Clinical Policy: AbobotulinumtoxinA (Dysport)

Reference Number: CP.PHAR.230
Effective Date: 07.01.16
Last Review Date: 05.19 Coding Implications
Line of Business: Commercial, HIM, Medicaid Revision Log

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 (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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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. 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/HIM – 12 weeks (single treatment session)
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/HIM – 12 weeks (single treatment session)
Commercial – 6 months

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. 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:
Medicaid/HIM – 12 weeks (single treatment session)
Commercial – 6 months

D. Other diagnoses/indications (1 or 2):
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit 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. 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: 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.

Approval duration:
Medicaid/HIM – 12 weeks (single treatment session)
Commercial – 12 months

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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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):
  - 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.

V. 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

VI. Product Availability

Vials: 300 units, 500 units

VII. 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	P&T 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
2Q 2018 annual review: added physical medicine and rehabilitation specialist for all indications; aligned pediatric specialist requirement with adult spasticity indication; removed specific diagnostic requirements for limb spasticity; combined Medicaid and Commercial lines of business; added HIM; Commercial: approval durations changed from length of benefit to 6 months initial and 12 months continued approval; references reviewed and updated.	04.24.18	05.18
No significant changes, added maximum dose of 1,500 units per treatment session for adult lower limb spasticity for continued approval	12.19.18	
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.15.19	05.19

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.