# Clinical Policy: AbobotulinumtoxinA (Dysport)

Reference Number: CP.PHAR.230
Effective Date: 07.01.16
Last Review Date: 05.20
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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)
    - With upper and lower limb spasticity
  - Pediatrics:
    - Upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy
    - Lower limb spasticity in pediatric patients 2 years of age and older
- For 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

## 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 *(focal dystonia)*** (must meet all):

1. Diagnosis of CD;
2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
3. Age ≥ 18 years;
4. Member is 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. Member meets both of the following (a and b):
   a. Dysport is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;

7. Treatment plan details number of Units per injection site and treatment session;
8. Dose does not exceed 500 Units per treatment session.

**Approval duration:**
**Medicaid/HIM –** 12 weeks (single treatment session)
**Commercial –** 6 months

**B. Upper and Lower Limb Spasticity *(includes cerebral palsy)*** (must meet all):

1. Diagnosis of upper or lower limb spasticity (e.g., associated with paralysis, central nervous system demyelinating diseases such as multiple sclerosis, cerebral palsy, stroke);
2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
3. Age ≥ 2 years;
4. Member meets both of the following (a and b):
   a. Dysport is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
5. Treatment plan details number of Units per injection site and treatment session;
6. Request meets one of the following (a or b):
   a. Age ≥ 18 years (i, ii, or iii):
      i. Upper limb spasticity: Dose does not exceed 1,000 Units per treatment session;
      ii. Lower limb spasticity: Dose does not exceed 1,500 Units per treatment session;
      iii. Upper and lower limb spasticity: Dose does not exceed 1,500 Units per treatment session staying within per limb dosing guidelines;
   b. Age ≥ 2 years to < 18 years (i, ii, or iii):
      i. Upper limb spasticity: Dose does not exceed the lower of 16 Units/kg or 640 Units;
      ii. Lower limb spasticity: Dose does not exceed the lower of 15 Units/kg (one limb), 30 Units/kg (two limbs), or 1,000 Units per treatment session;
      iii. Upper and lower limb spasticity: Dose does not exceed the lower of 30 Units/kg or 1,000 Units per treatment session staying within per limb dosing guidelines.

**Approval duration:**
**Medicaid/HIM –** 12 weeks (single treatment session)
**Commercial –** 6 months

**C. Other diagnoses/indications**

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. Member meets both of the following (a and b):
   a. Dysport is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
4. Treatment plan details number of Units per injection site and treatment session;
5. If request is for a dose increase, request meets one of the following (a or b):
   a. Age ≥ 18 years (i, ii, iii, or iv):
      i. CD: Dose does not exceed an increase of 250 Units per treatment session up to a total of 1,000 Units per treatment session;
      ii. Upper limb spasticity: Dose does not exceed 1,000 Units per treatment session;
      iii. Lower limb spasticity: Dose does not exceed 1,500 Units per treatment session;
      iv. Upper and lower limb spasticity: Dose does not exceed 1,500 Units per treatment session staying within per limb dosing guidelines;
   b. Age ≥ 2 years to < 18 years (i, ii, or iii):
      i. Upper limb spasticity: Dose does not exceed the lower of 16 Units/kg or 640 Units;
      ii. Lower limb spasticity: Dose does not exceed the lower of 15 Units/kg (one limb), 30 Units/kg (two limbs), or 1,000 Units per treatment session;
      iii. Upper and lower limb spasticity: Dose does not exceed the lower of 30 Units/kg or 1,000 Units per treatment session staying within per limb dosing guidelines.

**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);
**C.** Same-visit treatment of multiple indications with the exception of upper/lower limb spasticity.

## 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: Botulinum Toxin Product Interchangeability*
- Potency Units of Dysport are not interchangeable with other botulinum toxin product preparations (e.g., Botox®, Myobloc®, Xeomin®).

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| CD | Divided among affected muscles every 12 weeks:<br>• Up to 1,000 Units IM | See dosing regimen |
| Adult upper and lower limb spasticity | Divided among affected muscles every 12 weeks:<br>• Upper limb: Up to 1,000 Units IM<br>• Lower limb: Up to 1,500 Units IM<br>• Upper and lower limbs: Up to 1,500 Units IM staying within per limb guidelines | |
| Pediatric upper and lower limb spasticity | Divided among affected muscles every 12 weeks:<br>• Upper limb: Up to the lowr of 16 Units/kg/limb IM or 640 Units IM<br>• Lower limb: Up to the lower of 15 Units/kg/limb IM or 1,000 Units IM<br>• Bilateral lower limb: Up to the lower of 30 Units IM or 1,000 Units IM | |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| | • Upper and lower limbs: Up to the lower of 30 Units IM or 1,000 Units IM staying within per limb guidelines | |

## VI. Product Availability

Vial: 300 units, 500 units

## VII. References

1. Dysport Prescribing Information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125274s115lbl.pdf. Accessed March 2, 2020.

*Dystonia, Spasticity*

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. | 05.16 | 07.16 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Added prescriber requirement. Removed reauthorization criteria requiring attestation of significant improvement in symptoms and/or health-related quality of life. | | |
| 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 |
| RT4: added use for pediatric upper limb spasticity and updated dosing per updated Dysport prescribing information; references reviewed and updated. | 11.06.19 | |
| 2Q 2020 annual review: cerebral palsy included in spasticity criteria set without restriction; rehabilitation specialist incorporated under physiatrist; previous (last 12 weeks) or concurrent toxin product use restriction added to all initial/continuation criteria; dosing updated per package insert; same-visit treatment for multiple indications is limited to upper/lower limb spasticity (Section III); references reviewed and updated. | 03.02.20 | 05.20 |

**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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.