Clinical Policy Title:	abobotulinumtoxinA
Policy Number:	RxA.100
Drug(s) Applied:	Dysport®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All Line of Business

Background

Dysport® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- The treatment of cervical dystonia in adults.
- The temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age.
- The treatment of spasticity in patients 2 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
abobotulinumtoxinA (Dysport®)	Cervical Dystonia	Initial dose is 500 Units given intramuscularly as a divided dose among the affected muscles. Re-treatment every 12 to 16 weeks or longer, as necessary, based on return of clinical symptoms with doses administered between 250 Units and 1000 Units to optimize clinical benefit. Re-treatment should not occur in intervals of less than 12 weeks. Titrate in 250 Unit steps according to patient's response.	1,000 units/12 weeks
abobotulinumtoxinA (Dysport®)	Upper limb spasticity	Adults: between 500 Units and 1000 Units IM; Pediatric: 8 Units/kg to 16 Units/kg per limb.	Adults:1,000 units/12 weeks Pediatric: 16 Units/kg or 640 Units;
abobotulinumtoxinA (Dysport®)	Lower limb spasticity	Adults: Up to 1,500 units IM divided among selected muscles Pediatric: Lower limb: 10-15 units/kg/limb IM divided among selected muscles Upper limb: 8-16 units/kg/limb IM divided among selected muscles	Adults: 1,500 units/12 weeks Pediatric: Lower limb: 1,000 units/12 weeks Upper limb: 640 units/16 weeks

Dosage Forms

- For Injection: 300 Units or 500 Units lyophilized powder in a single-dose vial

Clinical Policy

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

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, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulders or head;
5. Contractions 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. Does not exceed 1,000 units per treatment session.

Approval Duration
Medicaid: 84 days
Commercial: 6 months

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. Does not exceed 1,500 units per treatment session.

Approval Duration
Medicaid: 84 days
Commercial: 6 months

C. Pediatric Upper and Lower Limb Spasticity (must meet all):

1. Diagnosis of one of the following (a or b)
   a. Upper limb spasticity not caused by cerebral palsy;
   b. 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. Does not exceed one of the following (a or b):

a. 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;
b. Upper limb spasticity: 16 Units/kg for unilateral upper limb injections, or 640 Units, whichever is lower.

Approval Duration
Medicaid: 84 days
Commercial: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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. Prescribed dose of Dysport® does not exceed the following indication-specific maximums per treatment session (a and b):
   a. Adults: CD, upper limb spasticity: 1,000 units, lower limb spasticity: 1,500 units;
   b. Pediatrics (i or ii)
      i. 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;
      ii. Upper limb spasticity: 16 Units/kg for unilateral upper limb injections, or 640 Units, whichever is lower.

Approval Duration:
Medicaid: 84 days
Commercial: 12 months

III. Appendices

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):
  - Hypersensitivity to any botulinum toxin preparation or excipients
  - Hypersensitivity to cow's milk protein
  - Infection at the proposed injection site(s)

- Boxed warning(s):
  - The effects of Dysport® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but

symptoms can occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

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.

- Dystonic movements are typically patterned and twisting and may be tremulous.
- Dystonia is often initiated or worsened by voluntary action and associated with overflow muscle activation.
- Dystonia is classified along two axes:
- Clinical characteristics: Age at onset, body distribution, temporal pattern, associated features (additional movement disorders or neurological features) - the clinical characteristics fall into several specific Dystonia syndromes that help to guide diagnosis and treatment;
- Etiology: Nervous system pathology, inheritance.

Reference

1. Dysport® Prescribing Information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125274Orig1s118lbl.pdf. Accessed February 4, 2021.
2. Simpson DM, Hallett M, Ashman EJ et al. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical Dystonia®, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2016; 86(19): 1818-1826.
3. Simpson DM, Gracies JM, Graham HK et al. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2008; 70(19): 1691-1698.
4. Simpson DM, Blitzer A, Brashear A et al. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2008; 70: 1699-1706.
5. Albanese A, Bhatia K, Bressman SB, et al. Phenomenology and classification of Dystonia®: a consensus update. *Mov Disord.* June 15, 2013; 28(7): 863-873. doi:10.1002/mds.25475.
6. De Boulle K, Fagien S, Sommer B, Glogau R. Treating glabellar lines with botulinum toxin type A-hemagglutinin complex: a review of the science, the clinical data, and patient satisfaction. Clinical Interventions in Aging. 2010; 5:101.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/01/2020	02/07/2020
Updated References	05/01/2020	05/20/2020
Policy was established	01/01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Drug(s) applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosing information was updated for indication.	02/05/2021	03/09/2021

5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 6. References were reviewed and updated. 7. Updated dosage form to: For Injection: 300 Units or 500 Units lyophilized powder in a single-dose vial.		