Botulinum Toxin (abobotulinumtoxinA, daxibotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB) Criteria for Use August 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive botulinum toxin injections:

- ☐ Hypersensitivity to botulinum toxins or any components in the formulation (e.g., human serum albumin, lactose, sucrose, disodium succinate)
- ☐ Co-administration with neuromuscular blockade
- ☐ Neurologic condition where botulinum toxins pose risk for additive neuromuscular compromise (e.g., myasthenia gravis, amyotrophic lateral sclerosis) unless risks/benefits have been discussed with the patient and documented in the medical record
- ☐ Used for cosmetic purposes

Inclusion Criteria

One of the following criteria must be met as the indication for which the botulinum toxin will be used:

- ☐ Cervical dystonia or focal dystonia[1]
- ☐ Blepharospasm or hemifacial spasm[1]
- ☐ Severe focal hyperhidrosis and patient had an inadequate response or had unmanageable intolerance to a prescription topical therapy (e.g., aluminum chloride hexahydrate 20% topical solution)[1]
- ☐ Upper or lower limb spasticity[1]
- ☐ Overactive bladder or neurogenic bladder dysfunction with contraindication, intolerance, or inefficacy to behavioral therapy and at least one pharmacotherapy (e.g., antimuscarinic agent, beta-3 adrenergic agonist)[1]
- ☐ Chronic migraine prevention and patient has contraindication, intolerance, or lack of therapeutic response after at least 12 weeks each of a therapeutic dose of at least 2 of the following: beta blocker, topiramate, divalproex, and ACE inhibitor or ARB [1,2]
- ☐ Pharyngoesophageal segment spasm (PES)[3]
- ☐ Sialorrhea and patient has contraindication, intolerance, or lack of therapeutic response to anticholinergics and/or speech therapy[1]
- ☐ Chronic anal fissure refractory to conservative treatment including supportive measures (e.g., dietary fiber, sitz bath) and topical vasodilator (e.g., topical nitrates)[3]
- ☐ Esophageal achalasia if patient is not a candidate for surgery[3]
- ☐ Idiopathic (primary or genetic) or symptomatic (acquired) torsion dystonia[3]

Footnotes

1. Indications for which at least one botulinum toxin is FDA approved

2. ACE: Angiotensin-Converting Enzyme; ARB: Angiotensin II Receptor Blocker. Therapeutic doses for oral preventive agents are as follows: beta blocker (e.g., metoprolol 50-100 mg BID, propranolol 20-80 mg BID), topiramate 50-200 mg BID, divalproex 500-1000 mg daily, ACE inhibitor or ARB (e.g., lisinopril 20 mg daily, enalapril 10 mg daily, telmisartan 80 mg daily). Divalproex is not recommended in patients who can become pregnant.
3. Indications for which botulinum toxin use is off-label.

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