

## Clinical Policy: OnabotulinumtoxinA (Botox)

Reference Number: CP.PHAR.232

Effective Date: 07/16

Last Review Date: 05/16

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene<sup>®</sup> clinical policy for onabotulinumtoxinA (Botox<sup>®</sup>).

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Botox is **medically necessary** when one of the following criteria are met:

### Contents

Description .....	1
Policy/Criteria .....	1
I. Initial Approval Criteria.....	2
A. Overactive Bladder or Urinary Incontinence (must meet all):.....	2
B. Chronic Migraines (must meet all):.....	2
C. Cervical Dystonia or Limb Spasticity (must meet all):.....	3
D. Primary Axillary Hyperhidrosis (must meet all):.....	3
E. Blepharospasm or Strabismus (must meet all): .....	4
F. Chronic Anal Fissures – Off Label Use (must meet all):.....	4
G. Cerebral Palsy – Off Label Use (must meet all): .....	4
H. Dystonias – Off Label Use (must meet all):.....	5
I. Esophageal Achalasia – Off Label Use (must meet all): .....	5
J. Laryngeal Spasm or Spasmodic Dysphonia – Off Label Use (must meet all):.....	5
K. Hirschsprung’s Disease – Off Label Use (must meet all):.....	6
L. Spastic Conditions – Off Label Use (must meet all):.....	6
M. Other diagnoses/indications: .....	6
II. Continued Approval.....	6
A. Overactive Bladder, Urinary Incontinence, Cervical Dystonia, Limb Spasticity, Primary Axillary Hyperhidrosis, Blepharospasm, Strabismus, Chronic Anal Fissures, Cerebral Palsy, Dystonias, Laryngeal Spasm, Hirschsprung’s Disease, or Spastic Conditions (must meet all):.....	6
B. Chronic Migraine (must meet all): .....	7
C. Esophageal Achalasia (must meet all): .....	7

D. Other diagnoses/indications (must meet either 1 or 2): .....	8
Background .....	8
References .....	10

**I. Initial Approval Criteria**

**A. Overactive Bladder or Urinary Incontinence (must meet all):**

1. Prescribed by or in consultation with a neurologist or urologist;
2. Age  $\geq$  18 years;
3. Diagnosis of one of the following:
  - a. Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency;
  - b. Urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis);
4. Botox will be administered as an intradetrusor injection;
5. Prescribed dose of Botox does not exceed:
  - a. 100 units for overactive bladder; or
  - b. 200 units for incontinence due to detrusor over activity associated with a neurologic condition;
6. Member has tried and failed behavioral therapy (e.g., bladder training, pelvic floor muscle training, and fluid management) for at least 8 weeks;
7. Member has tried and failed, or is intolerant or contraindicated to, at least 2 anticholinergic or oral beta-3 agonist medications (e.g., oxybutynin chloride, tolterodine tartrate; mirabegron) at the maximum tolerated dose for at least 30 days;
8. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s);
  - c. Urinary tract infection or urinary retention.

**Approval duration: 12 weeks (single treatment session)**

**B. Chronic Migraines (must meet all):**

1. Prescribed by or in consultation with a neurologist;
2. Age  $\geq$  18 years;
3. Diagnosis of chronic migraine ( $\geq$  15 days per month with headache lasting 4 hours a day or longer);
4. Botox will be administered as an intramuscular injection;
5. Prescribed dose of Botox does not exceed 155 units per single treatment session;
6. Member has tried and failed, or is intolerant or contraindicated to, at least 2 oral migraine preventative therapies, each for at least 8 weeks (e.g., antiepileptic drugs: divalproex sodium, sodium valproate, topiramate; beta-blockers: metoprolol, propranolol, timolol; antidepressants: amitriptyline, venlafaxine);
7. Member has none of the following contraindications:

- a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
- b. Infection at the proposed injection site(s).

**Approval duration: 24 weeks (two 12-week treatment sessions)**

**C. Cervical Dystonia or Limb Spasticity (must meet all):**

1. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
2. Age  $\geq$  18 years;
3. Diagnosis of one of the following:
  - a. Cervical dystonia and both i and ii:
    - i. Diagnosis is confirmed by involuntary tonic or clonic contractions in the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, posterior cervical) that result in sustained abnormal postures of the head, neck, and shoulders, and/or overlying spasms that produce tremor-like movements with directional quality;
    - ii. Member is experiencing pain and functional impairment;
  - b. Upper or lower limb spasticity and either i or ii:
    - i. For upper limb spasticity, intent of treatment is to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus);
    - ii. For lower limb spasticity, intent of treatment is to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus);
4. Botox will be administered as an intramuscular injection;
5. Prescribed dose of Botox does not exceed 400 units per single treatment session;
6. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**D. Primary Axillary Hyperhidrosis (must meet all):**

