Confirmed diagnosis
Age Restrictions:	N/A
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

MYOBLOC (RIMABOTULINUM TOXIN B)

Covered Uses:	Cervical dystonia including spasmodic torticollis (e.g. reduction of severity of abnormal head position and neck pain associated with involuntary contraction of the neck muscles resulting in twisting and repetitive movements)
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Confirmed diagnosis
Age Restrictions:	Must be age of 18 years or older
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

XEOMIN (INCOBOTULINUMTOXIN A)

Covered Uses:	Dystonia or spastic conditions including: a. Cerebral palsy including equines varus deformity b. Cervical dystonia in adult patient including spasmodic torticollis (e.g. reduction of severity of abnormal head position and neck pain associated with involuntary contraction of the neck muscles resulting in twisting and repetitive movements) c. Demyelinating diseases of the central nervous system (e.g. multiple sclerosis, Schilder's disease, etc.) d. Dysphonia including laryngeal spasm, spasmodic dysphonia e. Focal dystonia including Organic writer's cramp, oromandibular dystonia, orofacial dyskinesia, torsion dystonia f. Lower limb spasticity g. Spastic hemiplegia or paraplegia including hereditary, related to a stroke or related to a spinal cord injury h. Upper limb spasticity related to stroke, spinal cord injury, traumatic brain injury or related hemiplegia

Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Confirmed diagnosis
Age Restrictions:	Must be age of 18 years or older
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

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Covered Uses:	Facial nerve disorders including blepharospasm, benign essential blepharospasm, VII nerve disorders such as hemifacial spasm and facial nerve VII dystonia
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet the following requirement: a. Documentation of previous treatment with **Botox**
Age Restrictions:	Must be age of 18 years or older
Prescriber Restrictions:	N/A
Other Criteria:	Quantity Limit: See FDA recommended dosing table Reauthorization criteria: Must meet the following requirement: a. Clinical review by IEHP pharmacist

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Covered Uses:	Excessive salivation, sialorrhea or ptyalism
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet all of the following requirements: a. Excessive salivation associated with neurologic condition such as parkinsonism or cerebral palsy

b. Failure or clinically significant adverse effects to "1" of the following: glycopyrrolate, hyoscyamine or benztropine

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Quantity Limit: See FDA recommended dosing table

Reauthorization criteria: Must meet the following requirement:
a. Clinical review by IEHP pharmacist

Drug	FDA Recommended Dosing Note: FDA does not consider the various BTX products as interchangeable due to differences in concentration and/or dosing
Botox® Refer to product package insert for further information Age Restriction: Refer to FDA approved indications	Maximum cumulative dose should not exceed 400 units in a 3-month interval for one or more indication(s) Blepharospasm - 1.25-2.5 units injected per site - Maximum 5 units injected per site - Maximum dose of 200 units from all sites in a 30-day period - May repeat treatment in 3 months Primary Axillary Hyperhidrosis - 50 units given intradermally per axilla Strabismus - 1.25-5 units injected per site under electromyographic guidance - Maximum 25 units injected per site Upper Limb Spasticity - Treatment will vary depending on number of muscles involved, severity of spasticity, and patient response - Doses range from 75 units to 400 units divided among selected muscles - Maximum 50 units injected per site - May repeat treatment in 3 months Lower Limb Spasticity - Doses range from 300 units to 400 units divided among selected muscles - Maximum 25 units injected per site - May repeat treatment in 3 months

	Chronic Migraine - Total dose 155 units divided across 7 head/neck muscles - 0.1 mL (5 units) injected per site - May repeat treatment in 3 months Overactive Bladder - Total dose 100-200 units - 0.5 mL (1.6 to 3.3 units) injected per site - May repeat treatment in 3 months Cervical Dystonia - Patient-specific, range 100-300 units (25^{th}-75^{th} percentile) - Maximum 50 units injected per site - Limit the total dose to the sternocleidomastoid muscle to 100 units or less may decrease the occurrence of dysphagia - May repeat treatment in 3 months
Myobloc® Refer to product package insert for further information Age Restriction: ≥ 18 years of age	Cervical Dystonia - Initial dose: 2500-5000 units divided among affected muscles - Retreatment every 12 to 15 weeks or longer as necessary (dosing range 5000-10000 units) - Maximum dose per site is site-specific and generally no greater than 1000-5000 units per site - May repeat treatment in 3 months
Dysport® Refer to product package insert for further information	Cervical Dystonia - Initial dose: 500 units IM in divided dose among affected muscles - Retreatment every 12 weeks or longer as necessary (dosing range 250-1000 units) - Maximum dose per site is site-specific and generally no greater than 125-250 units per site - May repeat treatment in 3 months Upper Limb Spasticity - Treatment will vary depending on number of muscles involved, severity of spasticity and patient response - Dosage of 500 units and 1000 units divided among selected muscles - May repeat treatment in 3 months Lower Limb Spasticity - Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the size, number and location of muscles involved, severity or spasticity, the presence of local muscle

	weakness, the patient's response to previous treatment, and/or adverse event history with botulinum toxins. - 10 to 15 units/kg for unilateral lower limb injections or 20 to 30 units/kg for bilateral lower limb injections - Total dose administered per treatment session must not exceed 15 units/kg for unilateral lower limb injections or 30 units/kg for bilateral lower limb injections or 1000 units, whichever is lower - May repeat treatment in 3 months
Xeomin® Refer to product package insert for further information Age Restriction: ≥ 18 years of age	Maximum cumulative dose for any indication should not exceed 400 units in a treatment session Cervical Dystonia - Initial dose: 120 units IM in divided dose among affected muscles - Retreatment every 12 weeks or longer - May repeat treatment in 3 months Blepharospasm - Initial dose: 1.25-2.5 units injected at each site or the same dose as the patient's previous treatment of onabotulinumtoxin A (Botox) - Maximum total initial dose in both eyes should not exceed 70 units (35 units per eye) - May repeat treatment in 3 months Upper Limb Spasticity - Treatment will vary depending on number of muscles involved, severity of spasticity, and patient response - Dosage should not exceed 400 units divided among selected muscles - May repeat treatment in 3 months Chronic Sialorrhea - Recommended total dose is 100 units per treatment session consisting of 30 units per parotid gland and 20 units per submandibular gland, no sooner than every 16 weeks

Change Control		
Date	**Change**	**Author**
08/21/2019	• Renew with no changes	JM

08/15/2018	• Reformatted document
	• Bladder dysfunction: failure to one antimuscarinic alternative per LCD policy
	• Added newly FDA approved indication of Sialorrhea for Xeomin
	• Removed off-labeled indications:
	  • Botox - chronic anal fissure, esophageal achalasia/cardiospasm, ptyalism/ sialorrhea, Frey's syndrome
	  • Xeomin – blepharospasm previously treated with Botox
		HC