

## Clinical Edit Criteria Proposal

Drug/Drug Class: **Botulinum Toxin Clinical Edit**  
 Date: June 8, 2011  
 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:** The seven serologically distinct neurotoxins, designated A through G, share a common structural organization consisting of one Heavy Chain and one Light Chain polypeptide linked by a single disulfide bond. These toxins inhibit acetylcholine release at the neuromuscular junction. Botulinum toxin type A has both cosmetic and non-cosmetic FDA-approved uses. Non-cosmetic indications include blepharospasm, strabismus, cervical dystonia, spasticity, hyperhidrosis, and migraine. This clinical edit is designed to assure prudent prescribing of this agent for non-cosmetic uses only.

Program-specific information:	Drug	Claims	Expense
	• Botox <sup>®</sup>	735	\$1,422,413
	• Dysport <sup>®</sup>	0	\$0
	• Xeomin <sup>®</sup>	0	\$0
			11/09-10/10

**Setting & Population:** All patients.

**Type of Criteria:**

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

**Data Sources:**

<input checked="" type="checkbox"/> Only administrative databases	<input type="checkbox"/> Databases + Prescriber-supplied
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## Setting & Population

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

## Approval Criteria

- **Dysport Therapy** – will be approved for the following indications:

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Cervical Dystonia Torticollis, unspecified	723.5	--
Spasmodic torticollis	333.83	--

- **Xeomin Therapy** – will be approved for the following indications:

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Cervical Dystonia Torticollis, unspecified	723.5	--
Spasmodic torticollis	333.83	--
Blepharospasm	333.81	--

- **Botox Therapy** - will be approved for the following indications:

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Blepharospasm	333.81	--
Spasmodic torticollis	333.83	--
Strabismus	378.00 – 378.56 378.72 – 378.85 378.87 – 378.90	--
Cerebral Palsy	343	--
Cervical Dystonia Torticollis, unspecified	723.5	--
Spastic Hemiplegia	342.11	--
Migraine, chronic	346.0 – 346.9	--

- Approvals for Botox therapy for the following indications will be subject to review by a clinical consultant.
  - Diagnosis must be defined as “severe” – that is intolerable and interferes with daily activities.

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Hyperhidrosis	780.8	--
Primary focal hyperhidrosis	705.21	--
Secondary focal hyperhidrosis	705.22	--

## Denial Criteria

- Inappropriate Diagnosis
- For Diagnosis of severe Hyperhidrosis, primary focal, or secondary focal:
  - Adequate trial and failure on anticholinergics
  - 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. Allergen Pharmaceuticals Ireland. Botox prescribing information. Irvine, CA. July 2002. Accessed online June 9, 2003 at <http://www.botox.com/site/>.
2. Drug Facts and Comparisons, Online; 2010.
3. Mayer, NH., Simpson DM. “Spasticity, Etiology, Evaluation, Management and the Role of Botulinum Toxin”, *We Move*. September 2002.
4. Allergen Pharmaceuticals Ireland. Botox Notification Letter. Irvine, CA. October 2004.
5. Merz Pharmaceuticals, LLC; “Xeomin Package Insert”, Greensboro, NC, 27410; 2010.
6. Medicis Aesthetics, Inc; “Dysport Package Insert”, Scottsdale, AZ, 85256; April 2009.
7. Allergan Pharmaceuticals Ireland; “Botox Package Insert”, Irvine, CA, 92612; March 2010.