Drug Coverage Policy

Effective Date.....7/15/2025
Coverage Policy Number IP0638
Policy Title..... Dysport

Botulinum Toxin – Dysport

- Dysport® (abobotulinumtoxinA injection – Ipsen/Galderma)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Dysport (abobotulinumtoxinA), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

- **Cervical dystonia** in adults.
- **Spasticity** in patients ≥ 2 years of age.

Other Uses with Supportive Evidence

Botulinum toxins have been studied in a variety of indications outside of FDA-approved uses.[2-4] Literature is available to support use of Dysport in the following conditions:

- **Anal Fissure:** The American College of Gastroenterology (ACG) clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections (formulation not specified) may be attempted for patients with chronic anal fissures in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).[5] Dysport was also found to be more effective than isosorbide dinitrate ointment as the primary treatment for chronic anal fissures in a randomized, multicenter 4 year clinical trial.[21]

- **Blepharospasm:** Dysport has demonstrated efficacy in clinical trials in patients with blepharospasm.[6,7] American Academy of Neurology (AAN) guidelines (2016, reaffirmed 2022) support the use of Dysport for blepharospasm with a Level C recommendation ("possibly effective").[8] An evidenced-based review and assessment (2013) for the treatment of blepharospasm indicate Dysport should be considered (Level B recommendation).[20] Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.[14]
- **Hemifacial Spasm:** Per historical AAN guidelines for the treatment of movement disorders, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C recommendation).[9] Data with Botox® (onabotulinumtoxinA injection) and Dysport are cited in the recommendations regarding hemifacial spasm. An evidenced-based review and assessment (2013) for the treatment of hemifacial spasm indicate Botox ® (onabotulinumtoxinA injection) should be considered (Level B recommendation) and Dysport may be considered (Level C recommendation).[20]
- **Oromandibular Dystonia:** Small clinical trials have shown botulinum toxin A to be effective in treating oromandibular dystonia.[10,11] The American Academy of Oral Medicine clinical practice statement on oromandibular dystonia recommend the use of botulinum type A injections (Botox is mentioned).[12] A five year trial with Dysport for the treatment of focal movement disorders including oromandibular dystonia showed effectiveness and no new safety concerns.[13] An evidence-based review and assessment (2013) for the treatment of oromandibular dystonia indicate Botox and Dysport may be considered (level C recommendation).[20] Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.[14]
- **Sialorrhea:** Botulinum toxin A has been studied in the treatment of sialorrhea associated with Parkinson's Disease, parkinsonian syndromes, cerebral palsy, head and neck carcinoma, neurodegenerative disease, stroke, and amyotrophic lateral sclerosis.[2,] A review of the literature on medical treatment of sialorrhea found that Dysport is probably effective for the treatment of this condition (Level B evidence).[15]

Dosing Information

Toxin distribution varies between the commercially available botulinum toxin products.[1,16,17] The labels for the botulinum toxin products state that there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity. Studies have attempted to establish a conversion ratio between botulinum toxin products, with variable results.[18] In general, conversion ratios of 1:1 for Botox to Xeomin, 1:3 for Botox to Dysport, and 1:50 to 1:100 for Botox to Myobloc have been suggested.

Definitive dosing has not been established for off-label uses of botulinum toxins, including Dysport. Specific dosing considerations by indication are noted below. For other indications addressed in this policy, specific dosing guidance is not available. In these cases, dosing is based on the Botox prescribing information, which states that in a 3-month interval, adults should not exceed a total dose of 400 units, and pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval.[16] Recommendations for maximum dosing and frequency for Dysport are based on a suggested relative conversion of 3:1 between Dysport and Botox units.[1] Additionally, the maximum dose supported for a patient < 18 years of age in Dysport labeling is 30 units/kg (not to exceed 1,000 units).

- **Anal Fissures:** The ACG guidelines (2021) suggest botulinum toxin A injections (formulation not specified) may be used at doses of 5-100 units in patients with refractory, chronic anal fissures.[5] This is also supported by positive outcomes in a 4 year randomized, multicenter study for the treatment of chronic anal fissures which utilized a standard dosing of 60 units of Dysport.[21]
- **Blepharospasm:** A maximum dose of 120 units of Dysport, not more frequently than once every 12 weeks, has been suggested.[19]

- **Sialorrhea, Chronic:** Xeomin is indicated for this use.[17] Per Xeomin labeling, the maximum recommended dose for adults is 100 units (50 units per side) and for pediatric patients is 75 units (37.5 units per side), administered not more frequently than once every 16 weeks.

Coverage Policy

Policy Statement
Prior Authorization is recommended for prescription benefit coverage of Dysport. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Dysport as well as the monitoring required for adverse events and long-term efficacy, approval requires Dysport to be prescribed by a physician who has consulted with or who specializes in the condition.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

Dysport is considered medically necessary when ONE of the following criteria are met:

FDA-Approved Indications

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1. **Cervical Dystonia**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: Cervical dystonia is also referred to as spasmodic torticollis.

   A) Patient is ≥ 18 years of age; AND
   B) Patient has a diagnosis of cervical dystonia **[documentation required]**; AND
   C) Patient has sustained head torsion and/ or tilt with limited range of motion in the neck **[documentation required]**; AND
   D) Prescribed by or in consultation with a pain medicine specialist, neurologist, or physical medicine and rehabilitation physician

   Dosing. Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.

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2. **Spasticity, Limb(s).** Approve for 1 year if the patient is ≥ 2 years of age.

   Dosing. Approve one of the following regimens (A or B):
   A) Lower limb spasticity (or if treating BOTH upper AND lower limb spasticity): Approve one of the following regimens (i or ii):
      i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,500 units, administered not more frequently than once every 12 weeks.
      ii. Patient is < 18 years of age: Approve up to a maximum dose of 30 units/kg (not to exceed 1,000 units), administered not more frequently than once every 12 weeks.
   B) Upper limb spasticity: Approve one of the following regimens (i or ii):
      i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.
      ii. Patient is < 18 years of age: Approve up to a maximum dose of 16 units/kg (not to exceed 640 units), administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

3. **Anal Fissure, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

4. **Blepharospasm.** Approve for 1 year if the patient meets BOTH of the following (A, B, and C): Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

   A) Patient is ≥ 18 years of age; AND
   B) Patient has intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle **[documentation required]**; AND
   C) Prescribed by or in consultation with a neurologist or ophthalmologist

   Dosing. Approve up to a maximum dose of 120 units, administered not more frequently than once every 12 weeks.

5. **Hemifacial Spasm.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 1,200 units, administered not more frequently than once every 3 months.

6. **Oromandibular Dystonia.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Oromandibular dystonia is also referred to as orofacial dystonia.

   Dosing. Approve up to a maximum dose of 1,200 units, administered not more frequently than once every 3 months.

7. **Sialorrhea, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 300 units (150 units per side), administered not more frequently than once every 16 weeks.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Dysport (abobotulinumtoxinA) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

1. **Cosmetic Uses**. Cosmetic use is not recommended for coverage as this indication is excluded from coverage for a typical medical benefit.

Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, or rejuvenation of the periorbital region.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Cervical Dystonia
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)

HCPCS Codes	Description
J0586	Injection, AbobotulinumtoxinA, 5 units

Spasticity, Limb(s)
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles

HCPCS Codes	Description
J0586	Injection, AbobotulinumtoxinA, 5 units

References

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16. Botox® injection [prescribing information]. Madison, NJ: Allergan; August 2022.
17. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.
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Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	7/15/2025

The policy effective date is in force until updated or retired.