

**NC Medicaid Outpatient Pharmacy
Prior Approval Criteria Neuromuscular
Blocking Agents**

Medicaid and Health Choice

**Effective Date: March 4, 2002
Amended Date: October 1, 2021**

DRAFT

Therapeutic Class Code: S7A

Therapeutic Class Description: Neuromuscular Blocking Agents

Medication
Botox (onabotulinumtoxin A)
Myobloc (rimabotulinumtoxin B)
Dysport (abobotulinumtoxin A)
Xeomin (incobotulinumtoxin A)

Eligible Recipients

Medicaid recipients must be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

~~NCHC recipients, ages 6 through 18 years of age, must be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.~~

EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- that is unsafe, ineffective, or experimental/investigational.
- 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/or 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

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correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing Guide:

<http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page:<https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

~~Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Recipients ages 6 through 18 years of age~~

~~EPSDT does not apply to NCHC recipients.~~ If a NCHC recipient does not meet the clinical coverage criteria within the **~~Outpatient Pharmacy prior approval~~** clinical coverage criteria, the NCHC recipient will be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes will be covered for NCHC recipients.

Criteria:

Onabotulinumtoxin A (Botox):

Onabotulinumtoxin A (Botox) shall be covered as follows:

FDA-Indications:

- Blepharospasm
 - Disorders of eye movement (strabismus)
 - Spasmodic Torticollis, secondary to cervical dystonia
 - Treatment of spasticity in patients aged 2 and older
 - Chronic Migraine (Botox ONLY) age 18 and older:
 - 15 or more days each month with headache lasting 4 or more hours
- and
- tried and failed prophylactic medications from at least 3 different drug classes (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants) each for at least 3 months of therapy; or

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- has a documented contraindication, intolerable side effects, or allergy to prophylactic medications (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants)
- and
- Initial approval will be for 6 months
- For continuation of therapy:
 - assessment of response should be noted after the first 2 injections (6 months)
 - average number of headache days decreased by 6 or more days per month from the patient's baseline headache frequency
- Overactive Bladder:
 - Tried and failed two anticholinergic medications or
 - has a documented contraindication, intolerable side effects, or allergy to anticholinergic medications
- Urinary Incontinence:
 - due to detrusor overactivity (idiopathic or associated with neurologic conditions)
 - and
 - tried and failed two anticholinergic medications or
 - has a documented contraindication, intolerable side effects, or allergy to anticholinergic medications
- Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients. All of the following criteria must be met:
 - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
 - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant

Off-Label Indications:

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Infantile cerebral palsy, specified or unspecified
- Hemifacial spasms
- Laryngeal dystonia and adductor spasmodic dysphonia

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Abobotulinumtoxin A (Dysport):

Abobotulinumtoxin A (Dysport) shall be covered for the following conditions:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia
- Upper limb spasticity in adults and pediatric patients 2 years of age and older.
- ~~• Upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy~~
- Lower limb spasticity in adults and pediatric patients 2 years of age and older
- Off-label indications:
 - Blepharospasm
 - Hemifacial spasms
 - Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patientsAll of the following criteria must be met:
 - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
 - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant

Incobotulinumtoxin A (Xeomin):

Incobotulinumtoxin A (Xeomin) shall be covered as follows:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia
- Blepharospasm
- Upper limb spasticity in adult
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Chronic Sialorrhea in in patients 2 years of age and older

Rimabotulinumtoxin B (Myobloc)

Rimabotulinumtoxin B (Myobloc) shall be covered for the following conditions:

FDA indications:

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- Spasmodic Torticollis, secondary to cervical dystonia
- Chronic Sialorrhea in adults

There are several botulinum toxins, currently A through G. Only A and B are now FDA-approved and commercially available. This policy deals *only* with onabotulinumtoxin A (Botox), abobotulinumtoxin A (Dysport), incobotulinumtoxin A (Xeomin) and rimabotulinumtoxin B-(Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these agents are *not* identical, and have differing therapeutic and adverse event profiles. Furthermore, 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 use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each recipient, condition, and use.

