

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxin – Dysport Utilization Management Medical Policy

- Dysport® (abobotulinumtoxinA injection – Ipsen)

REVIEW DATE: 01/11/2023

OVERVIEW

Dysport (abobotulinumtoxinA), is indicated for the following uses:¹

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

Toxin distribution varies between the commercially available botulinum toxin A products, Botox® (onabotulinumtoxinA), Xeomin® (incobotulinumtoxinA), and Dysport.¹⁻⁴ It has been postulated that differences in albumin concentration control diffusion of toxin from the injection site (Botox contains 500 mcg of albumin, while Dysport contains 125 mcg of albumin and Xeomin contains 1 mg of albumin). In addition, the labels for the botulinum toxin type A products (Botox, Dysport, and Xeomin) state that there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity.^{1,2,4} Studies have attempted to establish a conversion ratio between botulinum toxin products, with variable results. 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.^{5,6}

Other Uses with Supportive Evidence

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

- **Anal Fissure:** There is an extensive amount of data from open-label studies; randomized, placebo-controlled trials; and randomized, comparative trials supporting the efficacy of botulinum toxin A in the treatment of anal fissures.⁷⁻⁹ Injection of botulinum toxin allows healing in approximately 60% to 80% of anal fissures.¹⁰ There is no consensus on the dose, site of injection, or number of injections. Botulinum toxin A has been shown to be more effective than topical nitroglycerin but less effective than surgery in inducing and maintaining fissure healing.¹¹ The American College of Gastroenterology clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections may be attempted for patients in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).⁹
- **Blepharospasm:** Dysport has demonstrated efficacy in clinical trials in patients with blepharospasm.^{12,13} American Academy of Neurology (AAN) guidelines (2016, reaffirmed 2022) support the use of Dysport for blepharospasm with a Level C recommendation (“possibly effective”).¹⁴
- **Hemifacial Spasm:** Per the AAN, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C).¹⁹ Data with Botox and Dysport are cited in the recommendations regarding hemifacial spasm.
- **Sialorrhea, Chronic:** 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.¹⁶⁻¹⁸ Data with Dysport come from two small controlled trials.^{16,17} AAN guidelines state that botulinum toxin is probably safe and effective and should be considered (Level B).¹⁵

Dosing Considerations

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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.² Recommendations for maximum dosing and frequency for Dysport are based on a suggested relative conversion of 3:1 between Dysport and Botox units.⁶ 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).¹ Specific considerations by indication are noted below.

- **Blepharospasm:** A maximum dose of 120 units of Dysport, not more frequently than once every 12 weeks, has been suggested.^{20,21}
- **Sialorrhea, Chronic:** Xeomin is indicated for this use.⁴ 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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Dysport. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for 1 year in duration. In cases where the dosing interval is provided in months, 1 month is equal to 30 days.

Medical benefit coverage is not recommended for cosmetic conditions.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Dysport is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Cervical Dystonia.** Approve for 1 year.

Note: Cervical dystonia is also known as spasmodic or cervical torticollis.

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.** Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

A) Lower limb spasticity (or combined upper and lower limb spasticity): Approve one of the following regimens (i or ii):

i. Patient is \geq 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. Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

- A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,200 units, administered not more frequently than once every 3 months.
 - B) 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 3 months.
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4. Blepharospasm. Approve for 1 year.

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.

Dosing. Approve one of the following regimens (A or B):

- A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,200 units, administered not more frequently than once every 3 months.
 - B) 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 3 months.
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6. Sialorrhea, Chronic. Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

- A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 300 units (150 units per side), administered not more frequently than once every 16 weeks.
- B) Patient is < 18 years of age: Approve up to a maximum dose of 225 units (112.5 units per side), administered not more frequently than once every 16 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Dysport is not recommended in the following situations:

1. **Cosmetic Uses.** Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, or rejuvenation of the periorbital region. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-----------------------|---|-------------|
| Annual Revision | No criteria changes. | 07/13/2022 |
| Early Annual Revision | <p>Hemifacial Spasm: This Other Use with Supportive Evidence was reworded to as listed; previously, the indication was titled “Spasticity, other than Limb (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm)”.</p> <p>Hyperhidrosis, Gustatory: This Other Use with Supportive Evidence was removed from the policy.</p> <p>Hyperhidrosis, Primary Axillary: This Other Use with Supportive Evidence was removed from the policy.</p> | 01/11/2023 |

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