SmartPA Criteria Proposal

Drug/Drug Class:	Botulinum Toxin Clinical Edit
First Implementation Date:	January 29, 2004
Revised Date:	January 28, 2021
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 7-1-2019 to 06-30-2020			
Drug	**Claims**	**Spend**	**Cost per vial**
BOTOX 100 UNITS VIAL	1,930	$2,271,630.56	$594.99 MAC
BOTOX 200 UNITS VIAL	804	$931,302.72	$1,189.98 MAC
DYSPORT 300 UNIT VIAL	68	$36,055.04	$520.65 MAC
DYSPORT 500 UNITS VIAL	68	$56,757.09	$867.59 MAC
MYOBLOC 2,500 UNIT/0.5 ML VIAL	6	$1,064.76	$287.59 MAC
MYOBLOC 5,000 UNITS/1 ML VIAL	10	$4,984.64	$575.19 MAC
MYOBLOC 10,000 UNITS/2 ML VIAL	2	$300.76	$1,150.38 MAC
XEOMIN 50 UNITS VIAL	5	$2,222.47	$255.53 MAC
XEOMIN 100 UNITS VIAL	14	$26,568.58	$486.82 MAC
XEOMIN 200 UNITS VIAL	1	$1,446.00	$973.64 MAC

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

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

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 therapeutic trial 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 ≥ 2 years AND**
    - Documented therapeutic trial 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
  - For use of Xeomin: **Participant age ≥ 2 years**
  - For use of Myobloc: Participant age ≥ 18 years
- 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: therapeutic trial 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:
    - Therapeutic trial of CGRP inhibitors **approved for prophylactic therapy** (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 all approval criteria are not met
- Inappropriate diagnosis or cosmetic use

Required Documentation

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

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- BOTOX® (onabotulinumtoxinA) Injection [package insert]. Madison, NJ: Allergan USA, Inc.; July 2020.
- DYSPORT® (abobotulinumtoxinA) Injection [package insert]. Basking Ridge, NJ: Ipsen
- MYOBLOC® (rimabotulinumtoxinB) Injection [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; August 2019.
- XEOMIN® (incobotulinumtoxinA) Injection [package insert]. Franksville, WI: Merz Pharmaceuticals, LLC; December 2020.
- 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