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5.75.002

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

Last Review Date: June 13, 2024

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** 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.; September 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 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 Policy changed from 5.12.02 to 5.75.02
August 2016	Addition of lower limb spasticity and Blepharospasm
December 2016	Annual editorial review Addition of no dual therapy with other botulinum toxins 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
March 2024	Annual review and reference update
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.