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HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	Botox (onabotulinumtoxinA)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Botox is a neurotoxin produced from Clostridium botulinum serotype A. It works through the inhibition of acetylcholine release from peripheral nerve endings, causing neuromuscular blockage and muscle paralysis. There are seven types of botulinum toxin serotypes. Only serotypes A and B are used for medicinal purposes. Botox was initially approved in 1989 by the FDA for the treatment of blepharospasm. Since then, Botox has gained additional therapeutic indications for overactive bladder, neurogenic detrusor overactivity, chronic migraine, spasticity, cervical dystonia, axillary hyperhidrosis, and strabismus.

Botox (onabotulinumtoxinA) will be considered for coverage when the following criteria are met:

Blepharospasm

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or ophthalmologist; AND
3. Member has a diagnosis of blepharospasm, characterized by spasms inducing narrowing or closure of the eyelids.
4. **Dosage allowed/Quantity limit:** The cumulative dose of Botox treatment for blepharospasm in a 30-day period should not exceed 200 Units. Treatment may be repeated every 3 months.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes show improved signs and symptoms (e.g., lessening of involuntary contraction).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Cervical Dystonia

For **initial** authorization:
1. Medication must be prescribed by or in consultation with a neurologist or other specialist experienced with treating cervical dystonia; AND
2. Member has a documented diagnosis of moderate to severe cervical dystonia as evidenced by involuntary contractions of neck muscles, leading to abnormal movements or postures.
3. **Dosage allowed/Quantity limit:** Up to 300 units every 3 months.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:
1. Chart notes show improved signs and symptoms (e.g., severity of abnormal head position, neck pain).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Esophageal Achalasia

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of achalasia confirmed by high resolution esophageal manometry; AND
4. Chart notes must document that the member is NOT a candidate for ALL of the following: Laparoscopic Heller myotomy, pneumatic dilation, and peroral endoscopic myotomy (POEM); AND
5. Other esophageal motility disorders and malignancy have been ruled out.
6. **Dosage allowed/Quantity limit:** 100 units every 6 months (off label).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show the member had symptomatic improvement of dysphagia and/or regurgitation.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Migraine Headache Prophylaxis

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is being prescribed for the prevention of chronic migraine, with **both** of the following documented in chart notes:
   a) ≥ 15 headache days per month for at least 3 months;
   b) ≥ 8 migraine days per month for at least 3 months; AND
3. Medication must be prescribed by a neurologist or a headache specialist; AND
4. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   a) Beta-blockers (e.g., metoprolol, timolol, or propranolol);
   b) Calcium channel blockers (e.g., verapamil);
   c) Antidepressants (e.g., amitriptyline or venlafaxine);
   d) Anticonvulsant medications (e.g., topiramate or valproic acid); AND
5. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); AND
6. Medication is NOT being used in combination with another prophylactic CGRP product (e.g., Emgality, Aimovig, Ajovy, or Vyepti); AND
7. Member does **not** have medication-overuse headaches.
8. **Dosage allowed/Quantity limit:** 155 Units every 3 months.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:
1. Member has improvement in prevention of migraines documented in chart notes (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Overactive Bladder (OAB)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a urologist or gynecologist; AND
3. Member has a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency; AND
4. Member has tried and failed at least TWO prior pharmacologic therapies for at least 30 days each (e.g. oxybutynin, solifenacin, Myrbetriq); AND
5. Member does not have a urinary tract infection.
6. **Dosage allowed/Quantity limit:** 100 Units every 12 weeks.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes have been provided that show decreased symptoms of urge urinary incontinence, urgency, and frequency.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Spasticity

For **initial** authorization:
1. Member is at least 2 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or other specialist experienced with treating spasticity (e.g., PM&R); AND
3. Member has a documented diagnosis of upper or lower limb spasticity that affects daily functioning and quality of life; AND
4. Spasticity is secondary to a neurologic condition such as cerebral palsy, stroke, or brain or spinal cord injury; AND
5. Member has tried or is unable to try one conventional treatment modality such as physical therapy or oral medication (e.g. baclofen, tizanidine).
6. **Dosage allowed/Quantity limit:** Adult: Not to exceed 400 total units every 12 weeks (given intramuscularly as a divided dose among affected muscles). Pediatric: Not to exceed 340 total units or 10 units per kg (whichever is lower) every 3 months.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes show improved signs and symptoms (e.g., decrease in severity of increased muscle tone, increased functional ability or range of motion).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Strabismus

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or ophthalmologist; AND
3. Member has a diagnosis of a strabismus type with binocular potential, unlikely to spontaneously resolve.
4. **Dosage allowed:** See package insert.[1]

