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PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Botox (onabotulinumtoxinA)
BILLING CODE	J0585
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office, Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— vary per diagnosis
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Botox (onabotulinumtoxinA) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AXILLARY HYPERHIDROSIS

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member has diagnosis of axillary hyperhidrosis, with resting sweat production of 50 mg per axilla measured over 5 minutes at room temperature documented in chart notes; AND
3. Member has failed conservative treatment using topical agents; AND
4. Secondary causes of hyperhidrosis (e.g., hyperthyroidism) have been evaluated and, if necessary, treated; AND
5. Condition is causing a significant effect on daily activities.
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 the member has shown improvement of signs and symptoms of disease.

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

BLEPHAROSPASM

For **initial** authorization:

1. Member is 12 years of age or older with diagnosis of blepharospasm, as indicated by **one** or more of the following:
   a) Benign essential blepharospasm;
   b) Blepharospasm associated with dystonia;
   c) Blepharospasm associated with facial nerve (cranial nerve VII) disorders such as Bell palsy; AND
2. Member does **not** have neuromuscular disease (e.g., myasthenia gravis).

3. **Dosage allowed:** The initial recommended dose is 1.25 Units-2.5 Units injected into the medial and lateral pre-tarsal orbicularis oculi of the upper lid and into the lateral pre-tarsal orbicularis oculi of the lower lid. At repeat treatment sessions, the dose may be increased up to two-fold if the response from the initial treatment is considered insufficient. The cumulative dose of Botox treatment for blepharospasm in a 30-day period should not exceed 200 Units.

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 the member has shown improvement of signs and symptoms of disease.

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

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:
1. Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
2. Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
3. Member does **not** have any of the following:
   a) Fixed contractures causing decreased neck range of motion;
   b) Neuromuscular disease (e.g., myasthenia gravis);
   c) Prior surgical treatment.
4. **Dosage allowed:** 50-300 Units.

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 the member has shown improvement of signs and symptoms of disease.

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

ESOPHAGEAL ACHALASIA

For **initial** authorization:
1. Achalasia confirmed by esophageal manometry; AND
2. Member has **no** response to pharmacologic treatment (e.g., long-acting nitrates, calcium channel antagonists); AND
3. Member is **not** candidate for pneumatic dilation or surgical myotomy; AND
4. Member has progressive dysphagia for liquids and solids; AND
5. Other causes of dysphagia (e.g., peptic stricture, carcinoma, lower esophageal ring or extrinsic compression) ruled out by upper gastrointestinal endoscopy.
6. **Dosage allowed:** 40-100 Units.

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

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For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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. Member has documented history of ≥15 headache days per month for more than 3 months, of which ≥ 8 days were migraine days characterized as ≥ 5 attacks lasting 4-72 hours with **both** of the following:
   a) **Two** or more of the following:
      i) Aggravation by or causing avoidance of routine physical activity;
      ii) Moderate or severe pain intensity;
      iii) Pulsating quality;
      iv) Unilateral location;
   b) **One** or more of the following:
      i) Nausea or vomiting;
      ii) Photophobia and phonophobia; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member does **not** have ANY of the following:
   a) No medication-overuse headaches;
   b) No neuromuscular disease (e.g., myasthenia gravis); AND
5. Other prophylactic therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by **two** or more of the following:
   a) Beta-blockers;
   b) Calcium channel blockers;
   c) Antidepressants such as amitriptyline, nortriptyline, doxepin, or protriptyline;
   d) Anticonvulsant medications such as topiramate or valproic acid; AND
6. Abortive therapeutic options (i.e., ergotamine, triptans, combination analgesics, or simple analgesics) have been ineffective or not tolerated for at least 30 days (for a minimum of 8 or more days per month).
7. **Dosage allowed:** 155 Units.

Note: Medication will not be covered for prophylaxis of episodic migraine (14 headache days or fewer per month). Medication will not be covered if used concomitantly with CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality).

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 the member has shown improvement of signs and symptoms of disease.

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

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OVERACTIVE BLADDER

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has tried and failed or has intolerance at least **three** adequately titrated prescription overactive bladder medications (e.g., oxybutynin, trospium, tolterodine, darifenacin, fesoterodine, mirabegron, solifenacin, duloxetine) OR **two** adequately titrated prescription overactive bladder medications AND an OTC bladder medication (oxybutynin transdermal patch (Oxytrol for Women); AND
3. Member does **not** have ANY of the following:
   a) Acute urinary retention;
   b) Acute urinary tract infection.
4. **Dosage allowed:** 100 Units.

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 the member has shown improvement of signs and symptoms of disease.

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

SPASTICITY

For **initial** authorization:

1. Chart notes submitted with documentation of abnormal muscle tone that is interfering with functional ability (or that is expected to affect joint contracture in future growth); AND
2. Medication is being requested to improve function or allow additional therapeutic modality to be employed; AND
3. **One** of the following:
   a) Member is a child with cerebral palsy;
   b) Member has hereditary spastic paraplegia;
   c) Member has limb spasticity due to multiple sclerosis or other demyelinating diseases of the central nervous system;
   d) Member is adult and has upper extremity spasticity due to stroke or brain injury.
4. **Dosage allowed:** No more than 50 Units per site.

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 the member has shown improvement of signs and symptoms of disease.

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

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STRABISMUS

For **initial** authorization:

1. Member is 12 years of age or older; AND
2. Member has **one** of the following:
   a) Esotropia;
   b) Horizontal strabismus with deviations of less than 50 prism diopters;
   c) Vertical strabismus;
   d) Persistent cranial nerve VI palsies of 1 month duration or longer (including gaze palsies accompanying diseases, such as neuromyelitis optica and Schilder's disease); AND
3. Member's strabismus is **not** due primarily to:
   a) Duane syndrome with lateral rectus weakness;
   b) Restrictive strabismus;
   c) Secondary strabismus caused by prior surgical over-recession of antagonist muscle.
4. **Dosage allowed:** 1.25-5 Units in any one muscle.

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 the member has shown improvement of signs and symptoms of disease.

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

UPPER EXTREMITY FOCAL DYSTONIA (e.g., Writer's Cramp)

For **initial** authorization:

1. Member is 16 years of age or older; AND
2. Member has extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning; AND
3. Member did not have prior surgical treatment.
4. **Dosage allowed:** Depends on intensity of spasm, the size of the muscle and number of muscles affected.

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 the member has shown improvement of signs and symptoms of disease.

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

URINARY INCONTINENCE

For **initial** authorization:

1. Member is 18 years of age or older and has diagnosis of neurogenic urinary incontinence, or neurogenic detrusor over activity, or detrusor sphincter dyssynergia; AND
2. Condition secondary to spinal cord injury or neurologic disease, including but not limited to multiple sclerosis; AND
3. Member does **not** have ANY of the following:

a) Acute urinary tract infection;
b) Acute urinary retention unless patient receiving regular clean intermittent catheterization; AND
4. Member is unresponsive or intolerant to pharmacologic therapy including anticholinergic medication (e.g., oxybutynin, tolterodine, trospium, darifenacin, fesoterodine, solifenacin).
5. **Dosage allowed:** 200 Units.

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

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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 the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease
- Sialorrhea due to Parkinson's disease

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.

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