

Dysport® (abobotulinumtoxinA)

When requesting Dysport® (abobotulinumtoxinA), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

- Cervical dystonia in adults
- Upper and lower limb spasticity in patients 2 years of age and older

Approved Off-label Compendial Uses

- Blepharospasm
- Hemifacial spasm
- Chronic anal fissure
- Chronic sialorrhea
- Oromandibular dystonia

Coverage Guidelines

The individual must be 18 years of age or older for approval of the following indications:

- Cervical dystonia (Spasmodic torticollis)
- Blepharospasm
- Hemifacial spasm
- Chronic anal fissure
- Chronic sialorrhea
- Oromandibular dystonia

The individual must be 2 years of age or older for approval of the following indications:

- Upper limb spasticity
- Lower limb spasticity

Approval Duration: 12 months

Dosing Recommendations

Cervical Dystonia

The recommended initial dose is 500 units administered intramuscularly. Dose adjustment can be made in 250 unit steps up to a maximum dose of 1000 units

according to the individual patient's response, with re-treatment every 12 weeks or longer.

Adult Spasticity (upper and lower)

The recommended dosing for upper limb spasticity is between 500 units and 1000 units and for lower limb spasticity is up to 1500 units, administered intramuscularly every 12 weeks or longer.

Pediatric Upper Limb Spasticity

The recommended dosing for upper limb spasticity is 8 units/kg to 16 units/kg per limb, administered intramuscularly. The maximum recommended total dose administered per treatment session must not exceed 16 units/kg or 640 units, whichever is lower. The re-treatment should occur no sooner than 12 weeks after the previous injection

Pediatric Lower Limb Spasticity

The recommended dosing for lower limb spasticity is 10 units/kg to 15 units/kg per limb, administered intramuscularly. Total dose per treatment session must not exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral injections, or 1000 units, whichever is lower. The re-treatment should occur no sooner than 12 weeks after the previous injection.

Blepharospasm

The recommended maximum dose is 120 units per eye, administered subcutaneously no more frequently than every 12 weeks.

Hemifacial Spasm

The recommended maximum dose is 220 units per treatment session, administered subcutaneously no more frequently than every 12 weeks.

Chronic Anal Fissure

The recommended dose is a maximum of 100 units, administered no more frequently than every 12 weeks.

Chronic Sialorrhea

The recommended dose is a maximum of 300 units (150 units per side), administered no more frequently than every 16 weeks.

Oromandibular Dystonia

The recommended dose is up to a maximum of 1,200 units administered not more frequently than once every 12 weeks.

References

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