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NC Division of Medical Assistance Botulinum Toxin Treatment: Serotype A (Botox, Dysport and Xeomin) Serotype B (Myobloc)	Medicaid and Health Choice Clinical Coverage Policy No: 1B-1 Amended Date: November 1, 2017

Related Clinical Coverage Policies

Refer to https://dma.ncdhhs.gov/ for the related coverage policies listed below:

1B, *Physician's Drug Program,*

9, *Outpatient Pharmacy Program*

1.0 Description of the Procedure, Product, or Service

OnabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin) and rimabotulinumtoxinB (Myobloc) injections are used for conditions in which neuromuscular blockade is indicated. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. They have the advantage of being potent neuromuscular blocking agents with good selectivity, duration of action, with the smallest antigenicity, and fewest side effects.

In clinical conditions, such as cervical dystonia, excessive and abnormal regional muscle contraction causes torsion, spasticity, and pain. Botulinum toxin, injected in a focal fashion, produces neuromuscular blockade and paralysis. As symptoms abate, repeat injections may be required. Eventual loss of response to repeated injections may occur in some patients who have received botulinum toxin treatment. Immunoresistance may be one of the reasons for this development. As experience accumulates with other toxin types, similar resistance could be observable.

There are several botulinum toxin serotypes, currently designated A through G. Only serotype A and serotype B products are now FDA approved and commercially available. This policy deals *only* with onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin) and rimabotulinumtoxinB (Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these four agents are *not* identical, and have differing therapeutic and adverse event profiles. Further, units and dosing are not equivalent, so they are not directly interchangeable with one another. It is expected that physicians familiar with and experienced in the use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each beneficiary, condition, and use.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. <u>Medicaid</u>
None Apply.

b. <u>NCHC</u>
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service

requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://dma.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when 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 beneficiary'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 statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Botulinum Toxins Serotypes A OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), and IncobotulinumtoxinA (Xeomin); and Serotype B RimabotulinumtoxinB (Myobloc)

Medicaid and NCHC shall cover botulinum toxin treatment when:

a. There are no contraindications to botulinum toxin injection, such as infection at the proposed injection site.
b. There is no hypersensitivity to any ingredient in the formulation.
c. All indications approved by the Food and Drug Administration (FDA) are covered unless specified otherwise. In addition, off-label uses of an approved drug may be covered if the data on drug use are consistent with the compendia and peer-reviewed medical literature, according to 42 U.S.C. 1396r-8(g)(1)(B) or as determined by DMA. Refer to **Subsection 3.3 below.**
d. Medically necessary for the treatment of sialorrhea, as follows:
    1. There is documented disability from sialorrhea due to conditions such as motor neuron disease or Parkinson's disease; or
    2. There is documented failure to respond to a reasonable trial of traditional therapies (such as anticholinergics, speech therapy, or surgical therapy) or a contraindication to the traditional therapy.

3.2.2 Botulinum Toxins Serotype A - OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), and IncobotulinumtoxinA (Xeomin)

Severe Axillary Hyperhidrosis

Medicaid and NCHC shall cover botulinum toxin treatment as follows:

a. For the purposes of this policy, severe axillary hyperhidrosis is defined as a condition involving focal, visible, and severe sweating that has lasted for at least six (6) months, has no apparent cause, and has at least two (2) of the following characteristics:
    1. Sweating is bilateral and relatively symmetric;

2. Sweating impairs daily activity;
3. Episodes occur at least once per week;
4. The age of onset was under 25 years;
5. There is a positive family history; or
6. Focal sweating stops during sleep.

b. Treatment of severe axillary hyperhidrosis with one of the botulinum toxin serotype A products is considered medically reasonable and necessary only when both of the following criteria are met:

1. The beneficiary has documented medical complications due to hyperhidrosis, (skin maceration with secondary skin infections, significant disruption of quality of life); and
2. There is health record documentation that the beneficiary has either failed a 6-month trial of conservative management, consisting of the use of topical aluminum chloride or extra-strength antiperspirants, or unable to tolerate these agents.

