Clinical Policy: AbobotulinumtoxinA (Dysport)

Reference Number: CP.PHAR.230
Effective Date: 07/16
Last Review Date: 07/17

Coding Implications
Revision Log

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

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for abobotulinumtoxinA (Dysport®).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® 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 and 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*;
   a. Upper limb: Intent of treatment is to decrease severity of increased muscle tone in elbow flexors (i.e., biceps brachii, brachialis, pronator teres, brachioradialis), wrist flexors (i.e., flexor carpi radialis, flexor carpi ulnaris), finger flexors (i.e., flexor digitorum profundus, flexor digitorum sublimis [superficialis]), or thumb flexors (i.e., adductor pollicis, flexor pollicis longus);
   b. Lower limb: Intent of treatment is to decrease severity of increased muscle tone in ankle or toe flexors (i.e., gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, flexor digitorum longus);
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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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 Centene benefit or member has previously met all 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;
5. Prescribed dose of Dysport does not exceed the following indication-specific maximums (a and b):
   a. Adults: CD, upper limb spasticity: 1000 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 Centene benefit and documentation supports positive response to therapy;
   Approval duration: 12 weeks (single treatment session); or
2. Refer to 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.

FDA Approved Indications (non-cosmetic):
Dysport is an acetylcholine release inhibitor/neuromuscular blocking agent formulated for intramuscular injection and indicated for:

- Treatment of adults with cervical dystonia.
- Treatment of spasticity in adults.
- Treatment of lower limb spasticity in pediatric patients 2 years of age and older.

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
Policy split from CP.PHAR.09. Created criteria for new indication of upper limb spasticity per FDA labeling. Added max dosing per FDA labeling. Added prescriber requirement. Removed reauthorization criteria requiring attestation of significant improvement in symptoms and/or health-related quality of life.	05/16	07/16
CD and upper limb spasticity for adults are split into separate criteria sets. Added CD definition and requirement of pain and functional impairment. Upper limb spasticity for adults is edited by adding lower limb spasticity indication, adding examples of muscle groups and an informational footnote, and changing the maximum dose from 1000 to 1500 per treatment session. Newly labeled pediatric lower limb spasticity added as an indication. Efficacy statement added under continuation criteria. Safety information removed. Dystonia information added at Appendix B. "Non-cosmetic" parenthetical added to the background FDA indication section and indication for glabellar lines is removed; cosmetic coverage restriction reworded under the "Other Diagnoses/Indications" section to include notation of glabellar lines.	06/17	07/17

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 July 12, 2017.
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. Delgado MR, Hirtz D, Aisen M et al. Practice parameter: pharmacologic treatment of spasticity in children and adolescents with cerebral palsy (an evidence-based review). *Neurology*. 2012; 74(4): 336-343.
6. 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.

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.