

## Clinical Edit Criteria Proposal

Drug/Drug Class: **Botulinum Toxin Clinical Edit**  
 Date: **August 15, 2017**  
 Prepared for:  
 Prepared by: **MO HealthNet**

**New Criteria**

**Revision of Existing Criteria**

### Executive Summary

**Purpose:** To control costs by following evidence based medical guidelines to ensure appropriate use of Botulinum Toxin Type A.

**Why was this Issue Selected:**

Botulinum toxin is a potent neurotoxin produced by the gram-positive anaerobic bacterium *Clostridium botulinum*. Of the seven known immunologically distinct serotypes of botulinum toxin (A to G), only types A and B have been developed for routine commercial use. Historically, the toxin's primary mechanism of action has been linked to its ability to inhibit the release of acetylcholine from cholinergic nerve terminals. However, it is now appreciated that these neurotoxins may also inhibit the release of glutamate, substance P, and calcitonin gene-related peptide. These effects may strongly contribute to the analgesic effects of these toxins. Botulinum toxin has been studied in a number of chronic pain conditions associated with painful muscle spasm, including cervicogenic headache, temporomandibular joint disorders, craniocervical dystonia syndromes, chronic myofascial pain, and chronic low back pain.

Botulinum toxin type A has both cosmetic and non-cosmetic FDA-approved uses. This clinical edit is designed to assure prudent prescribing of this agent for non-cosmetic uses only. FDA approved indications are specific to each type of Botulinum toxin.

**Program-Specific Information:**

Drug	2015		2016	
	Claims	Expense	Claims	Expense
Botox®	1362	\$ 2,002,971	2168	\$ 3,155,919
Dysport®	0	0	3	\$ 2,004
Xeomin®	0	0	0	0

**Setting & Population:** All patients.

**Type of Criteria:**  Increased risk of ADE  Non-Preferred Agent  
 Appropriate Indications

**Data Sources:**  Only administrative databases  Databases + Prescriber-supplied

## Setting & Population

- Drug class for review: Botulinum Toxin Type A
- Age range: All patients
- Gender: Male & female

## Approval Criteria

	DYSPO	XEOMIN	BOTOX
<b>Blepharospasm</b>		X <sup>2</sup>	X <sup>4</sup>
<b>Strabismus</b>			X <sup>4</sup>
<b>Cervical Dystonia</b>	X <sup>1</sup>	X <sup>1</sup>	X <sup>10</sup>
<b>Chronic Migraine</b>			X <sup>5</sup>
<b>Spasticity</b>	X <sup>1</sup>		
<b>Upper Limb Spasticity</b>		X <sup>1</sup>	X <sup>1,9</sup>
<b>Lower Limb Spasticity</b>	X <sup>1,3</sup>		X <sup>1,9</sup>
<b>Overactive Bladder*</b>			X <sup>6</sup>
<b>Urinary Incontinence*</b>			X <sup>7</sup>
<b>Primary Axillary Hyperhidrosis*</b>			X <sup>8</sup>

<sup>1</sup>Adult

<sup>2</sup>Adult previously treated with onabotulinumtoxinA (Botox)

<sup>3</sup>**Pediatric patients 2 years of age and older**

<sup>4</sup>Associated with dystonia in patients 12 years of age and above

<sup>5</sup>Adults with ≥ 15 days per month lasting 4 hours a day or longer

<sup>6</sup>Adults who have inadequate response to or are intolerant of an anticholinergic medication

<sup>7</sup>Adults where urinary incontinence is due to detrusor overactivity associated with a neurological condition who have an inadequate response to or are intolerant of an anticholinergic medication

<sup>8</sup>Inadequately managed with topical agents

<sup>9</sup>Elbow flexors, wrist flexors, finger flexors, thumb flexors, ankle flexors and toe flexors

<sup>10</sup>16 years of age and older

\*Subject to review by clinical consultant

## Denial Criteria

- Inappropriate Diagnosis
- For Diagnosis of Neurogenic Bladder, detrusor instability
  - Lack of Adequate trial and failure on Urinary Tract Antispasmodics
- For Diagnosis of Hypertonicity of bladder, Urge incontinence, Mixed incontinence
  - Lack of Adequate trial and failure on Urinary Tract Antispasmodics
- For Diagnosis of severe Hyperhidrosis, primary focal, or secondary focal:
  - Lack of Adequate trial and failure on anticholinergics
  - Lack of Adequate trial and failure on drying agents

## Required Documentation

Laboratory results:

  

MedWatch form:

Progress notes:

  

Other:

## Disposition of Edit

- **Denial:** Exception 682 “Clinical Edit”

## References

1. Dysport [package insert]. Basking Ridge, NJ; Ipsen; December 2016.
2. Xeomin [package insert]. Greensboro, NC; Merz; December 2015.
3. Botox [package insert]. Irvine, CA; Allergan; April 2017. Accessed online December 12, 2016 at [http://www.allergan.com/assets/pdf/botox\\_pi.pdf](http://www.allergan.com/assets/pdf/botox_pi.pdf)
4. Simpson DN, Hallett M, Ashman EJ, et al. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. *Neurology*. 2016; 86(19): 1818-1826. DOI: 10.1212/WNL.0000000000002560. Available at: <https://www.aan.com/Guidelines/Home/Search>. Accessed May 8, 2017.
5. Evidence-Based Medicine and Fiscal Analysis: Botulinum Toxins Therapeutic Review”, Magellan Rx Management, L.L.C., Mason, OH; July 2016.
6. Mayer, NH., Simpson DM. “Spasticity, Etiology, Evaluation, Management and the Role of Botulinum Toxin”, *We Move*. September 2002.
7. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2017.
8. USPDI, Micromedex; 2017.
9. Facts and Comparisons eAnswers (online); 2017 Clinical Drug Information, LLC. Last accessed August 1, 2017.