VENTURA COUNTY
HEALTH CARE PLAN

**Prior Authorization DRUG Guidelines**

**Botox (botulinum toxin type A; onabotulinumbotulinumtoxinA)**
Effective Date: 10/22/13
Date Developed: 9/3/13 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18,
1/22/19**(Archived 1/22/19)**

Botox is a commercial form of botulinum toxin (a neurotoxin which inhibits the release of acetyl choline from the presynaptic membrane of the neuromuscular junction, leading to paresis or paralysis).

**Pre-Authorization Criteria:**
VCHCP will approve Botox for: blepharospasm, cervical dystonia, axillary hyperhydrosis, sialorrhea, spasticity due to stroke or cerebral palsy, upper extremity dystonias, hyperactive Bladder; headache prophylaxis in adults with chronic migraines (at least 15 days of headache per month and at least 8 days of migraine) that have not responded to at least 3 prior pharmacologic prophylaxis therapies and whose condition is appropriately managed for medication overuse. (See Milliman Care Guidelines for additional details.)

**Adult Dosing:** varies, see product information

**PRECAUTIONS**: should be administered by a practitioner specially trained in its use; distant spread of toxin beyond site of injection [U.S. Boxed Warning]; loss of efficacy due to antibody formation after prolonged use; unwanted reactions at injection sites (bleeding; excessive paresis); dry cornea/corneal abrasion from reduced blink reflexes

**DRUG INTERACTIONS:** neuromuscular blocking agents; anticholinergic agents; aminoglycosides

**Note:** Onabotulinum (Botox) and abobotulinumtoxin (Dysport) have unique dosing, as spelled out in each agent's prescribing information. It is important that physicians be familiar with the respective dosing guidelines for each agent and be prepared to make appropriate treatment decisions in any clinical setting.

**REFERENCES**

1. Batra RS, Dover JS, and Arndt KA, "Adverse Event Reporting for Botulinum Toxin Type A," *J Am Acad Dermatol*, 2005, 53(6):1080-2.

2. Borodic GE and Pearce LB, “New Concepts in Botulinum Toxin Therapy,” *Drug Saf*, 1994, 11(3):145-52.
3. Brisinda G, Maria G, Bentivoglio AR, et al, “A Comparison of Injections of Botulinum Toxin and Topical Nitroglycerin Ointment for the Treatment of Chronic Anal Fistula,” *N Engl J Med*, 1999, 341:65-9.
4. Bushara KO, Jones JW, and Park DM, “Localized Graying of Eyebrow Hair, A Side Effect of Botulinum Toxin Injections,” *Mov Disord*, 1995, 10:382.
5. Childers MK, Brashear A, Jozefczyk P, et al, “Dose-Dependent Response to Intramuscular Botulinum Toxin Type A for Upper-Limb Spasticity in Patients After a Stroke,” *Arch Phys Med Rehab*, 2004, 85(7):1063-69.
6. “Clinical Use of Botulinum Toxin,” *Arch Neurol*, 1991, 48(12):1294-8.
7. Cohen S and Parkman HP, “Treatment of Achalasia - Whalebone to Botulinum Toxin,” *N Engl J Med*, 1995, 332(12):815-6.
8. Cohen V, Jellinek SP, Teperikidis L, et al, “Room-Temperature Storage of Medications Labeled for Refrigeration,” *Am J Health-Syst Pharm*, 2007, 64(16):1711-15.
9. “Cosmetic Use of Botulinum Toxin,” *Medical Letter*, 1999, 41:63-4.
10. Coté TR, Mohan AK, Polder JA, et al, "Botulinum Toxin Type A Injections: Adverse Events Reported to the U.S. Food and Drug Administration in Therapeutic and Cosmetic Cases," *J Am Acad Dermatol*, 2005, 53(3):407-15.
11. Cruz F, Herschorn S, Aliotta P, et al, “Efficacy and Safety of OnabotulinumtoxinA in Patients With Urinary Incontinence Due to Neurogenic Detrusor Overactivity: A Randomised, Double-Blind, Placebo-Controlled Trial,” *Eur Urol*, 2011, 60(4):742-50.
12. Ferrari AP Jr, Siqueira ES, and Brant CQ, “Treatment of Achalasia in Chagas' Disease With Botulinum Toxin,” *N Engl J Med*, 1995, 332(12):824-5.
13. Jankovic J and Brin MF, “Therapeutic Uses of Botulinum Toxin,” *N Engl J Med*, 1991, 324(17):1186-94.
14. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," *Curr Med Res Opin*, 2004, 20(7):981-90.
15. Pasricha PJ, Ravich WJ, Hendrix TR, et al, “Intrasphincteric Botulinum Toxin for the Treatment of Achalasia,” *N Engl J Med*, 1995, 322(12):774-8. [PubMed 2308606]
16. Pasricha PJ, Ravich WJ, Hendrix TR, et al, “Treatment of Achalasia With Intrasphincteric Injection of Botulinum Toxin,” *Ann Intern Med*, 1994, 121(8):590-1.
17. Repka MX, Savino PJ, and Reinecke RD, “Treatment of Acquired Nystagmus With Botulinum Neurotoxin A,” *Arch Ophthalmol*, 1994, 112(10):1320-4. Sheean GL, Murray NM, and Marsden CD, “Pain and Remote Weakness in Limbs Injected With Botulinum Toxin A for Writer's Cramp,” *Lancet*, 1995, 346(8968):154-6.

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VENTURA COUNTY
HEALTH CARE PLAN

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