3.3 Coverage of Botulinum Toxin Serotype A OnabotulinumtoxinA (Botox)

a. FDA-approved Indications

Medicaid and NCHC shall cover OnabotulinumtoxinA (Botox) for the following FDA-approved indications:

1. Treatment of spasticity in an adult (as defined in Policy 1B-1 as greater than 18 years of age) beneficiary.
2. Treatment of cervical dystonia in an adult beneficiary, to reduce the severity of abnormal head position and neck pain.
3. Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in an adult beneficiary.
4. Treatment of blepharospasm associated with dystonia in a beneficiary 12 years of age and older.
5. Treatment of strabismus in a beneficiary 12 years of age and older.
6. Refer to **Subsection 4.2.c** regarding coverage through the Outpatient Pharmacy Program for the treatment of headaches in adult beneficiaries with chronic migraine.
7. Refer to **Subsection 4.2.d** regarding coverage through the Outpatient Pharmacy Program for the treatment of urinary incontinence and over active bladder due to detrusor over activity or idiopathic detrusor over activity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

b. Off-Label Indications

Medicaid and NCHC shall cover OnabotulinumtoxinA (Botox) for the following off-label indications:

1. Chronic anal fissure refractory to conservative treatment;
2. Esophageal achalasia when surgical treatment is not indicated;
3. Spasticity (that is from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia,

quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, and stroke);

4. Infantile cerebral palsy, specified or unspecified, such as congenital diplegia; congenital hemiplegia; and quadriplegic, monoplegic, and infantile hemiplegia;
5. Hemifacial spasms;
6. Disorders of eye movement other than strabismus;
7. Achalasia and cardiospasm;
8. Secondary focal hyperhidrosis (Frey's syndrome);
9. Disturbance of salivary secretion (sialorrhea) (refer to **Subsection 3.2.1d** above).
10. Schilder's disease;
11. Idiopathic (primary or genetic) torsion dystonia;
12. Symptomatic (acquired) torsion dystonia; and
13. Laryngeal dystonia and adductor spasmodic dysphonia.

3.4 Coverage of Botulinum Toxin Serotype A AbobotulinumtoxinA (Dysport)

a. FDA-approved Indication

Medicaid and NCHC shall cover AbobotulinumtoxinA (Dysport) for the following FDA-approved indications:

1. Treatment of an adult (as defined in Policy 1B-1 as greater than 18 years of age) beneficiary with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated beneficiaries.
2. Treatment of upper limb spasticity in an adult beneficiary, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors.
3. Treatment of lower limb spasticity in pediatric patients two (2) years of age and older.

b. Off-label Indications

Medicaid and NCHC shall cover AbobotulinumtoxinA (Dysport) for the following off-label indications:

1. Chronic anal fissure refractory to conservative treatment.
2. Esophageal achalasia when surgical treatment is not indicated.
3. Spasticity (that is from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity in adults).
4. Infantile cerebral palsy, specified or unspecified, including congenital diplegia; congenital hemiplegia; and quadriplegic, monoplegic, and infantile hemiplegia.
5. Hemifacial spasms.
6. Strabismus and other disorders of eye movement.
7. Achalasia and cardiospasm.
8. Secondary focal hyperhidrosis (Frey's syndrome).
9. Disturbance of salivary secretion (sialorrhea) (refer to **Subsection 3.2.1.d** above).
10. Schilder's disease.
11. Idiopathic (primary or genetic) torsion dystonia.

12. Symptomatic (acquired) torsion dystonia.
13. Laryngeal dystonia and adductor spasmodic dysphonia.
14. Blepharospasm associated with dystonia in a beneficiary 12 years of age and older.
15. Treatment of severe axillary hyperhidrosis when there is documented failure to respond to a reasonable trial of traditional therapies (such as anticholinergics, speech therapy, or surgical therapy) or a contraindication to the traditional therapy.

