UM-CDG-027 Botulinum Toxins	Approved By: Director, Health Services	Effective Date: 10/22/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address botulinum toxins, potent neuromuscular blocking agents proven to be useful in treating various focal muscle spastic disorders and excessive muscle contractions. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated. The clinical indications for botulinum toxins have increased exponentially. They are used in the treatment of overactive skeletal muscles (e.g. hemifacial spasm, dystonia, spasticity), smooth muscles (e.g. detrusor overactivity and achalasia), glands (e.g. sialorrhoea and hyperhidrosis) and additional conditions that are being investigated.

There are currently four botulinum toxin products commercially available in the United States: Botox (onabotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA), and Xeomin (incobotulinumtoxinA). Each preparation has distinct pharmacological and clinical profiles specified on the product insert. Dosing patterns are also specific to the preparation of neurotoxin and are very different between different serotypes. Failure to recognize the unique characteristics of each formulation of botulinum toxin can lead to undesired patient outcomes. It is expected that physicians will be familiar with and experienced in the use of these agents and utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient condition. Physicians may decide which agent to use in member care except as noted below. Although botulinum toxins have only been approved by the US Food and Drug Administration (FDA) for limited uses, they are frequently used off-label as well. A member who is not responsive or who ceases to respond to one serotype may respond to the other.

This coverage determination guideline will provide guidance on these pharmaceutical products.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan considers botulinum toxin as medically necessary for the treatment of spasticity in members

to reduce spasticity or excessive muscle contractions, to relieve pain, to assist with posture and walking, to improve range of motion, to enhance the effectiveness of physical therapy, and to reduce severe spasm to allow better perineal hygiene in members with spasticity secondary to spastic hemiplegia and hemiparesis. Organic writer's cramp is uncommon, and so Botulinum toxin for the treatment of organic writer's cramp should be infrequent.

Botulinum toxin is indicated for disorders associated with spastic conditions as above and dystonia. The wide range of Botulinum toxin dosages used in a treatment session is determined by patient age, degree of spasticity, number of injections made into each muscle and number of muscles treated.

Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck and upper extremity.

OnabotulinumtoxinA is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

AbobotulinumtoxinA is indicated for the treatment of lower limb spasticity in adults.

SECUR Health Plan considers botulinum toxin injection therapy for first line treatment for members with blepharospasm and/or hemifacial spasm as medically necessary. If the upper and lower lid of the same eye and/or adjacent facial muscles, or brow are injected at the same surgery, the procedure is considered as unilateral. Bilateral procedures will only be considered when both eyes or both sides of the face are injected.

Botulinum toxin for achalasia is considered medically necessary for members who have not responded satisfactorily to conventional therapy, are at high risk of complication from pneumatic dilation or surgical myotomy, have had treatment failure with pneumatic dilation or surgical myotomy have had perforation from pneumatic dilation, have an epiphrenic diverticulum or hiatal hernia, or have esophageal varices.

Botulinum toxin for chronic anal fissure is considered medically necessary for members who have not responded satisfactorily to conventional therapy.

OnabotulinumtoxinA has been approved by the FDA for treatment of severe primary axillary hyperhidrosis (primary focal hyperhidrosis) that is inadequately managed with topical therapy. Compendia list onabotulinumtoxinA and rimabotulinumtoxinB as acceptable off-label agents for this condition. The definition of primary focal hyperhidrosis is severe sweating, beyond physiological needs; focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least two (2) of the following characteristics: bilateral and relatively symmetric, significant impairment in daily activities, age of onset less than 25 years, positive family history, and cessation of focal sweating during sleep. SECUR Health Plan considers this medically necessary.

The treatment of sialorrhea with botulinum toxin due to conditions such as motor neuron disease or Parkinson's disease in those patients who have failed to respond to a reasonable trial of traditional therapies (eg., anticholinergics and speech therapy) or who have a contraindication to or cannot tolerate anticholinergic therapy, will be considered medically necessary.

Urinary incontinence due to neurogenic detrusor overactivity (NDO) commonly occurs in patients with spinal cord injuries (SCI) or neurological diseases such as multiple sclerosis (MS). Members with NDO usually use

clean intermittent self-catheterization (CIC) to empty the bladder. When incontinence episodes occur between catheterizations, oral anticholinergic agents are used to decrease bladder contractility and improve incontinence. OnabotulinumtoxinA is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults and patients five years of age and older who have an inadequate response to or are intolerant of an anticholinergic medication. SECUR Health Plan considers this medically necessary.

SECUR Health Plan will consider the use of botulinum toxin as medically necessary for the treatment of headaches and/or migraines for members with chronic daily headaches (headache disorders occurring greater than 15 days a month - in many cases daily with a duration of four or more hours - for a period of at least 3 months) who have significant disability due to the headaches, and have been refractory to standard and usual conventional therapy. The etiology of the chronic daily headache may be chronic tension-type headache or chronic migraine (CM). CM is characterized by headache on $\geq$15 days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment. For continuing Botulism toxin therapy the member must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin.

SECUR Health Plan will cover one injection per site regardless of the number of injections made into the site. A site is defined as one eye (including all muscles surrounding the eye including both upper and lower lids), one side of the face, the neck, or extremity and/or trunk muscle(s) for medically necessary indications.

Failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further medical necessity of the serotype used in the treatment for a period of one (1) year after the second session. It may be reasonable, however, to attempt treatment with a different serotype.

Treatment of wrinkles using botulinum toxins is cosmetic and is not considered medically necessary.

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