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing that the member's ocular alignment has improved.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Urinary Incontinence (associated with neurologic condition)

For **initial** authorization:
1. Member is at least 5 years of age; AND
2. Medication is prescribed by or in consultation with a urologist, neurologist, or gynecologist; AND
3. Member has a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g. brain or spinal cord injury, stroke, multiple sclerosis, Parkinson's, spina bifida); AND
4. Member has tried and failed at least one anticholinergic medication for 30 days (e.g. oxybutynin, solifenacin, tolterodine); AND
5. Member does not have a urinary tract infection.
6. **Dosage allowed/Quantity limit:** For adults and pediatric patients weighing 34kg or more: 200 units per treatment, no sooner than every 12 weeks. If weight is less than 34kg: 6mg/kg, no sooner than every 12 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided that show decreased frequency of urinary incontinence.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Common Ground considers Botox (onabotulinumtoxinA) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/03/2018	Criterion “no infection at proposed injection site” removed from Blepharospasm and Cervical Dystonia diagnosis. Age limitation removed from Cervical Dystonia; pain and abnormal head position requirements clarified and medications trial added. On diagnosis of Urinary Incontinence criterion “Surgical treatment or balloon sphincter dilatation is not indicated, has been refused, or has failed” was removed. On diagnosis of Spasticity rehabilitation program is not required anymore. Strabismus diagnosis got criteria expanded. Lower Limb Spasticity is combined into Spasticity diagnosis. For diagnosis of Migraine Headache Prophylaxis trial length for abortive therapeutic options decreased.
01/19/2020	Updated Overactive Bladder criteria from three to two trials of an adequately titrated overactive bladder medication.
08/17/2020	Removed criteria for upper extremity focal dystonia/writer’s cramp (off label). Hyperhidrosis: added specialist requirement, changed re-auth duration, changed dx title to match drug label, changed the ordering, removed sweat quantification requirement and changed diagnostic phrase to match guidelines. Added reference. Blepharospasm: Extend re-auth duration to 12 mo, added specialist, re-phrased dose, revised diagnostic phrasing. Added reference. Strabismus: Added specialist, referred dose to PI, simplified diagnostic wording. Added reference. Cervical dystonia: Added specialist. Re-worded the diagnosis requirement. Removed trial of oral medication. Removed exclusions. Added frequency to dose. Extended re-auth duration. Added references. Achalasia (off label use): added age and specialist, changed initial auth duration from 12 mo to 6mo. Removed requirement for oral therapy (not effective). Specified high resolution manometry per guideline. Included surgical procedures per guideline. Removed redundancy. Simplified other causes. Added frequency to dose. Added references. Migraine: removed symptoms and duration of migraine episode from diagnostic requirement; trial length reduced to 2 months/trial; added one of the abortive trials must be a triptan; added no concurrent use with prophylactic CGRP; removed statement about episodic migraine because not an FDA approved indication. OAB: added frequency to dose. Added specialist. Amended dx per drug label. Specified length of alternate drug trials. Added examples of drugs. Added reference. Urinary incontinence: added specialist, added frequency to dose, edited dx to match fda label wording, changed initial auth duration. Changed order of criteria to match others. Removed statement about urinary retention. Expanded examples of neurologic disease, added examples of anticholinergic, specified length of trial. Added reference. Spasticity: Add age and specialist. Update to match latest drug label. Generalized list of co-existing conditions. Added trial of conventional treatment. Extended initial auth duration. Edited dose allowed. Added reference. All: specified type of symptom improvement to look for at re-auth.
11/23/2020	Hyperhidrosis: Replaced “Drysol” with “Xerac” and changed trial length to 60 days.
02/15/2021	Per label change: Updated age to 5 yrs old for urinary incontinence due to detrusor overactivity assoc. with neurologic condition; added spina bifida to list of examples; added dosing for peds.
08/10/2021	Transferred to new template. Allowing additional specialists for cervical dystonia and spasticity indications.
03/04/2022	Annual review; no changes

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11/14/2023	Cervical dystonia: removed “Symptoms affect quality of life and daily functions.” Updated references.