3.5 Coverage of Botulinum Toxin Serotype A IncobotulinumtoxinA (Xeomin)

a. **FDA-approved Indications**

Medicaid and NCHC shall cover IncobotulinumtoxinA (Xeomin) for the following FDA-approved indications:

1. Treatment of an adult beneficiary with cervical dystonia, to decrease the severity of abnormal head position and neck paid in both botulinum toxin-naïve and a previously treated beneficiary.
2. Treatment of blepharospasm in adults (as defined in Policy 1B-1 as greater than 18 years of age) previously treated with onabotulinumtoxinA (Botox).
3. Treatment of upper limb spasticity in an adult beneficiary.

b. **Off-label Indications**

Medicaid and NCHC shall cover IncobotulinumtoxinA (Xeomin) for the following off-label indications:

1. Chronic anal fissure refractory to conservative treatment.
2. Esophageal achalasia when surgical treatment is not indicated.
3. Spasticity (that is, from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity in adults (as defined in Policy 1B-1 as greater than 18 years of age).
4. Infantile cerebral palsy, specified or unspecified, including congenital diplegia; congenital hemiplegia; and quadriplegic, monoplegic, and infantile hemiplegia.
5. Hemifacial spasms.
6. Strabismus and other disorders of eye movement.
7. Achalasia and cardiospasm.
8. Secondary focal hyperhidrosis (Frey's syndrome).
9. Disturbance of salivary secretion (sialorrhea) (refer to **Subsection 3.2.1.d** above).
10. Schilder's disease.
11. Idiopathic (primary or genetic) torsion dystonia.
12. Symptomatic (acquired) torsion dystonia.
13. Laryngeal dystonia and adductor spasmodic dysphonia.
14. Treatment of severe axillary hyperhidrosis when there is documented failure to respond to a reasonable trial of traditional therapies (such as anticholinergics, speech therapy, or surgical therapy) or a contraindication to the traditional therapy.

3.6 Coverage of Botulinum Toxin Serotype B RimabotulinumtoxinB (Myobloc)

a. FDA-approved Indication

Medicaid and NCHC shall cover RimabotulinumtoxinB (Myobloc) for the following FDA-approved indication:

Treatment of adults (as defined in Policy 1B-1 as greater than 18 years of age) with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

1. The beneficiary's health record must document findings consistent with spasmodic torticollis.
2. The choice of selecting a botulinum toxin serotype A product or serotype B product as the preferred initial agent for cervical dystonia treatment is based on the clinical judgment of the managing provider.

b. Off-label Indication

Medicaid and NCHC shall cover RimabotulinumtoxinB (Myobloc) for the following off-label indication:

Treatment of sialorrhea as detailed in **Subsection 3.2.1.d** above.

3.7 Electrical Stimulation or Electromyography Guidance for Chemodenervation

Medicaid and NCHC shall cover Electrical Stimulation or Electromyography when it is medically necessary to determine the proper injection site(s). Refer to **Attachment A** for billing information.

3.7.1 Medicaid Additional Criteria Covered

None Apply.

3.7.2 NCHC Additional Criteria Covered

None Apply.

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

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

a. Botulinum toxin serotype A or serotype B to treat disorders or conditions other than those listed in **Section 3.0;**

b. Any botulinum toxin treatment of other spastic conditions not listed in **Section 3.0:** treatment of smooth muscle spasm, anal spasm, irritable colon, or biliary dyskinesia is considered to be investigational, unsafe, and ineffective or is considered to be cosmetic; and is not accepted as the standard of practice within the medical community; and

c. Treatment of craniofacial wrinkles

d. Treatment of headaches is covered through the Outpatient Pharmacy Program only and only by prior approval. Coverage criteria and prior approval request forms can be found at http://www.nctracks.nc.gov.

e. Treatment of urinary incontinence and overactive bladder due to detrusor over activity or idiopathic detrusor over activity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication is covered through the Outpatient Pharmacy Program only and only by prior approval. Coverage criteria and prior approval request forms can be found at http://www.nctracks.nc.gov

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
   1. No services for long-term care.
   2. No nonemergency medical transportation.
   3. No EPSDT.
   4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for Botulinum Toxin Treatment.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.3 FDA Guidelines for Administration of Botulinum Toxins

Before considering botulinum toxin treatment, it should be established that the beneficiary has been unresponsive to conventional methods of treatments such as medication, physical therapy, and other appropriate methods used to control or treat spastic conditions.

