Clostridium Botulinum Neurotoxins

Covered Medications

- Botulinum Toxin Type A (Botox®)
- Botulinum Toxin Type B (Myobloc®)
- AbobotulinumtoxinA (Dysport™)

What they do and how they're used

- There are seven serologically distinct botulinum neurotoxins, designated A through G, that act to block neuromuscular transmission by binding to motor nerve terminals and inhibiting the release of acetylcholine. Blocking the effects of acetylcholine leads to muscle paralysis. Botulinum Toxin Type A achieves this inhibition by cleaving SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. Botulinum Toxin Type B has been specifically demonstrated to cleave synaptic Vesicle Associated Membrane Protein (VAMP, also known as synaptobrevin) which is a component of the protein complex responsible for the docking and fusion of the synaptic vesicle to the presynaptic membrane, a necessary step to acetylcholine (neurotransmitter) release.
- Botulism toxins have FDA-approval for the treatment of cervical dystonia a condition in which the neck muscles undergo prolonged contraction. Cervical dystonia can lead to torticollis – twisting of the neck due to muscle contraction. Treatment with botulinum toxins is used to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
- Botox® is also FDA-approved for the treatment of strabismus (crossed eyes) and blepharospasm (twitching, spasmodic contraction of the muscles around the eye) and for the treatment of severe primary axillary hyperhidrosis (severe underarm sweating) that is inadequately managed with topical agents, such as over-the-counter antiperspirants and topical aluminum products.
- Severe primary axillary hyperhidrosis is a medical condition that involves hyperactive sweat glands. Sweating regulates the body's temperature. In severe primary axillary hyperhidrosis, sweating significantly exceeds the body's normal requirements.
- Botox® treatment helps control severe underarm sweating by temporarily blocking the nerves that stimulate the sweat glands.
- Other off-label uses for Botulinum toxin reported in the medical literature include treatment of; dystonia of the arms, legs, or face resulting from neurological conditions such as cerebral palsy, multiple sclerosis, stroke, and traumatic brain or spinal cord injuries, hyperhidrosis (excessive sweating), anal sphincter spasm; swallowing disorders (achalasia), chronic headaches (both migraine and tension-type), hyperlacrimation (excessive eye tearing) and sialorrhea (excessive salivation) in children.
- Botox Cosmetic® and Dysport™ are approved for the treatment of brow furrows (glabellar lines).
- Botulinum toxins may also be used in the treatment of wrinkles (crows feet), forehead creases, and thick bands in the neck resulting from hyperactivity of underlying muscles. Lines and wrinkles due to sun damage or from sagging skin would not be improved.
- 1 unit of Botox® is approximately equivalent to 30 to 50 units of Myobloc®. There is no conversion factor for Dysport™.
- The onset of action is 48-72 hours with peak effects occurring as early as 2-4 weeks and the duration of action lasts from 3 to 6 months.
- Botox®, Dysport™, and Myobloc® are administered by a physician. The physician may inject 3 to 4 different muscles when treating cervical dystonia resulting in an average total dose of 230 U (units) Botox® or 500-1000 U of Dysport™ per visit. Cervical dystonia treatment with Myobloc® may include 2500 to 5000 units injected into each neck muscle. Smaller doses are used in the treatment of blepharospasm (e.g., 25 units of Botox®) and strabismus (e.g., up to 5 units Botox® per ocular muscle). Doses of 20 to 40 units Botox® have been used to reduce/eliminate facial lines and wrinkles. For glabellar lines, a total of 50 U of Dysport™ is given in 5 equal aliquots of 10 U. Treatment is individualized for each patient with the physician re-evaluating the need for additional injections at subsequent visits.

Rationale for Prior Authorization

To reduce exposure to cost associated with use for appearance enhancement such as use in the treatment of facial lines and wrinkles. Other unlabeled uses are not assessed in this prior authorization process.
**Benefit Design**
Coverage will be determined through a prior authorization process for all claims.

**Prior Authorization Criteria**
Coverage for Botox® or Myobloc® is provided for uses other than for the cosmetic treatment of frown lines, wrinkles, brow furrow, forehead creases or thick neck bands.

**References**


Product Information Dysport™ (Medicis Aesthetics Inc) 2009.