



Clinical Edit Criteria Proposal

Drug/Drug Class: **Botulinum Toxin Clinical Edit**

Date: October 23, 2013

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, migraine, detrusor instability, **overactive bladder, urge incontinence and hypertonicity of bladder**. This clinical edit is designed to assure prudent prescribing of this agent for non-cosmetic uses only.

Program-specific information:	Drug	Claims	Expense
	• Botox [®]	731	\$1,224,946
	• Dysport [®]	1	\$781
	• Xeomin [®]	0	\$0
			07/11-06/12

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

- **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	--

- Additional Botox Indications:
 - Approvals for Botox therapy for the following indications will be subject to review by a clinical consultant.

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Hyperhidrosis	780.8	--
Primary focal hyperhidrosis	705.21	--
Secondary focal hyperhidrosis	705.22	--
Neurogenic Bladder, Detrusor over-activity	596.59 596.54	--
Hypertonicity of bladder, Urge incontinence, mixed incontinence	596.51 788.31 788.33	--

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. Allergan 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. Allergan 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; Updated August 2011; Updated January 2013