Procedures:

- 1) Not approved for cosmetic purposes
- 2) Approval length up to 12 months
- 3) Dosage limitations for onabotulinumtoxin A (Botox): the cumulative dosage should not exceed 600 units per 90 days.
- 4) Dosage limitations for rimabotulinumtoxin B (Myobloc): 10,000 units per 12 weeks (84 days).
- 5) Dosage limitations for abobotulinumtoxin A (Dysport): 1500 units per 12 weeks (84 days)
- 6) Dosage limitations for incobotulinumtoxin A (Xeomin): 500 Units per 12 weeks (84 days)

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References:

1. Lim M, Mace A, Nouraei SA, Sandhu G Botulinum toxin in the management of sialorrhea: a systemic review. *Clinical Otolaryngol.* 2006 Aug; 31(4) 267-72
2. Allergan Pharmaceuticals, Inc. Botox package insert. Irvine (CA); Revised September 2013
3. Solstice Neurosciences, Inc. Myobloc package insert. South San Francisco (CA); Revised November 2004.
4. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 1. *Am J Health-Syst Pharm.* 2005; 63(2):145-152. Accessed through <http://www.medscape.com> on February 6, 2006.
5. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 2. *Am J Health-Syst Pharm.* 2006; 63(3):225-232. Accessed through <http://www.medscape.com> on March 8, 2006.
6. Sycha T, Kranz G, Auff E, Schnider P. Botulinum toxin in the treatment of rare head and neck pain syndromes: a systematic review of the literature. *J Neurol* (2004) 251 [Suppl 1]; I/19-I/30.
7. Wasiak J, Hoare B, Wallen M. Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy. *The Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD003469.pub3. DOI: 10.1002/14651858.CD003469.pub3.
8. North Carolina State Health Plan. Clostridium Botulinum Neurotoxins. Medco Health Solutions, April 2005.
9. Ipsen Biopharm Ltd., Dysport package insert. Wrexham, LL13, 9UF, UK and Brisbane, CA; May 2009.
10. Merz Group Services GmbH; Xeomin package insert. Dessau-Rosslau, Germany and Greensboro, NC; 2010.
11. Cephalalgia. 2010 Jul; 30 (7): 793-803 and 804-814. Epub 2010 Mar 17.
12. Nitti VW, Dmochowski R, Herschorn S, et al. OnabotulinumtoxinA for the treatment of patients with overactive bladder and urinary incontinence: results of a phase 3, randomized, placebo controlled trial. *J Urol.* 2013;189:2186-93.
13. Botox Prescribing Information. Allergan Inc., Irvine, CA 92612. Updated January 2016, June 2019, October 2019. Updated February 2021.
14. Ipsen Biopharm Ltd., Dysport package insert. Wrexham, LL13, 9UF, UK and Brisbane, CA; July 2016. Updated September 2019. **updated January 2023.**
15. Merz Group Services GmbH; Xeomin package insert. Dessau-Rosslau, Germany and Greensboro, NC; 12/2015. Updated December 2020.

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16. MYOBLOC® US Prescribing Information. Solstice Neurosciences, LLC; Louisville, KY: August 2019.

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Criteria Change Log	
03/04/2002	Criteria effective date
03/26/2007	<p>Addition: Botulinum Toxin Type A (Botox): Medicaid covers botulinum toxin type A (Botox) for the following conditions:</p> <ul style="list-style-type: none"> • Chronic anal fissure refractory to conservative treatment • Esophageal achalasia patients in whom surgical treatment is not indicated\ • Blepharospasm • Spasmodic Torticollis, secondary to cervical dystonia • Hereditary spastic paraplegia • Multiple Sclerosis for patients with spasticity • Neuromyelitis Optica for patients with spasticity secondary to spinal cord involvement • Other Demyelinating diseases of central nervous system with secondary spasticity • Spastic hemiplegia and hemiparesis affecting dominant side • Spastic hemiplegia and hemiparesis affecting non-dominant side • Congenital Diplegia – Infantile hemiplegia • Infantile cerebral palsy, specified or unspecified • Disorders of eye movement (strabismus) • Laryngeal spasm • Achalasia and cardiospasm • Gustatory hyperhidrosis (Frey's syndrome) • Hemifacial spasms • Primary focal hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met: <ul style="list-style-type: none"> ○ The patient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and ○ Documentation that the patient

