SmartPA Criteria Proposal

Drug/Drug Class:	Botulinum Toxin Clinical Edit
First Implementation Date:	January 29, 2004
Proposed Date:	September 16, 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 7-1-2020 to 06-30-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
BOTOX 100 UNITS VIAL	2,124	$2,604,780.63	$1,226.35
BOTOX 200 UNITS VIAL	768	$919,066.31	$1,196.70
DYSPORT 300 UNIT VIAL	54	$30,393.74	$562.84
DYSPORT 500 UNITS VIAL	69	$64,720.35	$937.97
MYOBLOC 2,500 UNIT/0.5 ML VIAL	2	$422.28	$211.14
MYOBLOC 5,000 UNITS/1 ML VIAL	11	$5,206.71	$473.33
MYOBLOC 10,000 UNITS/2 ML VIAL	0	-	-
XEOMIN 50 UNITS VIAL	8	$1,284.59	$160.57
XEOMIN 100 UNITS VIAL	17	$15,069.08	$886.41
XEOMIN 200 UNITS VIAL	3	$4,839.28	$1,613.09

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List** ☒ **Appropriate Indications** ☒ **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
- **Diagnosis of idiopathic constipation or Hirschsprung's disease:**
  - **Botox only 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 2021.
- DYSPORT® (abobotulinumtoxinA) Injection [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2020.
- MYOBLOC® (rimabotulinumtoxinB) Injection [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
- XEOMIN® (incobotulinumtoxinA) Injection [package insert]. Franksville, WI: Merz Pharmaceuticals, LLC; April 2021.
- IPD Analytics. IPD Rx Insights - Botulinum Toxin Management. April 2017.
- IPD Analytics. Dermatology: Neurotoxins-Botulinum Toxin. Accessed August 4, 2021.
- 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