Clinical Policy: AbobotulinumtoxinA (Dysport)

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

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established Pennsylvania Health and Wellness® clinical policy for abobotulinumtoxinA (Dysport®).

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. Prescribed by or in consultation with a neurologist, orthopedist or physiatrist;
2. Age ≥ 18 years;
3. Diagnosis of cervical dystonia (CD) (see definition in Appendix B);
4. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, posterior cervical) 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. Prescribed by or in consultation with a neurologist, orthopedist or physiatrist;
2. Age ≥ 18 years;
3. Diagnosis of upper or lower limb spasticity;
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. Prescribed by or in consultation with a neurologist;
2. Age ≥ 2 years to < 18 years;
3. Diagnosis of lower limb spasticity*;
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.PHAR.57 - Global Biopharm Policy; coverage is not approved for cosmetic use of Dysport, including treatment of glabellar lines.

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 (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, per treatment session.

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.PHAR.57 - Global Biopharm Policy; coverage is not approved for cosmetic use, including for treatment of glabellar lines.

Background

Description/Mechanism of Action:
AbobotulinumtoxinA is a purified neurotoxin type A complex produced by fermentation of the bacterium Clostridium botulinum. It inhibits release of the neurotransmitter, acetylcholine, from peripheral cholinergic nerve endings. This accounts for the therapeutic utility of the toxin in diseases characterized by excessive efferent activity in motor nerves. Recovery of transmission occurs gradually as the neuromuscular junction recovers and as new nerve endings are formed.

Formulations:
Dysport: Freeze dried powder for reconstitution in single-use glass vials containing 500 units or 300 units of abobotulinumtoxinA.

Appendices

Appendix A: Abbreviation Key
CD: cervical dystonia
CNS: central nervous system
CP: cerebral palsy

Appendix B: 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.

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	

References

1. Dysport Prescribing Information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; June 2017. Available at http://dysport.com/pdfs/Dysport_Full_Prescribing_Information.pdf. Accessed February 16, 2018.
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.