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 indication: 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 adults
4. The treatment of lower limb spasticity in pediatric 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**
Duration 12 months

**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.
5.75.02

Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Neuromuscular Drugs  Original Policy Date: December 18, 2009
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References


Policy History

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<td>October 2011</td>
<td>Addition to PA</td>
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<tr>
<td>December 2012</td>
<td>Annual editorial review</td>
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<tr>
<td>September 2014</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>September 2015</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Addition of new indication of upper limb spasticity</td>
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<tr>
<td>February 2016</td>
<td>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]</td>
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<tr>
<td>March 2016</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Policy changed from 5.12.02 to 5.75.02</td>
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<tr>
<td>August 2016</td>
<td>Addition of lower limb spasticity and Blepharospasm</td>
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<td>Addition of no dual therapy with other botulinum toxins</td>
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<td>Removal of clarifying examples of spasticity</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on
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September 13, 2019 and is effective on October 1, 2019.