PRIOR AUTHORIZATION POLICY

POLICY: Botulinum Toxin – Dysport Prior Authorization 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]

POLICY STATEMENT

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

Prior Authorization and prescription benefit coverage are 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.
   Note: Cervical dystonia is also known as spasmodic or cervical torticollis.

2. **Spasticity, Limb**. Approve for 1 year.

Other Uses with Supportive Evidence

3. **Anal Fissure.** Approve for 1 year.

4. **Blepharospasm.** Approve for 1 year.

5. **Hemifacial Spasm.** Approve for 1 year.

6. **Sialorrhea, Chronic.** Approve for 1 year.

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, platsymal bands, or rejuvenation of the periorbital region. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy 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.

REFERENCES

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