

Dysport® (abobotulinumtoxinA)

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

FDA-Approved Indications

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

Approved Off-label Compensial Uses

- Blepharospasm
- Hemifacial spasm
- Anal fissure
- Chronic sialorrhea

Coverage Guidelines

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

- Cervical dystonia
- Blepharospasm
- Hemifacial spasm
- Anal fissure
- Chronic sialorrhea

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. The maximum recommended total dose per treatment session (upper and lower limb combined) is 1500 units with re-treatment 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 16 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.

Anal Fissure

The recommended dose is 90 units to 150 units in two divided doses, administered no more frequently than every 12 weeks.

Chronic Sialorrhea

The recommended dose is 15 to 75 units per gland (submandibular, parotid, or both), administered no more frequently than every 16 weeks.

References

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