Clinical Policy: AbobotulinumtoxinA (Dysport)

Reference Number: PA.CP.PHAR.230
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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 (CD)
- For the treatment of 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 adult patients
- For the treatment of lower limb spasticity in pediatric patients 2 years of age and older

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Dysport is **medically necessary** when one of 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, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulders or head;
5. Contractions are causing pain or functional impairment;
6. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site;
7. Prescribed dose of Dysport does not exceed 1000 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;
5. Prescribed dose of Dysport does not exceed 1500 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;
6. Prescribed dose of Dysport does not exceed 15 Units/kg for unilateral lower limb injections, 30 Units/kg for bilateral lower limb injections, or 1000 units, whichever is lower, per treatment session.

Approval duration: 12 weeks (single treatment session)

D. Other diagnoses/indications (1 or 2):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Provider submits treatment plan detailing the quantity (in units) of Dysport to be injected in each muscle site;
4. Prescribed dose of Dysport does not exceed the following indication-specific maximums per treatment session (a and b):
   a. Adults: CD, upper and lower limb spasticity: 1500 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 1000 units, whichever is lower.

   Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

   Approval duration: 12 weeks (single treatment session); or
2. Refer to PA.CP.PMN.53; coverage is not approved for cosmetic treatment of hyperfunctional wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet).

III. 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):
  - Hypersensitivity to any botulinum toxin preparation or excipients
  - Hypersensitivity to cow's milk protein
  - Infection at the proposed injection site
- Boxed warning(s): distant spread of toxin effect

Appendix D: Definition and Classification of Dystonia [6]
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.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cervical dystonia	500 units IM as a divided dose among the affected muscles	1,000 units/12 weeks
Upper limb spasticity	500-1,000 units IM divided among selected muscles	1,000 units/12 weeks
Lower limb spasticity	Adults: Up to 1,500 units IM divided among selected muscles Pediatric: 10-15 units/kg/limb IM divided among selected muscles	Adults: 1,500 units/12 weeks Pediatric: 1,000 units/12 weeks

V. Product Availability
Vials: 300 units, 500 units

VI. References
1. Dysport Prescribing Information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; November 2018. Available at: https://www.dysport.com/docs/pdfs/Dysport_Full_Prescribing_Information.pdf. Accessed January 25, 2019.

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.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0586	Injection, abobotulinumtoxinA, 5 units

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed specific diagnostic requirements for limb spasticity; removed requirement of at least 12 weeks have passed since last treatment; references reviewed and updated.	2.9.18	
2Q 2019 annual review: • added physical medicine and rehabilitation specialist for all indications; • aligned pediatric specialist requirement with adult spasticity indication; • updated statement for non-covered cosmetic uses; • references reviewed and updated.	04/19	