The beneficiary who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin. Other spastic or muscular contraction conditions, such as eye muscle disorders (such as blepharospasm) may require lesser amounts of botulinum toxin. For larger muscle groups, it is generally agreed that once a maximum dosage per site has been reached and there is no response, the treatment is discontinued. With response, the effect of the injections generally lasts for three (3) months, at which time the beneficiary may need repeat injections to control the spastic or excessive muscular condition. It is usually considered not medically necessary to give botulinum toxin injections for spastic or excess muscular contraction conditions more frequently than every 90 days, unless acceptable justification is documented for more frequent use in the initial therapy.

Treatments may be continued unless any two (2) treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin, failed to produce satisfactory clinical response. Providers shall also document the response to these injections after every third session.

5.3.1 Limitations for OnabotulinumtoxinA (Botox)

The cumulative dosage must not exceed 600 units in 90 days.

5.3.2 Limitations for AbobotulinumtoxinA (Dysport)

The cumulative dosage must not exceed 1000 units in 12 weeks (84 days).

5.3.3 Limitations for IncobotulinumtoxinA (Xeomin)

The cumulative dosage must not exceed 600 units in 12 weeks (84 days).

5.3.4 Limitations for RimabotulinumtoxinB (Myobloc)

The cumulative dosage must not exceed 10,000 units in 12 weeks (84 days).

5.4 Unit Limitations

Medicaid and NCHC covers one injection of botulinum toxins serotype A or serotype B for each site, regardless of the number of injections made into the site. A site is defined as the muscles of a single contiguous body part (a single limb, eyelid, face, neck).

5.5 Limitations on Coverage

Note: Providers who determine that the indications or dosing for a particular drug is medically necessary for a beneficiary, but those parameters fall outside of the guidelines for that drug, may submit health record information to the DMA Assistant Director for Clinical Policy and Programs for a case-by-case review. The address and fax number to send this information is:

Pharmacy Manager of Clinical Policy and Programs
Division of Medical Assistance
2501 Mail Service Center

Raleigh, NC 27699-2501
Fax (919)715-1255

5.6 Health Record Documentation

Documentation in the beneficiary's health record must contain ALL of the following elements:

a. Support for the medical necessity of the botulinum toxin injection;
b. A covered diagnosis;
c. A statement that traditional methods of treatments have been unsuccessful;
d. Dosage and frequency of the injections;
e. Support for the medical necessity of electrical stimulation or electromyography procedures, if used;
f. Support of the clinical effectiveness of the injections; and
g. Specific site(s) injected.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All DMA's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: April 1, 1991

Revision Information:

Date	Section Revised	Change
03/01/2007	Throughout policy	Coverage criteria and diagnoses for botulinum toxin type A (Botox) were clarified.
03/01/2007	Throughout policy	Coverage of botulinum toxin type B (Myobloc) was implemented as a covered treatment when provided in accordance with the criteria and guidelines in the policy.
05/01/2007	Sections 2 through 5	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age
11/01/2008	Section 1.1	Added section about safety and compliance.
11/01/2008	Section 2.2	Added citation for EPSDT information.
11/01/2008	Throughout	Updated standard language to match revised policy template; revised general English usage for greater clarity.
11/01/2008	Section 3.2	Separated the specific requirements (no contraindications, no hypersensitivity) from the general criteria for coverage; renumbered subsequent sections.
11/01/2008	Section 3.3	Added a paragraph deferring to clinical judgment; added the diagnoses of quadriplegia, Schilder's disease, and sialorrhea; moved Congenital diplegia—Infantile hemiplegia to be included in infantile cerebral palsy and added detail in that line.
11/01/2008	Sections 3.3.1 and 3.3.2	Assigned subheadings for primary axillary hyperhidrosis and sialorrhea (3.3.1 and 3.3.2, respectively).
11/01/2008	Section 3.4.1	Added heading for spasmodic torticollis and cervical dystonia; combined two sentences into one.
11/01/2008	Section 3.4.2	Added the diagnosis of sialorrhea.
11/01/2008	Section 4.2	Moved restriction on type B to introductory sentence of Specific Criteria; removed sialorrhea from the non-covered list (Specific Criteria will become Section 4.2 if this is approved).
11/01/2008	Section 7.0	Added heading (now 7.2) for medical record documentation; added standard sections on federal & state requirements and records retention.
11/01/2008	Attachment A	Added additional diagnosis and procedure codes for quadriplegia, Schilder's disease, sialorrhea, spasticity, and infantile cerebral palsy; added or updated code descriptions per 2008 guides; added CPT code 46505; added table headings; revised billing guidelines; deleted some CPT procedure codes for electromyography (92265, 95860, 95861, 95867, 95868, 95869, 95870).

