

Blue Cross and Blue Shield of Vermont and The Vermont Health Plan

Prior Approval Guidelines

Botox® (Botulinum Toxin Type A)

DESCRIPTION: Botox® (Botulinum toxin type A) is a sterile, vacuum-dried form of purified botulinum toxin type A, produced from a culture of the Hall strain of Clostridium botulinum. Botox® blocks neuromuscular conduction by binding to receptor sites on nerve terminals, entering the nerve terminals and inhibiting the release of acetylcholine. This causes a localized chemical denervation that paralyzes the muscle reducing excessive, abnormal contractions that occur in certain disorders.

INDICATION(S) : Treatment of cervical dystonia in adults to decrease the severity of associated abnormal head position and neck pain, strabismus, facial nerve VII disorders and blepharospasm associated with dystonia.

REASONS FOR PA: Cost Potential for misuse Toxicity

- CRITERIA for APPROVAL:**
1. Treatment of cervical dystonia in adults to decrease the severity of abnormal head position and associated neck pain
 - OR**
 2. Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm and facial nerve VII disorders
 - AND**
 3. Patient is \geq 16 years of age for indication of cervical dystonia
 - AND**
 4. Patient is \geq 12 years of age for indications of strabismus or blepharospasm
 - AND**
 5. Patient is \geq 18 years of age for any other indication
 - OR**
 6. Treatment of other types of dystonia resulting in functional impairment and/or pain in patients with any of the following hereditary, degenerative, or demyelinating diseases of the central nervous system including: idiopathic torsion dystonia, symptomatic torsion dystonia, orofacial dyskinesia, organic writer's cramp, hereditary spastic paraplegia, neuromyelitis optica, Schilder's disease, spastic hemiplegia, spasticity related to stroke, infantile cerebral palsy, spasmodic torticollis
 - OR**
 7. Treatment of laryngeal spasm and torticollis
 - OR**
 8. Treatment of achalasia if patient has not responded to dilation therapy or is considered poor surgical candidate
 - OR**
 9. Treatment of chronic anal fissure

- REASONS for DENIAL of BENEFIT:**
1. Treatment of wrinkles or other cosmetic indications
 2. Treatment in restrictive strabismus, Duane's syndrome with lateral rectus weakness, secondary strabismus caused by surgical over-recession of the antagonist
 3. Treatments considered investigational including but not limited to: headache or migraine, myofascial pain syndrome, tremors such as benign essential tremor, chronic motor tic, tics associated with Tourette syndrome
 4. Infection at injection site
 5. Hypersensitivity to any ingredient in the formulation
 6. Patient does not meet above criteria

RENEWAL CRITERIA: Review of past 3 months demonstrates symptomatic improvement in health related quality of life

BENEFIT APPROVAL: Initial approval for a period of 3 months Renewal approval period: 3 months

- References:**
1. Botox® Prescribing Information, Allergan Pharmaceuticals. Irvine, CA. July 2002.
 2. Scott AB. Botulinum toxin treatment of strabismus. American Academy of Ophthalmology, Focal Points 1989: Clinical Modules for Ophthalmologists vol. VII; Module 12.