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	<p>has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant</p> <p>Botulinum Toxin Type B (Myobloc):</p> <p>Medicaid covers botulinum toxin type B (Myobloc) for the following condition:</p> <p>1. Spasmodic Torticollis, secondary to cervical dystonia</p> <p>3) Dosage Limitations for Botulinum Toxin Type A (Botox): the cumulative dosage should not exceed 600 units per 90 days.</p> <p>4) Dosage Limitations for Botulinum Toxin Type B (Myobloc): 10,000 units per 12 weeks (three months).</p>
03/26/2007	Deletion: 1) Patient must have a diagnosis of strabismus or blepharospasm associated with dystonia in patients 12 years or older OR 2) Cervical Dystonia
02/1/2008	Added EPSDT Provision
11/03/2008	Added coverage for Sialorrhea
11/07/2008	Added that Exemption Forms will not be accepted for these drugs.
05/01/2012	Added Dysport and Xeomin coverage criteria, generic names for all 4 toxins, coverage for upper limb spasticity in adults, coverage for chronic migraine, coverage for urinary incontinence, changed primary focal hyperhidrosis to severe axillary hyperhidrosis, updated off label uses
08/15/2014	Added coverage under Botox for overactive bladder
04/06/2017	<p>Added coverage under Botox for lower limb spasticity in adults</p> <p>Added coverage under Dysport- upper limb spasticity in adults, lower limb spasticity in pediatrics age 2 and older</p> <p>Added coverage under Xeomin for upper limb spasticity in adults</p>
03/21/2019	Change Dysport max dose to 1500u every 12 weeks

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10/01/2021	<p>Botox: Overactive Bladder and Urinary Incontinence change from one to two anticholinergics tried first</p> <p>Botox: Upper limb spasticity add indication for pediatric patients age 2 and older</p> <p>Botox: Add lower limb spasticity in pediatric patients age 2 and older, excluding spasticity caused by cerebral palsy</p> <p>Dysport: Add upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy</p> <p>Dysport: Add lower limb spasticity in adults</p> <p>Xeomin and Myobloc: Add chronic sialorrhea in adults</p> <p>Myobloc: Sialorrhea moved to on label use</p> <p>Remove off label uses not listed in compendia:</p> <p>Botox</p> <ul style="list-style-type: none"> • Chronic anal fissure refractory to conservative treatment, Schilder's disease • Congenital Diplegia – Infantile hemiplegia, Achalasia and cardiospasm • Secondary focal hyperhydrosis (Frey's syndrome), Idiopathic (primary or genetic) torsion dystonia • Symptomatic (acquired) torsion dystonia <p>Dysport</p> <ul style="list-style-type: none"> • Sialorrhea • Chronic anal fissure refractory to conservative treatment • Esophageal achalasia recipients in whom surgical treatment is not indicated • Spasticity (e.g., 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) • Schilder's disease • Congenital Diplegia – Infantile hemiplegia • Infantile cerebral palsy, specified or unspecified
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- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhidrosis (Frey's syndrome)
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Xeomin

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Spasticity (e.g., 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)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhidrosis (Frey's syndrome)
- Hemifacial spasms
- Severe axillary hyperhidrosis due to axillary hyperhidrosis.
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
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10/01/2021	<ul style="list-style-type: none">• Added Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy for Xeomin• Changed age for chronic siallorhea to age 2 & older for Xeomin
xx/xx/xxxx	<ul style="list-style-type: none">• Removed cerebral palsy as non covered for Dysport