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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2024 |
| **Subsection:** | Neuromuscular Drugs | **Original Policy Date:** | December 18, 2009 |
| **Subject:** | Dysport | **Page:** | 1 of 5 |

***Last Review Date:*** December 8, 2023

# Dysport

## Description

### Dysport (abobotulinum toxin A)

**Background**
Dysport (abobotulinum toxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent. Dysport acts as a neuromuscular blocking agent that works by preventing the release of neurotransmitters. This produces a paralyzing effect of the surrounding area of injection. Dysport, like Botox and Myobloc, is a botulinum toxin. Although Botox and Dysport are both botulinum type-A toxins, they are not interchangeable. The two drugs have distinct dosing differences (1).

**Regulatory Status**
FDA-approved indications: Dysport is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: (2)

1. The treatment of adults with cervical dystonia
2. The temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients <65 years of age
3. The treatment of spasticity in patients 2 years of age and older

Dysport has a boxed warning regarding the distant spread of toxin effect. The effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties that can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in patients who have underlying conditions that would predispose them to these symptoms (2).

Off-Label Uses:
Dysport is recommended for additional compendial indications for spasticity (upper and lower limbs) due to multiple causes (i.e., cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury) in both adults and children as well as benign essential blepharospasm (3-4).

Safety and effectiveness have not been established in patients under the age of 18 years of age for cervical dystonia and blepharospasm (2).

**Related policies**
Botox, Myobloc, Xeomin

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Dysport may be considered **medically necessary** for patients with upper and/or lower limb spasticity and if the conditions indicated below are met.

Dysport may be considered **medically necessary** for patients 18 years of age and older for the treatment of cervical dystonia and blepharospasm and if the conditions indicated below are met.

Dysport may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** No age restriction

**Diagnosis**

Patient must have the following:

1. Upper and/or lower limb spasticity

**AND** the following:

1. **NO** dual therapy with other botulinum toxins

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Cervical dystonia (spasmodic torticollis)
2. Blepharospasm

**AND** the following:

1. **NO** dual therapy with other botulinum toxins

## Prior – Approval *Renewal* Requirements

Same as above

## Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Dysport (abobotulinum toxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent. Dysport, like Botox and Myobloc, is a botulinum toxin. Although Botox and Dysport are both botulinum type-A toxins, they are not interchangeable. Dysport has a boxed warning regarding the distant spread of toxin effect after injection (2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Dysport while maintaining optimal therapeutic outcomes.

**References**

1. Simonetta Moreau M, Cauhepe C, Magues JP, Senard JM. A double-blind, randomized, comparative study of Dysport vs. Botox in primary palmar hyperhidrosis. *Br J Dermatol*. 2003 Nov;149(5):1041-5.
2. Dysport. [package insert]. Wrexham, LL 13 9UF, UK: Ipsen Biopharm Ltd.; January 2023.
3. Love SC, Novak I, Kentish M, et al. Botulinum toxin assessment, intervention and after-care for lower lumb spasticity in children with cerebral palsy: international consensus statement. *Eur J Neurol.* 2010 Aug;17 Supple 2:9-37.
4. Truong D, Comella C, Fernandez HH, et al. Efficacy and safety of purified botulinum toxin type A (Dysport) for the treatment of benign essential blepharospasm: a randomized, placebo-controlled, phase II trial. *Parkinsonism Relat Disord.* 2008;14(5):207-14.

## Policy History

| Date | Action |
|---|---|
| October 2011 | Addition to PA |
| December 2012 | Annual editorial review |
| September 2014 | Annual editorial review and reference update |
| September 2015 | Annual review<br>Addition of new indication of upper limb spasticity |
| February 2016 | Addition of off label use for spasticity (upper and lower limbs) due to multiple causes [i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury |
| March 2016 | Annual review<br>Policy changed from 5.12.02 to 5.75.02 |
| August 2016 | Addition of lower limb spasticity and Blepharospasm |
| December 2016 | Annual editorial review<br>Addition of no dual therapy with other botulinum toxins<br>Removal of clarifying examples of spasticity |
| September 2017 | Annual review and reference update |
| September 2018 | Annual review and reference update |
| September 2019 | Annual review and reference update |
| September 2020 | Annual editorial review and reference update |
| March 2021 | Annual review |
| March 2022 | Annual review |
| March 2023 | Annual review and reference update. Changed policy number to 5.75.002 |
| December 2023 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.**