Clinical Policy: AbobotulinumtoxinA (Dysport)
Reference Number: ERX.SPA.193
Effective Date: 01.11.17
Last Review Date: 05.19

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

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 (must meet all):
      1. Diagnosis of CD (see Appendix D);
      2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
      3. Age ≥ 18 years;
      4. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius capitis, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulders or head;
      5. Contraindicated are causing pain and functional impairment;
      6. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
      7. Dose does not exceed 1,000 units per treatment session.

   Approval duration: 12 weeks (single treatment session)

   B. Upper and Lower Limb Spasticity in Adults (must meet all):
      1. Diagnosis of upper or lower limb spasticity;
      2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
      3. Age ≥ 18 years;
      4. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
      5. Dose does not exceed 1,500 units per treatment session.

   Approval duration: 12 weeks (single treatment session)
C. Pediatric Lower Limb Spasticity (must meet all):
   1. Diagnosis of lower limb spasticity;
   2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
   3. Age ≥ 2 years to < 18 years;
   4. Focal increased muscle tone interferes with function or is likely to lead to joint contracture with growth;
   5. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
   6. Dose does not exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1,000 units, whichever is lower, per treatment session.
   
   Approval duration: 12 weeks (single treatment session)

D. 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. All Indications in Section I (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;
   3. It has been at least 12 weeks since the last injection of Dysport;
   4. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
   5. If request is for a dose increase, new dose does not exceed the following indication-specific maximums (a or b):
      a. Adults: CD, upper limb spasticity: 1,000 units per treatment session;
      b. Pediatrics: Lower limb spasticity: 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1,000 units, whichever is lower, per treatment session.
   
   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: 12 weeks (single treatment session); 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 treatment of hyperfunctional wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow’s feet).

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

   Appendix B: Therapeutic Alternatives
   Not applicable
Appendix C: Contraindications and Boxed Warnings

• Contraindication(s):
  o Hypersensitivity to any botulinum toxin preparation or excipients
  o Hypersensitivity to cow’s milk protein
  o Infection at the proposed injection site

• Boxed warning(s): distant spread of toxin effect

Appendix D: Definition and Classification of Dystonia

Dystonia is defined as a movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements, postures, or both.
  o Dystonic movements are typically patterned and twisting, and may be tremulous.
  o Dystonia is often initiated or worsened by voluntary action and associated with overflow muscle activation.

Dystonia is classified along two axes:
  o Clinical characteristics: Age at onset, body distribution, temporal pattern, associated features (additional movement disorders or neurological features)
  o Etiology: Nervous system pathology, inheritance.

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>1,000 units/12 weeks</td>
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<tr>
<td>Upper limb spasticity</td>
<td>500-1,000 units IM divided among selected muscles</td>
<td>1,000 units/12 weeks</td>
</tr>
<tr>
<td>Lower limb spasticity</td>
<td>Adults: Up to 1,500 units IM divided among selected muscles</td>
<td>Adults: 1,500 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: 1,000 units/12 weeks</td>
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</tbody>
</table>

VI. Product Availability

Vials: 300 units, 500 units

VII. References

Reviews, Revisions, and Approvals  

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td><strong>4Q17 Annual Review</strong></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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<tr>
<td>- Added age limit requirements.</td>
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<td>- Updated maximum dosing limits.</td>
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<td>- Added requirement for documentation of positive response to therapy, for</td>
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<td>reauthorization.</td>
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<tr>
<td><strong>2Q 2018 annual review</strong></td>
<td>02.09.18</td>
<td>05.18</td>
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<tr>
<td>- added physical medicine and rehabilitation specialist for all indications</td>
<td></td>
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<tr>
<td>- broke up cervical dystonia and limb spasticity into separate criteria</td>
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<tr>
<td>- added pediatric limb spasticity criteria; required provider submission of</td>
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<td>treatment plan for all initial and continued approval indications;</td>
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<tr>
<td>references reviewed and updated.</td>
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<tr>
<td><strong>2Q 2019 annual review</strong></td>
<td>02.15.19</td>
<td>05.19</td>
</tr>
<tr>
<td>- no significant changes; references reviewed and updated.</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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