Date	Section Revised	Change
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
03/12/2012	Throughout	"NC Health Choice Program Clinical Coverage Policy revised to be equivalent to NC Medicaid Program Clinical Coverage Policy 1B-1 pursuant to SL2011-145, Section 10.41.(b)."
09/01/2012	Throughout	Changed "recipient" to "beneficiary"
09/01/2012	Sections 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0	Updated standard DMA policy language.
09/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
09/01/2012	Section 1.0, Subsections 3.4.1, 5.1.2, and 5.1.3	Added coverage for Dysport and Xeomin to policy.
09/01/2012	Attachment A	Added CPT code 64611 for sialorrhea per CPT update 2010. Added CPT codes 43201, 64600 and 64653. Deleted code 64640. Added diagnoses spinal cord or traumatic brain injury; idiopathic (primary or genetic) torsion dystonia; symptomatic (acquired) torsion dystonia; adductor spasmodic dysphonia; subacute dyskinesia due to drugs; trigeminal nerve disorder; spasticity related to CVA.
08/15/2014	Section 3.3 a, Sections 4.2 c and d	Added diagnosis of over active bladder as not covered by this policy, but covered in the outpatient pharmacy program
08/15/2014	All Sections and Attachments	Reviewed policy grammar, readability, typographical accuracy, and format. Policy amended as needed to correct, without affecting coverage.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
12/01/2015	Section 3.3 a, Sections 4.2 c and d	Amendments made to these subsections, left out during the ICD-10 transition, were returned to the policy.
11/01/2017	All Sections and Attachments	Added indications to Section 3.3 – 3.6, and added/deleted ICD-10 codes to Attachment A to comply with federally mandated implementation.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10-CM Code(s)			
a. Botulinum Toxin Serotype A (Botox, Dysport, or Xeomin)			
G04.1	H49.9	I69.242	S14.0
G11.4	H50.00	I69.243	S14.101
G24.01	H50.011	I69.244	S14.102
G24.02	H50.012	I69.249	S14.103
G24.09	H50.021	I69.331	S14.104
G24.1	H50.022	I69.332	S14.105
G24.2	H50.031	I69.333	S14.106
G24.3	H50.032	I69.334	S14.107
G24.4	H50.041	I69.339	S14.108
G24.5	H50.042	I69.341	S14.109
G24.8	H50.05	I69.342	S14.111
G24.9	H50.06	I69.343	S14.112
G35	H50.07	I69.344	S14.113
G36.0	H50.08	I69.349	S14.114
G36.1	H50.10	I69.831	S14.115
G36.8	H50.111	I69.832	S14.116
G36.9	H50.112	I69.833	S14.117
G37.0	H50.121	I69.834	S14.118
G37.1	H50.122	I69.839	S14.119
G37.2	H50.131	I69.841	S14.121
G37.3	H50.132	I69.842	S14.122
G37.4	H50.141	I69.843	S14.123
G37.5	H50.142	I69.844	S14.124
G37.8	H50.15	I69.849	S14.125
G37.9	H50.16	I69.931	S14.126
G51.2	H50.17	I69.932	S14.127
G51.3	H50.18	I69.933	S14.128