1. Prescribed by or in consultation with a neurologist or dermatologist;
2. Age  $\geq$  18 years;
3. Diagnosis of severe primary axillary hyperhidrosis (e.g., resulting in medical complications such as skin maceration and infection or significant disruption of professional/social life);
4. Botox will be administered as an intradermal injection;
5. Prescribed dose of Botox does not exceed 50 units per axilla;
6. Member has tried and failed 6 months of topical aluminum chloride;
7. Member has none of the following contraindications:

- a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
- b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**E. Blepharospasm or Strabismus (must meet all):**

1. Prescribed by or in consultation with a neurologist or ophthalmologist;
2. Age  $\geq$  12 years;
3. Diagnosis of one of the following:
  - a. Blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders;
  - b. Strabismus;
4. Member has had significant disability in daily, functional activities due to interference with vision;
5. Botox will be administered as an intramuscular injection;
6. Prescribed dose of Botox does not exceed:<sup>1</sup>
  - a. 5 units per site for blepharospasm (maximum 200 units total dose in a 30-day period); or
  - b. 25 units per muscle for strabismus;
7. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**F. Chronic Anal Fissures – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a gastroenterologist or colorectal surgeon;
2. Age  $\geq$  18 years;
3. Diagnosis of chronic anal fissures;
4. Prescribed dose of Botox does not exceed 100 units;
5. Member has tried and failed, or is intolerant or contraindicated to, at least 2 months of conventional therapy (e.g., high fiber diet and adequate fluids, bulk fiber supplements, stool softeners, warm sitz baths, nitroglycerin 0.2% ointment);
6. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**G. Cerebral Palsy – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a neurologist;
2. Age  $\geq$  2 years;

3. Diagnosis of spasticity associated with cerebral palsy with focal increased muscle tone that interferes with function or is likely to lead to joint contracture with growth;
4. Prescribed dose of Botox does not exceed 400 units;
5. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**H. Dystonias – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
2. Diagnosis of dystonias (e.g., idiopathic torsion dystonia, myoclonus dystonia, oromandibular dystonia);
3. Prescribed dose of Botox does not exceed 400 units per single treatment session or indication-specific maximum if applicable, whichever is lower:
  - a. 25 units per muscle for oromandibular dystonia;
4. Member has tried and failed, or is intolerant or contraindicated to, carbidopa/levodopa and trihexyphenidyl;
5. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**I. Esophageal Achalasia – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a gastroenterologist;
2. Age  $\geq$  18 years;
3. Diagnosis of esophageal achalasia;
4. Prescribed dose of Botox does not exceed 100 units;
5. Member is not a good candidate for pneumatic dilation or myotomy;
6. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 24 weeks (single treatment session)**

**J. Laryngeal Spasm or Spasmodic Dysphonia – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a neurologist or otolaryngologist;
2. Age  $\geq$  18 years;
3. Diagnosis of adductor laryngeal dystonia (spasmodic dysphonia);
4. Prescribed dose of Botox does not exceed 3 units;
5. Member has none of the following contraindications:

- a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
- b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**K. Hirschsprung's Disease – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a gastroenterologist;
2. Diagnosis of one of the following:
  - a. Hirschsprung's disease and Botox will be used for constipation due to increased internal anal sphincter tone after surgery;
  - b. Ultra-short segment Hirschsprung's disease;
  - c. Internal anal sphincter achalasia associated with Hirschsprung's disease;
3. Prescribed dose of Botox does not exceed 100 units;
4. Member has tried and failed, or is intolerant or contraindicated to, high fiber diet, adequate fluids, stool softeners, and laxatives for at least 2 months;
5. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**L. Spastic Conditions – Off Label Use (must meet all):**

1. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
2. Diagnosis of spastic condition (e.g., spasticity associated with stroke, spinal cord injury, or traumatic brain injury; hereditary spastic paraplegia);
3. Prescribed dose of Botox does not exceed 400 units;
4. Member has tried and failed, or is intolerant or contraindicated to, at least 2 conventional therapies (e.g., baclofen, benzodiazepines, dantrolene sodium, tizanidine, physical therapy);
5. Member has none of the following contraindications:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**M. Other diagnoses/indications:**

1. Refer to CP.PHAR.57 - Global Biopharm Policy if requested indication is non-cosmetic.

**II. Continued Approval**

**A. Overactive Bladder, Urinary Incontinence, Cervical Dystonia, Limb Spasticity, Primary Axillary Hyperhidrosis, Blepharospasm, Strabismus, Chronic Anal**

