SmartPA Criteria Proposal

Drug/Drug Class:	Botulinum Toxin Clinical Edit
First Implementation Date:	January 29, 2004
Revised Date:	February 13, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of botulinum toxin agents

Why Issue Selected: Botulinum toxin has been in use since the 1970s. Over the last few years utilization of botulinum toxin has expanded to a larger range of cosmetic and non-cosmetic approved indications. Three preparations of botulinum toxin type A (Botox®, Dysport® and Xeomin®) and one preparation of botulinum toxin type B (Myobloc®) are commercially available. Botox first earned FDA approval in 1989. Dysport and Myobloc were approved in 2009, and Xeomin was approved in 2010. The clinical effect of botulinum toxin is the result of a reversible inhibition of acetylcholine release which prevents contraction of muscle. The molecules and pharmacokinetics of the botulinum toxin products differ, making a straight conversion ratio of equivalent therapeutic doses difficult. MO HealthNet will edit botulinum toxin agents to ensure appropriate prescribing of these agents for non-cosmetic uses only.

Program-Specific Information:

Date Range FFS 01-01-2019 to 06-30-2019			
Drug	**Claims**	**Spend**	**Cost per unit**
BOTOX 100 UNITS VIAL	16	$22,714.92	$601.00 WAC
BOTOX 200 UNITS VIAL	38	$46,357.45	$1,202.00 WAC
BOTOX COSMETIC 50 UNITS VIAL	0	0	$331.00 WAC
BOTOX COSMETIC 100 UNITS VIAL	0	0	$601.00 WAC
DYSPORT 300 UNIT VIAL	1	$130.01	$515.50 WAC
DYSPORT 500 UNITS VIAL	1	$460.73	$859.00 WAC
MYOBLOC 2,500 UNIT/0.5 ML VIAL	0	0	$581.00 WAC
MYOBLOC 5,000 UNITS/1 ML VIAL	0	0	$581.00 WAC
MYOBLOC 10,000 UNITS/2 ML VIAL	0	0	$581.00 WAC
XEOMIN 50 UNITS VIAL	0	0	$253.00 WAC
XEOMIN 100 UNITS VIAL	0	0	$482.00 WAC
XEOMIN 200 UNITS VIAL	0	0	$964.00 WAC

Type of Criteria:
☐ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

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Setting & Population

- Drug class for review: Botulinum toxin agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Diagnosis of blepharospasm:
  - For use of Botox:
    - Participant age ≥ 12 years **AND**
    - Documented diagnosis of cervical dystonia torticollis
  - For use of Xeomin:
    - Participant age ≥ 18 years **AND**
    - Documented trial and failure of Botox in the past year
- Diagnosis of upper limb spasticity:
  - For use of Botox or Dysport: Participant age ≥ 2 years
  - For use of Xeomin:
    - Participant age ≥ 18 years **AND**
    - Documented trial and failure of Botox or Dysport in the past year
- Diagnosis of lower limb spasticity:
  - Participant age ≥ 2 years **AND**
  - Botox or Dysport
- Diagnosis of chronic sialorrhea
  - Participant age ≥ 18 years **AND**
  - Xeomin or Myobloc
- Diagnosis of strabismus:
  - Participant age ≥ 12 years **AND**
  - Botox only
- Diagnosis of cervical dystonia torticollis:
  - Participant age ≥ 18 years **AND**
  - For use of Xeomin or Myobloc: trial and failure of Botox or Dysport in the past year
- Diagnosis of chronic migraine:
  - Participant age ≥ 18 years **AND**
  - Botox only **AND**
  - If no previous history of Botox therapy in the past year:
    - Trial and failure of CGRP inhibitors (90 days out of the past 150 days) AND
    - Documented history of ≥ 4 migraines per month
- Diagnosis of hyperhidrosis, primary focal hyperhidrosis, secondary facial hyperhidrosis, neurogenic bladder, detrusor over-activity, hypertonicity of bladder, urge incontinence, or mixed incontinence:
  - Botox only **AND**
  - Documented trial and failure of anticholinergics, antispasmodics, or drying agents **AND**
  - Subject to Clinical Consultant Review

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Inappropriate diagnosis or cosmetic use

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Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- Myobloc® (rimabotulinumtoxinB) Injection [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; May 2010.
- XEOMIN® (incobotulinumtoxinA) Injection [package insert]. Franksville, WI: Merz Pharmaceuticals, LLC; May 2019.
- DYSPORT® (abobotulinumtoxinA) Injection [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019.
- BOTOX® (onabotulinumtoxinA) Injection [package insert]. Madison, NJ: Allergan USA, Inc.; October 2019.
- IPD Analytics. IPD Rx Insights - Botulinum Toxin Management. April 2017.
- Simpson D, Hallett, M, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology May 2016, 86 (19) 1818-1826; DOI: 10.1212/WNL.0000000000002560

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