G51.4	H50.21	I69.934	S14.129
G51.8	H50.22	I69.939	S14.131
G51.9	H50.30	I69.941	S14.132
G80.0	H50.311	I69.942	S14.133
G80.1	H50.312	I69.943	S14.134
G80.2	H50.32	I69.944	S14.135
G80.3	H50.331	I69.949	S14.136
G80.4	H50.332	J38.00	S14.137
G80.8	H50.34	J38.01	S14.138
G80.9	H50.40	J38.02	S14.139
G81.10	H50.411	J38.5	S14.141
G81.11	H50.412	K11.0	S14.142
G81.12	H50.42	K11.1	S14.143
G81.13	H50.43	K11.20	S14.144
G81.14	H50.50	K11.21	S14.145
G82.20	H50.51	K11.22	S14.146
G82.21	H50.52	K11.23	S14.147
G82.22	H50.53	K11.7	S14.148
G82.50	H50.54	K11.8	S14.149
G82.51	H50.55	K11.9	S14.151
G82.52	H50.60	K22.0	S14.152
G82.53	H50.611	K22.4	S14.153
G82.54	H50.612	K60.0	S14.154
G83.0	H50.69	K60.1	S14.155
G83.10	H50.811	K60.2	S14.156
G83.11	H50.812	L74.510	S14.157
G83.12	H50.89	L74.511	S14.158
G83.13	H50.9	L74.512	S14.159
G83.14	H51.0	L74.513	S24.0
G83.20	H51.11	L74.519	S24.101
G83.21	H51.12	L74.52	S24.102
G83.22	H51.20	M43.6	S24.103
G83.23	H51.21	M62.831	S24.104
G83.24	H51.22	M62.838	S24.109
G83.30	H51.23	Q39.5	S24.111
G83.31	H51.8	R25.2	S24.112
G83.32	H51.9	R25.3	S24.113
G83.33	I69.031	R49.0	S24.114
G83.34	I69.032	S06.2X0	S24.119
G83.81	I69.033	S06.2X1	S24.131
G96.8	I69.034	S06.2X2	S24.132
H49.00	I69.039	S06.2X3	S24.133
H49.01	I69.041	S06.2X4	S24.134
H49.02	I69.042	S06.2X5	S24.139
H49.03	I69.043	S06.2X6	S24.141
H49.10	I69.044	S06.2X7	S24.142
H49.11	I69.049	S06.2X8	S24.143
H49.12	I69.131	S06.2X9	S24.144

H49.13	I69.132	S06.300	S24.149
H49.20	I69.133	S06.301	S24.151
H49.21	I69.134	S06.302	S24.152
H49.22	I69.139	S06.303	S24.153
H49.23	I69.141	S06.304	S24.154
H49.30	I69.142	S06.305	S24.159
H49.31	I69.143	S06.306	S34.01
H49.32	I69.144	S06.307	S34.02
H49.33	I69.149	S06.308	S34.101
H49.40	I69.231	S06.309	S34.102
H49.41	I69.232	S06.9X0	S34.103
H49.42	I69.233	S06.9X1	S34.104
H49.43	I69.234	S06.9X2	S34.105
H49.881	I69.239	S06.9X3	S34.109
H49.882	I69.241	S06.9X4	S34.111
H49.883		S06.9X5	S34.112
H49.889		S06.9X6	S34.113
		S06.9X7	S34.114
		S06.9X8	S34.115
		S06.9X9	S34.119
			S34.121
			S34.122
			S34.123
			S34.124
			S34.125
			S34.129
			S34.131
			S34.132
			S34.139
			S34.3

ICD-10-CM Code(s)			
b. Botulinum Toxin Serotype B (Myobloc)			
G24.3	K11.20	K11.23	K11.9
K11.0	K11.21	K11.7	
K11.1	K11.22	K11.8	

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

a. HCPCS Procedure Codes

HCPCS Code(s)
J0585
J0586
J0587
J0588

b. CPT Codes for Botulinum Toxin Serotype A (Botox, Dysport, or Xeomin)

CPT Code(s)
31513
31570
31571
43201
46505
64611
64612
64616
64617
64640
64642
64643
64644
64645
64650
67345

c. CPT Codes for Botulinum Toxin Serotype B (Myobloc)

