

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
- Adult upper and lower limb spasticity
- Pediatric lower limb spasticity

Approved Off-label Compensial Uses

- Blepharospasm
- Hemifacial spasm

Coverage Guidelines

Approval duration of 12 months will be granted for the following indications:

- Cervical dystonia
- Adult upper and lower limb spasticity
- Pediatric lower limb spasticity
- Blepharospasm
- Hemifacial spasm

Dosing Recommendations

Cervical Dystonia

Approve up to a maximum dose of 1,000 units, administered intramuscularly not more frequently than once every 12 weeks.

Adult Upper Limb Spasticity

Approve up to a maximum dose of 1,000 units, administered intramuscularly not more frequently than once every 12 weeks. Maximum volume is 1mL per injection site.

Adult Lower Limb Spasticity

Approve up to a maximum dose of 1,500 units, administered intramuscularly not more frequently than once every 12 weeks. Maximum volume is 1mL per injection site.

Pediatric Lower Limb Spasticity

Approve up to 15 units/kg for unilateral lower limb injections or 30 units/kg for bilateral lower limb injections, or 1,000 units (whichever is lower), administered intramuscularly not more frequently than once every 12 weeks. Maximum volume is 0.5mL per injection site.

Blepharospasm

Approve up to a maximum dose of 120 units (per eye), administered subcutaneously not more frequently than once every 12 weeks.

Hemifacial Spasm

Approve up to a maximum dose of 220 units, administered subcutaneously not more frequently than once every 3 months.

References

1. Dysport® (abobotulinumtoxinA) [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.: July 2016. Accessed July 1, 2019.
2. Dysport® (abobotulinumtoxinA). In: DRUGDEX system Micromedex. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. [Updated March 12, 2019: Accessed July 1, 2019]
3. Simpson, DN, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016; 26 86(19):1818-1826.
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):407-414.