UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxins – Dysport Utilization Management Medical Policy
- Dysport® (abobotulinumtoxinA injection – Ipsen/Galderma)

REVIEW DATE: 09/23/2026

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] The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures (2023) provide a strong recommendation (Grade 1B, moderate-quality evidence) that botulinum toxin A injection yields healing rates comparable to topical therapies as first-line treatment and offers modest improvement in healing as second-line therapy after failed topical treatment for chronic anal fissures.[25] Dysport was also found to be more effective than isosorbide dinitrate ointment as the primary treatment for chronic anal fissures in a randomized, multicenter clinical trial.[6]
- **Blepharospasm:** Dysport has demonstrated efficacy in patients with blepharospasm.[7-16] American Academy of Neurology (AAN) guidelines (2016, reaffirmed 2022) support the use of Dysport for blepharospasm with a Level C recommendation (possibly effective).[9] An evidenced-based review and assessment (2013) for the treatment of blepharospasm indicate Dysport should be considered (Level B recommendation).[15]

  Note: Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.
- **Hemifacial Spasm:** Dysport has demonstrated efficacy in patients with hemifacial spasm.[13-17] Per historical AAN guidelines for the treatment of movement disorders, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C recommendation); data with Botox® (onabotulinumtoxinA injection) and Dysport are cited in the recommendations regarding hemifacial spasm.[15] 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).[16]
- **Oromandibular Dystonia:** Dysport has demonstrated efficacy in patients with oromandibular dystonia.[10-12,14-16,18,19] In a pilot single-blind trial, Dysport improved quality of life, speech, and dystonia severity in patients with oromandibular dystonia, with dysphagia identified as the primary dose-limiting adverse effect.[18] The American Academy of Oral Medicine clinical practice statement on oromandibular dystonia recommends the use of botulinum type A injections (Botox is referenced).[19] An evidence-based review and assessment (2013) for the treatment of

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oromandibular dystonia indicated Botox and Dysport may be considered (level C recommendation).[16]
Note: Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.

- **Sialorrhea:** Dysport has demonstrated efficacy in patients with sialorrhea.[20-24] An evidenced-based review and assessment for the treatment of secretory disorders including sialorrhea indicate Dysport should be considered (Level B recommendation).[23] Botulinum toxin A has been studied in the treatment of sialorrhea associated with neurological disorders such as Parkinson's Disease, parkinsonian syndromes, cerebral palsy, and amyotrophic lateral sclerosis.[21,24] 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).[20] The American College of Chest Physicians (2023) suggests botulinum toxin injection to the salivary glands for patients with neuromuscular disease and sialorrhea who have an inadequate response to, or intolerance of, anticholinergic therapy (conditional recommendation, very low certainty of evidence).[26]

Dosing Information

Potency units are specific to each botulinum toxin product and are not interchangeable with, or directly convertible to, the units of another botulinum toxin product.[1]

Definitive dosing has not been established for off-label uses of botulinum toxins, including Dysport. Specific dosing considerations by indication are noted below:

- **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 randomized, multicenter study for the treatment of chronic anal fissures which utilized a standard dosing of 60 units of Dysport.[6] The ASCRS guidelines (2023) note there is no consensus on dosing, with reported doses ranging from approximately 20-100 units and a meta-analysis finding no dose dependency for healing, while a separate meta-analysis reported greater efficacy and lower incontinence and recurrence with lower doses.[25]
- **Blepharospasm:** A maximum dose of 120 units per eye of Dysport, not more frequently than once every 12 weeks, has been suggested.[2,11]
- **Hemifacial Spasm**: A long-term study involving 175 consecutive cases treated with Dysport over a period of up to 7 years reported a treatment dose range of 28 to 220 units, with a mean dose of 92 units per session.[17]
- **Oromandibular Dystonia**: Dysport-specific dosing for jaw-closing oromandibular dystonia has been reported at 30 units per masseter and approximately 100 units per temporalis muscle, titrated to response, corresponding to a total of up to approximately 260 units per session for bilateral treatment.[11] In a single-blind Dysport trial for oromandibular dystonia, a low-dose regimen (total session dose of up to 150 units) was utilized from the dose-finding phase and carried into the treatment phase as adverse effects including dysphagia occurred in 50% of patients.[18]
- **Sialorrhea, Chronic:** A double-blind, placebo-controlled, randomized study in parkinsonism patients with sialorrhea found doses up to 450 units of Dysport to be safe and effective.[21] A double-blind, randomized, controlled trial in adults with sialorrhea associated with neurological diseases utilized Dysport doses up to 200 units.[24]

Safety

Botulinum toxin products carry a Boxed Warning regarding the risk of distant spread of toxin effect.[1] Postmarketing reports suggest symptoms consistent with botulinum toxin effects may occur beyond the injection site and may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia,

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dysphonia, dysarthria, urinary incontinence, and breathing difficulties. Serious cases, including life-threatening swallowing and breathing difficulties, have been reported.

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.

Medical benefit coverage is not recommended for cosmetic use.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. Cervical Dystonia. Approve for 1 year if the patient is ≥ 18 years of age.
Note: Cervical dystonia is also referred to as spasmodic torticollis.

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

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 is ≥ 18 years of age.

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Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

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

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

   Dosing. Approve up to a maximum dose of 220 units, administered not more frequently than once every 3 months.

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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 260 units, administered not more frequently than once every 3 months.

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

   Dosing. Approve up to a maximum dose of 450 units, administered not more frequently than once every 12 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Dysport is not recommended in the following situations:

1. **Cosmetic Use**. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in 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.

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	**Anal Fissure, Chronic**: The diagnosis was updated from "Anal Fissure" to as listed. The dosing limitation was lowered from 1,200 units to 100 units. **Oromandibular Dystonia:** This Other Use with Supportive Evidence was added to the Policy. A new dosing limitation was added.	10/02/2024
Annual Revision	**Hemifacial Spasm:** The dosing limitation was decreased from 1200 units to 220 units.	09/17/2025
Update	**06/11/2026: Overview**: The dosing section was updated to remove details regarding dose conversions between botulinum toxins.	--
Annual Revision	**Blepharospasm:** The dosing limitation was clarified to add "per eye". **Oromandibular Dystonia**: The dosing limitation was decreased from 1200 units to 260 units. **Sialorrhea, Chronic:** The dosing limitation was clarified from a "maximum dose of 300 units (150 per side), administered not more frequently than once every 16 weeks" to "maximum dose of 450 units, administered not more frequently than once every 12 weeks".	09/23/2026

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