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1.0 Description of the Procedure, Product, or Service

Botulinum is a family of toxins produced by the anaerobic organism *Clostridia botulinum*. There are 7 distinct serotypes designated as type A, B, C-1, D, E, F, and G. In this country, 2 preparations of botulinum are available, produced by 2 different strains of bacteria: type A (Botox, Dysport) and type B (Myobloc). When administered intramuscularly, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings.

The label for Botox (Onabotulinumtoxin A) approved by the U.S. Food and Drug Administration (FDA) states that it is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients older than 12 years. The FDA approved label for Myobloc (Rimabotulinumtoxin B) states that it is indicated for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain. On April 29, 2009 the FDA approved the use of Dysport (Abobotulinumtoxin A) to treat patients with cervical dystonia.

Dystonia is a general term describing a state of abnormal or disordered tonicity of muscle. As an example, esophageal achalasia is a dystonia of the lower esophageal sphincter, while cervical dystonia is also known as torticollis. Spasticity is a subset of dystonia, describing a velocity-dependent increase in tonic-stretch reflexes with exaggerated tendon jerks. Spasticity typically is associated with injuries to the central nervous system. Spasticity is a common feature of cerebral palsy. Since its FDA approval in 1991, Botox has been used for a wide variety of off-label indications, ranging from achalasia, spasticity after strokes, cerebral palsy, and anal fissures. In addition to widening indications, Botox has also been used in children under 12, particularly for the treatment of cerebral palsy. It is anticipated that Myobloc will be used for the same range of off-label indications as Botox. After successful extended use of botulinum toxin (usually A), some initial responders become nonresponders. Such secondary nonresponse may occur for a variety of reasons; one cause in a small percentage of patients is the development of antibodies that neutralize the activity of the administered botulinum toxin. These patients are likely to respond to another botulinum toxin type. A clinically useful assay for toxin-reactive antibodies would detect only neutralizing antibodies, as non-neutralizing antibodies can be present in the serum of patients who have not developed resistance to treatment. Assay formats best suited to the clinical laboratory, such as immunoprecipitation, western blot, or enzyme-linked immunosorbent assay, typically do not discriminate between neutralizing and non-neutralizing antibodies and would thus generate false-positive results in some patients.

Note: The US Food & Drug Administration (FDA) now requires a boxed warning and a Risk Evaluation and Mitigation Strategy (REMS) for all Botulinum Toxin products. Refer to the FDA Website for additional information located at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm174949.htm>

1.1 Medical Term Definitions

- a. Achalasia: failure of the smooth muscle fibers of the gastrointestinal tract to relax at any point of junction of one part with another.
- b. Blepharospasm: twitching of the eyelid.
- c. Cervical Dystonia: another term for spasmodic torticollis.
- d. Clonic: contraction/relaxation in rapid succession

- e. Detrusor: bundles of smooth muscle fibers forming the muscular coat of the urinary bladder which are arranged in a longitudinal and a circular layer and on contraction, serve to expel urine.
- f. Detrusor sphincteric dyssynergia: contraction of the sphincter muscle of the urethra at the same time the detrusor muscle of the bladder is contracting, resulting in obstruction of normal urinary outflow.
- g. Dyskinesia: distortion or impairment of voluntary movement.
- h. Dystonia: distortion or impairment of voluntary movements due to disordered tonicity of muscle.
- i. Frey's Syndrome: also called auriculotemporal syndrome. The appearance of a red area and of sweating on the cheek in connection with eating; seen in lesions of the parotid gland and due to some involvement of the auriculotemporal nerve.
- j. Hemifacial spasm: spasm of muscles of one half of the face.
- k. Myoclonus: rapid, shock-like muscle jerks that are involuntary.
- l. Myofascial pain syndrome: a chronic pain syndrome occurring in a region of the body, characterized by painful muscles with increased tone and stiffness containing trigger points. A trigger point is a hyperirritable spot within a taut band of skeletal muscle or muscle fascia that is painful on compression, gives rise to characteristic pain referral patterns, and may elicit a twitch in the muscle.
- m. Neuromuscular: pertains to the nerves and the muscles.
- n. Spasmodic: sudden violent and involuntary contractions of a muscle or group of muscles; may also involve pain and interference with function producing involuntary movement and distortion.
- o. Spasmodic dysphonia: difficulty in speaking due to excessively vigorous adduction, or rarely abduction, of the vocal cords against each other, so that the voice is hoarse, soft, and strained.
- p. Spasticity: increased muscle tone with heightened deep tendon reflexes.
- q. Strabismus: deviation of the eye which the patient cannot overcome.
- r. Tics: habitual, repeated contraction of certain muscles, resulting in stereotyped individualized actions that can be voluntarily suppressed for only brief periods, e.g., clearing of the throat, sniffing, pursing the lips, excessive blinking, etc. These tics are especially prominent when the person is under stress.
- s. Tonic: a prolonged muscular contraction.
- t. Torticollis: a contracted state of the cervical muscles, producing twisting of the neck and an unnatural position of the head.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Botulinum toxin injection is covered when it is determined to be medically necessary because the following medical criteria are met:

