Clinical Edit Criteria Proposal

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

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.

Why was this Issue Selected:

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>2015 Claims</th>
<th>Expense</th>
<th>2016 Claims</th>
<th>Expense</th>
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</thead>
<tbody>
<tr>
<td>Botox®</td>
<td>1362</td>
<td>$ 2,002,971</td>
<td>2168</td>
<td>$ 3,155,919</td>
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<tr>
<td>Dysport®</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>$ 2,004</td>
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<tr>
<td>Xeomin®</td>
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<td>0</td>
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</table>

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

Approval Criteria

<table>
<thead>
<tr>
<th>Condition</th>
<th>DYSPORT</th>
<th>XEOMIN</th>
<th>BOTOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blepharospasm</td>
<td>X²</td>
<td>X⁴</td>
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<tr>
<td>Strabismus</td>
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<td></td>
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<tr>
<td>Cervical Dystonia</td>
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<td>X¹</td>
<td>X¹⁰</td>
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<tr>
<td>Chronic Migraine</td>
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<td></td>
<td>X³</td>
</tr>
<tr>
<td>Spasticity</td>
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<td></td>
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</tr>
<tr>
<td>Upper Limb Spasticity</td>
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<td>X¹</td>
<td>X¹⁰</td>
</tr>
<tr>
<td>Lower Limb Spasticity</td>
<td>X¹,³</td>
<td></td>
<td>X¹⁰</td>
</tr>
<tr>
<td>Overactive Bladder*</td>
<td>X⁸</td>
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<tr>
<td>Urinary Incontinence*</td>
<td>X⁸</td>
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<tr>
<td>Primary Axillary Hyperhidrosis*</td>
<td></td>
<td></td>
<td>X⁹</td>
</tr>
</tbody>
</table>

1. Adult
2. Adult previously treated with onabotulinumtoxinA (Botox)
3. Pediatric patients 2 years of age and older
4. Associated with dystonia in patients 12 years of age and above
5. Adults with ≥ 15 days per month lasting 4 hours a day or longer
6. Adults who have inadequate response to or are intolerant of an anticholinergic medication
7. 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
8. Inadequately managed with topical agents
9. Elbow flexors, wrist flexors, finger flexors, thumb flexors, ankle flexors and toe flexors
10. 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

2. Xeomin [package insert]. Greensboro, NC; Merz; December 2015.
8. USPDI, Micromedex; 2017.