Clinical Policy: AbobotulinumtoxinA (Dysport)  
Reference Number: ERX.SPA.193  
Effective Date: 01.11.17  
Last Review Date: 11.17  

See Important Reminder at the end of this policy for important regulatory and legal information.

Description  
AbobotulinumtoxinA (Dysport®) is an acetylcholine release inhibitor and a neuromuscular blocking agent.

FDA Approved Indication(s)  
Dysport is indicated:  
- For the treatment of adults with cervical dystonia  
- For the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age  
- For the treatment of spasticity in adults  
- For the treatment of lower limb spasticity in pediatric patients 2 years of age and older

Policy/Criteria  
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Dysport is medically necessary when the following criteria are met:

I. Initial Approval Criteria  
A. Cervical Dystonia or Limb Spasticity (must meet all):  
   1. Diagnosis of one of the following (a, b, or c):  
      a. Cervical dystonia;  
      b. Upper limb spasticity;  
      c. Lower limb spasticity;  
   2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;  
   3. Age ≥ 18 years (≥ 2 years for lower limb spasticity);  
   4. Dose does not exceed 1000 units per single treatment session (1500 units for lower limb spasticity in adults only).  
   Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications  
   1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy  
A. Cervical Dystonia or Limb Spasticity (must meet all):  
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;  
   2. Member is responding positively to therapy (e.g., improvement in dystonia symptoms or limb spasticity);  
   3. At least 12 weeks have elapsed since the last injection of Dysport;  
   4. If request is for a dose increase, new dose does not exceed 1000 units per single treatment session (1500 units for lower limb spasticity in adults only).  
   Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications (must meet 1 or 2):  
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;
B. Cosmetic uses.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
N/A

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Cervical dystonia</td>
<td>500 units IM as a divided dose among the affected muscles</td>
<td>1000 units/12 weeks</td>
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<tr>
<td>Upper limb spasticity</td>
<td>500-1000 units IM divided among selected muscles</td>
<td>1000 units/12 weeks</td>
</tr>
<tr>
<td>Lower limb spasticity</td>
<td>Adults: Up to 1500 units IM divided among selected muscles</td>
<td>Adults: 1500 units/12 weeks</td>
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<td></td>
<td>Pediatric: 10-15 units/kg/limb IM divided among selected muscles</td>
<td>Pediatric: 1000 units/12 weeks</td>
</tr>
</tbody>
</table>

VI. Product Availability
Vials: 300 units, 500 units

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created.</td>
<td>12.01.16</td>
<td>01.17</td>
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<tr>
<td>4Q17 Annual Review</td>
<td>10.03.17</td>
<td>11.17</td>
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<tr>
<td>- Converted to new template.</td>
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<td>- Added age limit requirements.</td>
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<td>- Updated maximum dosing limits.</td>
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<tr>
<td>- Added requirement for documentation of positive response to therapy, for reauthorization.</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of
physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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