CPT Code(s)
64612
64613
64616

Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Coding Guidelines

Botulinum Toxin Serotype A (Botox, Dysport, or Xeomin)
For services rendered starting October 1, 2015, the following CPT procedure codes are to be reported with the respective listed covered ICD-10-CM diagnosis codes when billing for botulinum toxin serotype A (Botox, Dysport or Xeomin):

CPT Code(s)	ICD-10-CM Code(s)		
31513	J38.00 J38.01	J38.02 J38.5	R49.0
31570	J38.00 J38.01	J38.02 J38.5	R49.0
31571	J38.00 J38.01	J38.02 J38.5	R49.0
43201	K22.0 K22.4	Q39.5 Q40.0	
46505	K60.0	K60.1	K60.2
64611	K11.0 K11.1	K11.20 K11.21 K11.22 K11.23	K11.7 K11.8 K11.9
64612	G24.01 G24.4 G24.5 G51.2	G51.3 G51.4 G51.8 G51.9	G81.10 G81.11 G81.13 G81.14
64616	G24.01 G24.02 G24.09 G24.1 G24.2	G24.3 G24.8 G24.9 G80.3	J38.01 J38.5 M43.6 R49.0
64617	J38.01	J38.02	J38.5

64642 or 64644 (use 64643 or 64645 if needed)	G04.1	I69.333	S14.123
	G11.4	I69.334	S14.124
	G35	I69.339	S14.125
	G36.0	I69.341	S14.126
	G36.1	I69.342	S14.127
	G36.8	I69.343	S14.128
	G36.9	I69.344	S14.129
	G37.0	I69.349	S14.131
	G37.1	I69.831	S14.132
	G37.2	I69.832	S14.133
	G37.3	I69.833	S14.134
	G37.4	I69.834	S14.135
	G37.5	I69.839	S14.136
	G37.8	I69.841	S14.137
	G37.9	I69.842	S14.138
	G80.0	I69.843	S14.139
	G80.1	I69.844	S14.141
	G80.2	I69.849	S14.142
	G80.3	I69.931	S14.143
	G80.4	I69.932	S14.144
	G80.8	I69.933	S14.145
	G80.9	I69.934	S14.146
	G81.11	I69.939	S14.147
	G81.12	I69.941	S14.148
	G81.13	I69.942	S14.149
	G81.14	I69.943	S14.151
	G82.20	I69.944	S14.152
	G82.21	I69.949	S14.153
	G82.22	M62.831	S14.154
	G82.50	M62.838	S14.155
	G82.51	R25.2	S14.156
	G82.52	R25.3	S14.157
	G82.53	S06.2X0	S14.158
	G82.54	S06.2X1	S14.159
	G83.0	S06.2X2	S24.0
	G83.10	S06.2X3	S24.101
	G83.11	S06.2X4	S24.102
	G83.12	S06.2X5	S24.103
	G83.13	S06.2X6	S24.104
	G83.14	S06.2X7	S24.109
	G83.20	S06.2X8	S24.111
	G83.21	S06.2X9	S24.112
	G83.22	S06.300	S24.113
	G83.23	S06.301	S24.114
	G83.24	S06.302	S24.119
	G83.30	S06.303	S24.131
	G83.31	S06.304	S24.132