**Fissures, Cerebral Palsy, Dystonias, Laryngeal Spasm, Hirschsprung's Disease, or Spastic Conditions** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Prescribed dose of Botox does not exceed 400 units total over the last 3 months and indication-specific maximum if applicable:<sup>1</sup>
  - a. 100 units for treatment of overactive bladder, chronic anal fissures, or Hirschsprung's disease;
  - b. 200 units for treatment of incontinence due to detrusor over activity associated with a neurologic condition;
  - c. 155 units per single treatment session for chronic migraines;
  - d. 400 units per single treatment session for cervical dystonia or limb spasticity, spastic conditions, or cerebral palsy;
  - e. 50 units per axilla for treatment of primary axillary hyperhidrosis;
  - f. 5 units per site for treatment of blepharospasm (maximum 200 units total dose in a 30-day period);
  - g. 25 units per muscle for treatment of strabismus;
  - h. 3 units for treatment of laryngeal spasm/spasmodic dysphonia;
  - i. 25 units per muscle for treatment of oromandibular dystonia;
3. It has been at least 12 weeks since the last injection of Botox;
4. Member is responding positively to therapy;
5. Member has none of the following reasons to discontinue:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s);
  - c. Urinary tract infection or urinary retention (intradetrusor injection only).

**Approval duration: 12 weeks (single treatment session)**

**B. Chronic Migraine** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Prescribed dose of Botox does not exceed 155 units per single treatment session;
3. It has been at least 12 weeks since the last injection of Botox;
4. Member has experienced and maintained a 30% reduction in monthly headache frequency from baseline after 2 or more Botox treatment sessions;<sup>7</sup>
5. Member has none of the following reasons to discontinue:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 12 weeks (single treatment session)**

**C. Esophageal Achalasia** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;

2. Prescribed dose of Botox does not exceed 100 units;
3. It has been at least 24 weeks since the last injection of Botox;
4. Member is responding positively to therapy;
5. Member has none of the following reasons to discontinue:
  - a. Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation;
  - b. Infection at the proposed injection site(s).

**Approval duration: 24 weeks (single treatment session)**

**D. Other diagnoses/indications (must meet either 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy if requested indication is non-cosmetic.

**Background**

*Description/Mechanism of Action:*

OnabotulinumtoxinA is a purified botulinum toxin type A produced from fermentation of *Clostridium botulinum*. It blocks neuromuscular transmission by binding to acceptor sites on motor or sympathetic nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. This inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings.

*FDA Approved Indication(s):*

Botox is an acetylcholine release inhibitor and neuromuscular blocking agent/intramuscular, intradermal, and intradetrusor injection indicated for:

- Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine ( $\geq 15$  days per month with headache lasting 4 hours a day or longer)
- Treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus)
- 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)
- Treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia



**CLINICAL POLICY**  
**OnabotulinumtoxinA**

- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents
- Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above

Limitations of use:

- Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.
- Safety and effectiveness of Botox have not been established for the treatment of other upper or lower limb muscle groups. Safety and effectiveness of Botox have not been established for the treatment of spasticity in pediatric patients under age 18 years. Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture. Treatment with Botox is not intended to substitute for usual standard of care rehabilitation regimens.
- The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of Botox have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0585	Injection, onabotulinumtoxinA, 1 unit

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.09. Added new FDA indication of lower limb spasticity per FDA labeling. Added compendial indication of laryngeal spasm/spasmodic dysphonia. -Overactive bladder: modified requirement for trial/failure of previous therapy to include oral beta-3 agonist medications per AUA guidelines. -Migraine: modified continuation criteria to require 30% reduction in headache frequency after 2 injections rather than just 1 per literature review and NICE guidelines. -Added general max dosing limit for cerebral palsy and spastic conditions and indication-specific max dosing limit for cervical dystonia, strabismus,	05/16	07/16

Reviews, Revisions, and Approvals	Date	Approval Date
primary axillary hyperhidrosis, upper limb spasticity, overactive bladder, urinary incontinence, and chronic migraine per PI. -Added indication-specific max dosing limit for chronic anal fissures, esophageal achalasia, laryngeal spasm/spasmodic dysphonia, Hirschsprung’s disease, and dystonias per literature review. -Added prescriber requirement for overactive bladder, urinary incontinence, chronic migraines, upper limb spasticity, primary axillary hyperhidrosis, chronic anal fissures, cerebral palsy, esophageal achalasia, dystonias, Hirschsprung’s disease, and spastic conditions. -Added age restriction for upper limb spasticity and primary axillary hyperhidrosis per PI, and for chronic anal fissures, esophageal achalasia, and Hirschsprung’s disease per literature review. -Added route of administration for each labeled indication per PI. -Removed reauthorization criteria requiring attestation of significant improvement in symptoms and/or health-related quality of life. Added positive response to therapy to continuation criteria.		
-Chronic migraine initial approval duration lengthened from 12 to 24 weeks (from one to two treatment sessions) to allow assessment of response as outlined in continuation criteria.	11/16	

