PRIOR AUTHORIZATION POLICY

POLICY: Botulinum Toxin – Dysport Prior Authorization Policy
- Dysport® (abobotulinumtoxinA injection – Ipsen/Galderma)

REVIEW DATE: 10/02/2024

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 oromadibular 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

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on medical treatment of sialorrhea found that Dysport is probably effective for the treatment of this condition (Level B evidence).[15]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Dysport. All approvals are provided for 1 year in duration.

Prescription 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

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.

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

Other Uses with Supportive Evidence

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

4. **Blepharospasm**. Approve for 1 year if the patient is ≥ 18 years of age.
   Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

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

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.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Dysport is not recommended in the following situations:

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