- a. Botulinum toxin may be considered medically necessary to treat the following FDA labeled indications:
 1. strabismus;
 2. blepharospasm;
 3. facial nerve (VII) disorders, such as hemifacial spasm; or
 4. cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) when **ALL** of the following criteria are met:
 - (a) Postural disturbance and pain must be of moderate or greater severity as documented by interference with specific activities of daily living and unresponsive to a trial of appropriate standard conservative therapy that may include non-narcotic analgesics, muscle relaxants and physical modalities;
 - (b) there are clonic and/or tonic involuntary contractions of one or more neck muscles (that is, sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles);
 - (c) there is sustained head torsion and/or tilt with limited range of motion in the neck;
 - (d) the duration of the condition must be greater than six months; **AND**
 - (e) alternative causes of the patient's symptoms have been considered and ruled out, including chronic neuroleptic treatment, cervicogenic headaches, myofascial pain syndrome, contractures or other neuromuscular conditions.
- b. Botulinum toxin may be considered medically necessary for off-labeled FDA indications for the treatment of dystonia/spasticity resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or

pain in patients with the following hereditary, degenerative, or demyelinating diseases of the central nervous system:

Note: Use of botulinum toxin for off-label indications should only be done when the treating physician has determined that the benefits of the treatment clearly outweigh the risks of the therapy.

1. idiopathic (primary or genetic) torsion dystonia;
 2. symptomatic (acquired) torsion dystonia;
 3. oromandibular dystonia (orofacial dyskinesia, Meige syndrome);
 4. laryngeal dystonia and adductor spasmodic dysphonia;
 5. organic writer's cramp (focal upper limb dystonia);
 6. hereditary spastic paraparesis;
 7. neuromyelitis optica;
 8. multiple sclerosis or Schilder's disease;
 9. spastic hemiplegia;
 10. spasticity related to stroke;
 11. spinal cord or traumatic brain injury;
 12. infantile cerebral palsy.
- c. Botulinum toxin may be considered medically necessary in recipients with the following off-labeled FDA indications:

Note: Use of botulinum toxin for off-label indications should only be done when the treating physician has determined that the benefits of the treatment clearly outweigh the risks of the therapy.

1. lower esophageal achalasia where the recipient has not responded to dilation therapy or where the recipient is considered a poor surgical candidate;
 2. chronic anal fissure;
 3. sialorrhea (drooling) associated with Parkinson disease;
 4. incontinence due to detrusor overreactivity (urge incontinence), either idiopathic or due to neurogenic causes (i.e., spinal cord injury, multiple sclerosis), that is inadequately controlled with anticholinergic therapy.
- d. Botulinum toxin may be considered medically necessary in recipients with gustatory hyperhidrosis (Frey's Syndrome) following parotid surgery.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Botulinum Toxin Injection is not covered in the following situations:

- a. For conditions other than those listed in Section 3.2.
- b. Botulinum toxin is considered not medically necessary as a treatment of:
 1. wrinkles; and
 2. Other cosmetic indications.
- c. Botulinum toxin is considered investigational for other indications, including:
 1. Headaches including migraine, chronic tension, chronic daily, and cervicogenic or "cervicodystonic" headaches;
 2. Chronic low back pain;
 3. Joint pain;
 4. Mechanical neck disorders;
 5. Neuropathic pain after neck dissection;
 6. Myofascial pain syndrome;
 7. Pain after hemorrhoidectomy or lumpectomy;
 8. Tremors such as benign essential tremor (upper extremity);
 9. Tinnitus;
 10. Chronic motor tic disorder;
 11. tics associated with Tourette syndrome (motor tics);
 12. Sialorrhea (drooling) except that associated with Parkinson disease;
 13. Lateral epicondylitis;
 14. Benign prostatic hyperplasia;
 15. Interstitial cystitis;
 16. Detrusor overreactivity not due to spinal cord injury;
 17. Detrusor sphincteric dyssynergia (after spinal cord injury);and

18. Piriformis syndrome.
- d. The use of assays to detect antibodies to botulinum toxin is considered investigational.
- e. Other Guidelines: Botulinum Toxin should not be used when it is contraindicated. Contraindications for use of Botulinum Toxin include:
 1. Absolute:
 - (a) Inflammation or infection at the site of injection; and
 - (b) Allergy to the drug.
 2. Relative:
 - (a) inability of patient to cooperate;
 - (b) coagulopathy; and
 - (c) disease of neuromuscular transmission:
 - i. myasthenia gravis;
 - ii. Eaton Lambert Syndrome;
 - iii. amyotrophic lateral sclerosis;
 - iv. peripheral neuropathy, and
 - v. motor neuron disease.
 - (d) Concurrent use of medications that affect neuromuscular transmission such as aminoglycoside antibiotics.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for the use of botulinum toxin injection.

5.2 Medical Records

In cases for which botox has been approved in the past, medical records are required at least annually to document ongoing effectiveness.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

Code	Description
46505	Chemodenervation of internal anal sphincter
64612	Chemodenervation of muscle(s); innervated by facial nerve (eg, for blepharospasm, hemifacial spasm)
64613	Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)
64614	Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)
64653	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle
+95873	Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)
+95874	Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)
J0585	Injection, onabotulinumtoxinA, 1 unit
J0587	Injection, rimabotulinumtoxinB, 100 units
S2340	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation of adductor muscle(s) of vocal cord

If prior approval is not obtained, claims filed with these codes will deny.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

Botulinum Toxin Type A: 1 billing unit = 1 unit

Botulinum Toxin Type B: 1 billing unit = 100 units

F. Place of Service

Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.