References:

1. Botox [package insert]. Madison, NJ: Allergan USA, Inc.; 2023.
2. Clinical use of botulinum toxin. National Institutes of Health Consensus Development Conference Statement, November 12-14, 1990. *Arch Neurol*. 1991;48(12):1294-1298.
3. Borodic GE and Pearce LB, “New Concepts in Botulinum Toxin Therapy,” Drug Saf, 1994, 11(3):145-52.
4. Jankovic J and Brin MF, “Therapeutic Uses of Botulinum Toxin,” N Engl J Med,1991, 324(17):1186-94.
5. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," Curr Med Res Opin, 2004, 20(7):981-90.
6. Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, Muscle Nerve Suppl 1997; 6:S181.
7. Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome Am J Phys Med Rehabil. 2002 Dec;81(12):936-42.
8. Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008;70(19):1699-706.
9. Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. Neurology. 2008; 70:1707-14.
10. Koivusalo A.I., Pakarinen M.P., Rintala R.J. Botox injection treatment for anal outlet obstruction in patients with internal anal sphincter achalasia and Hirschsprung’s disease. *Pediatr Surg Int* (2009) 25: 873. https://doi.org/10.1007/s00383-009-2438-3.
11. Pasricha, P.J., Ravich, W.J., Hendrix, T.R., et al. M.D. Intrasphincteric Botulinum Toxin for the Treatment of Achalasia. *N Engl J Med* (1995); 332:774-778. March 23, 1995. DOI: 10.1056/NEJM199503233321203
12. Storr M, Born P, Frimberger E, et al. Treatment of achalasia: the short-term response to botulinum toxin injection seems to be independent of any kind of pretreatment. *BMC Gastroenterology*. 2002;2:19. doi:10.1186/1471-230X-2-19.
13. Fock J, Galea MP, Stillman BC, 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.
14. Biglan AW, Burnstine RA, Rogers GL, Saunders RA. Management of strabismus with botulinum A toxin. Ophthalmology. 1989;96(7):935-943.
15. Munksgaard SB, et al. Medication overuse headache. Headache. 2014 Jul-Aug;54(7):1251-7.
16. Gómez-Caravaca MT, et al. The use of botulinum toxin in the treatment of sialorrhea in parkinsonian disorders. Neurol Sci. 2015 Feb;36(2):275-9.
17. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. *J Am Acad Dermatol*. 2004;51(2):274-286. doi:10.1016/j.jaad.2003.12.029
18. Simpson DM, Hallett M, Ashman EJ, 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. doi:10.1212/WNL.0000000000002560
19. Defazio G, Hallett M, Jinnah HA, Berardelli A. Development and validation of a clinical guideline for diagnosing blepharospasm. *Neurology*. 2013;81(3):236-240. doi:10.1212/WNL.0b013e31829bfdf6
20. Rowe FJ, Noonan CP. Botulinum toxin for the treatment of strabismus. Cochrane Database of Systematic Reviews 2017, Issue 3. Art. No.: CD006499. DOI: 10.1002/14651858.CD006499.pub4.
21. Dressler D, Altenmueller E, Bhidayasiri R, et al. Strategies for treatment of dystonia. *Journal of Neural Transmission*. 2015;123(3):251-258. doi:10.1007/s00702-015-1453-x
22. Khashab MA, Vela MF, Thosani N, et al. ASGE guideline on the management of achalasia. *Gastrointest Endosc*. 2020;91(2):213-227.e6. doi:10.1016/j.gie.2019.04.231
23. Zaninotto G, Bennett C, Boeckxstaens G, et al. The 2018 ISDE achalasia guidelines. *Dis Esophagus*. 2018;31(9):10.1093/dote/doy071. doi:10.1093/dote/doy071
24. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013;108(8):1238-1250. doi:10.1038/ajg.2013.196

25. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019;59: 1-18.
26. Gormley EA, Lightner DJ, Faraday M, Vasavada SP; American Urological Association; Society of Urodynamics, Female Pelvic Medicine. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. *J Urol*. 2015;193(5):1572-1580. doi:10.1016/j.juro.2015.01.087
27. Groen J, Pannek J, Castro Diaz D, et al. Summary of European Association of Urology (EAU) Guidelines on Neuro-Urology. *Eur Urol*. 2016;69(2):324-333. doi:10.1016/j.eururo.2015.07.071
28. Lindsay C, Kouzouna A, Simcox C, Pandyan AD. Pharmacological interventions other than botulinum toxin for spasticity after stroke. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD010362. DOI: 10.1002/14651858.CD010362.pub2.
29. Dashtipour K, Mari Z, Jankovic J, Adler CH, Schwartz M, Brin MF. Minimal clinically important change in patients with cervical dystonia: Results from the CD PROBE study. J Neurol Sci. 2019;405:116413. doi:10.1016/j.jns.2019.07.031
30. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. J Neural Transm (Vienna). 2021;128(4):531-537. doi:10.1007/s00702-020-02266-z
31. Rodrigues FB, Duarte GS, Marques RE, et al. Botulinum toxin type A therapy for cervical dystonia. Cochrane Database Syst Rev. 2020;11(11):CD003633. Published 2020 Nov 12. doi:10.1002/14651858.CD003633.pub4

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