**References**

1. Botox Prescribing Information. Irvine, CA: Allergan, Inc; January 2016. Available at <http://www.botox.com>. Accessed May 11, 2016.
2. Gormley EA et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA (American Urological Association)/SUFU guideline. American Urological Association Education and Research, Inc. <http://www.auanet.org/education/guidelines/overactive-bladder.cfm>. Published May 2014. Accessed May 12, 2016.
3. Gormley EA, Lightner DJ, Faraday M, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. Journal of Urology. 2015; 193(5): 1572-1580.
4. Nambiar A, Lucas M. Chapter 4: guidelines for the diagnosis and treatment of overactive bladder (OAB) and neurogenic detrusor overactivity (NDO). NeuroUrol Urodynam. 2014; 33(S3): S21-S25.
5. Silberstein SD, US Headache Consortium. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review) – report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2000; 55(6): 754-762.
6. Silberstein SD, Holland S, Freitag F, Dodwick DW, Argoff C, Ashman E. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults – report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012; 78(17): 1337-1345.
7. National Institute for Health and Care Excellence (NICE). Technology appraisal guidance: Botulinum toxin type A for the prevention of headaches in adults with chronic migraine.

- NICE Guidance. <https://www.nice.org.uk/guidance/ta260>. Published June 27, 2012. Accessed July 27, 2016.
8. Simpson DM et al. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache - report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016; 86(19): 1818-1826.
  9. International Hyperhidrosis Society. Clinical guidelines - Primary focal axillary. <http://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html>. Accessed May 12, 2016.
  10. Hornberger J et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. *J Am Acad Dermatol*. 2004; 51(2): 274-286.
  11. Utzig MJ, Kroesen AJ, Buhr HJ. Concepts in pathogenesis and treatment of chronic anal fissure – a review of the literature. *American Journal of Gastroenterology*. 2003; 98(5): 968-974.
  12. Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. *Cochrane Database of Systematic Reviews*. 2012; Issue 2. Art. No.: CD003431. doi: 10.1002/14651858.CD003431.pub3.
  13. Delgado MR et al. Practice parameter: pharmacologic treatment of spasticity in children and adolescents with cerebral palsy (an evidence-based review). *Neurology*. 2012; 74(4): 336-343.
  14. Vaezi MF, Pandolfino JE, Vela MF. ACG (American College of Gastroenterology) clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013; 108(8): 1238-1259.
  15. Simpson DM et al. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review) - report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70: 1699-1706.
  16. Delnooze CC, van de Warrenburg BP. Current and future medical treatment in primary dystonia. *Ther Adv Neurol Disord*. 2012; 5(4): 221-240.
  17. Jankovic J. Treatment of dystonia. *Lancet Neurol*. 2006; 5(10): 864-872.
  18. Blitzer A, Brin MF, Stewart CF. Botulinum toxin management of spasmodic dysphonia (laryngeal dystonia): a 12-year experience in more than 90 patients. *Laryngoscope*. 1998; 108: 1435-1441.
  19. Nurko S, Center for Motility and Functional Gastrointestinal Disorders. Hirschsprung's disease in children and adults. International Foundation for Functional Gastrointestinal Disorders Publications Library. <http://iffgd.smtdomain.com/resources/publications-library-home/library/194.html>. Published September 14, 2008. Accessed May 16, 2016.
  20. Wesson DE. Congenital aganglionic megacolon (Hirschsprung disease). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at [www.UpToDate.com](http://www.UpToDate.com). Accessed June 8, 2016.
  21. Koivusalo AI, Pakarinen MP, Rintala RJ. Botox injection treatment for anal outlet obstruction in patients with internal anal sphincter achalasia and Hirschsprung's disease. *Pediatr Surg Int*. 2009; 25: 873-876.
  22. Simpson DM et al. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review) - report of the Therapeutics and Technology Assessment

- Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70(19): 1691-1698.
23. Fock J et al. Functional outcome following botulinum toxin A injection to reduce spastic equinus in adults with traumatic brain injury. *Brain Inj*. 2004; 18(1): 57-63.
  24. Geva-Dayan K, Domenievitz D, Zahalka R, Fattal-Valevski A. Botulinum toxin injections for pediatric patients with hereditary spastic paraparesis. *Journal of Child Neurology*. 2010; 25(8): 969-975.
  25. OnabotulinumtoxinA. In: Micromedex. Ann Arbor, MI: Truven Health Analytics; 2013. Available from: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed June 8, 2016.
  26. Hallet M, Benecke R, Blitzer A, Comella CL. Treatment of focal dystonias with botulinum neurotoxin. *Toxicon*. 2009; 54(5): 628-633.

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene<sup>®</sup> and Centene Corporation<sup>®</sup> are registered trademarks exclusively owned by Centene Corporation.