	G83.32	S06.305	S24.133
	G83.33	S06.306	S24.134
	G83.34	S06.307	S24.139
	G83.81	S06.308	S24.141
	G96.8	S06.309	S24.142
	I69.031	S06.9X0	S24.143
	I69.032	S06.9X1	S24.144
	I69.033	S06.9X2	S24.149
	I69.034	S06.9X3	S24.151
	I69.039	S06.9X4	S24.152
	I69.041	S06.9X5	S24.153
	I69.042	S06.9X6	S24.154
	I69.043	S06.9X7	S24.159
	I69.044	S06.9X8	S34.01
	I69.049	S06.9X9	S34.02
	I69.131	S14.0	S34.101
	I69.132	S14.101	S34.102
	I69.133	S14.102	S34.103
	I69.134	S14.103	S34.104
	I69.139	S14.104	S34.105
	I69.141	S14.105	S34.109
	I69.142	S14.106	S34.111
	I69.143	S14.107	S34.112
	I69.144	S14.108	S34.113
	I69.149	S14.109	S34.114
	I69.231	S14.111	S34.115
	I69.232	S14.112	S34.119
	I69.233	S14.113	S34.121
	I69.234	S14.114	S34.122
	I69.239	S14.115	S34.123
	I69.241	S14.116	S34.124
	I69.242	S14.117	S34.125
	I69.243	S14.118	S34.129
	I69.244	S14.119	S34.131
	I69.249	S14.121	S34.132
	I69.331	S14.122	S34.139
	I69.332		S34.3
64650	L74.510	L74.512	L74.519
	L74.511	L74.513	L74.52
67345	H49.00	H50.031	H50.40
	H49.01	H50.032	H50.411
	H49.02	H50.041	H50.412
	H49.03	H50.042	H50.42
	H49.10	H50.05	H50.43
	H49.11	H50.06	H50.50
	H49.12	H50.07	H50.51
	H49.13	H50.08	H50.52
	H49.20	H50.10	H50.53

	H49.21	H50.111	H50.54
	H49.22	H50.112	H50.55
	H49.23	H50.121	H50.60
	H49.30	H50.122	H50.611
	H49.31	H50.131	H50.612
	H49.32	H50.132	H50.69
	H49.33	H50.141	H50.811
	H49.40	H50.142	H50.812
	H49.41	H50.15	H50.89
	H49.42	H50.16	H50.9
	H49.43	H50.17	H51.0
	H49.881	H50.18	H51.11
	H49.882	H50.21	H51.12
	H49.883	H50.22	H51.20
	H49.889	H50.30	H51.21
	H49.9	H50.311	H51.22
	H50.00	H50.312	H51.23
	H50.011	H50.32	H51.8
	H50.012	H50.331	H51.9
	H50.021	H50.332	
	H50.022	H50.34	

Botulinum Toxin Serotype B (Myobloc)

The following procedure codes are to be reported with the corresponding ICD-10-CM diagnosis codes when billing for botulinum toxin serotype B (Myobloc).

Code(s)	
CPT Code(s)	**ICD-10-CM Code(s)**
64611	K11.0 K11.1 K11.20 K11.21 K11.22 K11.23 K11.7 K11.8 K11.9
64616	G24.3

Electrical Stimulation or Electromyography Guidance for Chemodenervation

Only one electrical stimulation or electromyography code may be reported for each injection site. The following procedure codes for electrical stimulation or EMG guidance may be billed if appropriate. (List separately in addition to a code for a primary procedure).

CPT Code(s)
95873
95874

E. Modifiers

Provider(s) shall follow applicable modifier guidelines.

F. Billing Units

Provider(s) shall report the appropriate procedure code(s) used which determines the billing unit(s).

1. Injection, onabotulinumtoxinA (Botox, J0585): 1 billing unit = 1 unit
2. Injection, abobotulinumtoxinA (Dysport, J0586) for dates of service 04/01/2011 forward: 1 billing unit = 5 units
3. Injection, incobotulinumtoxinA (Xeomin, Q2040): for dates of service 04/01/2011 through 12/31/2011: 1 billing unit = 1 unit
4. Injection, incobotulinumtoxinA (Xeomin, J0588): for dates of service 01/01/2012 forward = 1 unit
4. Injection, rimabotulinumtoxinB (Myobloc, J0587): 1 billing unit = 100 units
5. Medicaid covers an administration fee when billed with the injection (J0585, J0586, J0587, or J0588) on the same day of service with the J0585, J0586, J0587, or J0588 code.

Note: An administration fee is not covered on the same day of service as an evaluation and management code for beneficiaries ages 21 and over.

G. Place of Service

Office

H. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at https://dma.ncdhhs.gov/.
For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

I. Reimbursement

Refer to Clinical Coverage Policy 1B, *Physician's Drug Program,* for detailed billing guidelines regarding the Physician's Drug Program.

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, see: https://dma.ncdhhs.gov/