CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Botox (onabotulinumtoxinA)
BILLING CODE	J0585
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office, Outpatient
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. Today, Botox is FDA-approved for additional therapeutic indications, such as overactive bladder, urinary incontinence, cervical dystonia, axillary hyperhidrosis, migraine prevention, strabismus and blepharospasm.

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

PRIMARY AXILLARY HYPERHIDROSIS

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of severe axillary hyperhidrosis, including documentation in the chart notes of visible, excessive sweating of at least 6 months duration which significantly impairs daily activities; AND
4. Secondary causes of hyperhidrosis (e.g., hyperthyroidism) have been ruled out; AND
5. Member has tried and failed topical prescription-strength aluminum chloride (e.g. Xerac) for at least 60 days.
6. **Dosage allowed:** 50 Units per axilla.

Note: Medication will not be covered for treatment of hyperhidrosis in body areas other than axillary.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show improvement of signs and symptoms (i.e. reduced axillary sweat production).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

BLEPHAROSPASM

For **initial** authorization:
1. Member is 12 years of age or older; 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:** 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 member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. lessening of involuntary contraction).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

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; AND
3. Symptoms affect quality of life and daily functions.
4. **Dosage allowed:** Up to 300 units every 3 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. severity of abnormal head position, neck pain).

If member meets all the reauthorization requirements above, 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:** 100 units every 6 months (off label).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes must show the member had symptomatic improvement of dysphagia and/or regurgitation.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

MIGRAINE HEADACHE PROPHYLAXIS

For **initial** authorization:
1. Member is 18 years of age or older; 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:** 155 Units every 3 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

OVERACTIVE BLADDER (OAB)

For **initial** authorization:
1. Member is 18 years of age or older; 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:** 100 Units every 12 weeks.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show decreased symptoms of urge urinary incontinence, urgency, and frequency.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SPASTICITY

For **initial** authorization:
1. Member is 2 years of age or older; 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:** 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 member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. decrease in severity of increased muscle tone, increased functional ability or range of motion).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

STRABISMUS

For **initial** authorization:
1. Member is 12 years of age or older; 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 member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing that the member's ocular alignment has improved.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

URINARY INCONTINENCE (associated with neurologic condition)

For **initial** authorization:
1. Member is 5 years of age or older; 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:** 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 member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show decreased frequency of urinary incontinence.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource 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.

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