Draft Revised Policy: Do Not Implement

OnabotulinumtoxinA (Botox®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- 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., spinal cord injury, multiple sclerosis) in adults or pediatric patients 5 years of age or older who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Safety and effectiveness have not been established in patients under age 18.
- Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Compendial Uses

- Achalasia
- Chronic anal fissures
- Essential tremor
- Excessive salivation (ptyalism)
- Hemifacial spasm
- Spasmodic dysphonia (laryngeal dystonia)
- Oromandibular dystonia
- Myofascial pain syndrome
- Focal hand dystonia
- Facial myokymia
- Hirschsprung disease with internal sphincter achalasia
- Orofacial tardive dyskinesia

- Painful bruxism
- Palatal myoclonus
- First bite syndrome
- Palmar or gustatory (Frey's syndrome) hyperhidrosis

All other indications are considered experimental/investigational and not medically necessary.

EXCLUSIONS

Coverage will not be provided for cosmetic use.

COVERAGE CRITERIA

Blepharospasm
Authorization of 12 months may be granted for treatment of blepharospasm when all of the following are met:
- Member is 12 years of age or older
- Member is diagnosed with blepharospasm including blepharospasm associated with dystonia, benign essential blepharospasm or VII nerve disorder.

Cervical Dystonia
Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:
- There is abnormal placement of the head with limited range of motion in the neck
- Member is 18 year of age and older.

Chronic Migraine Prophylaxis
Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:
- Member experiences headaches 15 days or more per month.
- Member experiences headaches lasting 4 hours or longer on at least 8 days per month.
- Member completed an adequate trial of (or has a contraindication to) two migraine preventative therapies coming from at least 2 of the following classes with a trial of each medication at least 60 days in duration:
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)
  - Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)
  - Calcitonin gene-related peptide (CGRP)-targeting therapies (e.g., fremanezumab, galcanezumab, epitinezumab, rimegepant, atogepant).
- Member has signs and symptoms consistent with chronic migraine diagnostic criteria as defined by the International Headache Society (IHS).
- Member is 18 years of age or older

Overactive Bladder with Urinary Incontinence
Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence, urgency, and frequency when all of the following criteria are met:
- The member has tried and failed behavioral therapy.
- The member has had an inadequate response or experienced intolerance to two agents from either of the following classes:
  - Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
  - Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron], Gemtesa [vibegron]).

- Member is 18 years of age or older.

Primary Axillary, Palmar, and Gustatory (Frey's Syndrome) Hyperhidrosis
Authorization of 12 months may be granted for treatment of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis when all of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating.
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.
- Member is 18 years of age or older.

Strabismus
Authorization of 12 months may be granted for treatment of strabismus when all of the following criteria are met:

- Strabismus interference with normal visual system development is likely to occur and spontaneous recovery is unlikely.
- Member is 12 years of age or older.
- Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

Upper or Lower Limb Spasticity
Authorization of 12 months may be granted for treatment of upper or lower limb spasticity when all of the following are met

- Member is 2 years of age or older
- Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition causing limb spasticity (including focal spasticity or equinus gait due to cerebral palsy).

Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurologic Condition (e.g., Spinal Cord Injury, Multiple Sclerosis)
Authorization of 12 months may be granted for treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met:

- The member has tried and failed behavioral therapy
- The member has had an inadequate response or experienced intolerance to one agent from either of the following classes:
  - Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
  - Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron]
- Member is 5 years of age or older.

Achalasia
Authorization of 12 months may be granted for treatment of achalasia when the member has tried and failed or is a poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy.

Chronic anal fissures
Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates.

Essential tremor
Authorization of 12 months may be granted for treatment of essential tremor.

Excessive Salivation

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea or ptyalism) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

Hemifacial Spasm
Authorization of 12 months may be granted for treatment of hemifacial spasm.

Spasmodic Dysphonia (laryngeal dystonia)
Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

Oromandibular Dystonia
Authorization of 12 months may be granted for treatment of oromandibular dystonia.

Myofascial Pain Syndrome
Authorization of 12 months may be granted for treatment of myofascial pain syndrome when the member has tried and failed all of the following:

- Physical therapy
- Injection of local anesthetics into trigger points
- Injection of corticosteroids into trigger points

Focal Hand Dystonia
Authorization of 12 months may be granted for the treatment of focal hand dystonias.

Facial Myokymia
Authorization of 12 months may be granted for the treatment of facial myokymia.

Hirschsprung Disease with Internal Sphincter Achalasia
Authorization of 12 months may be granted for the treatment of Hirschsprung's disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy.

Orofacial Tardive Dyskinesia
Authorization of 12 months may be granted for the treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine).

Painful Bruxism
Authorization of 12 months may be granted for the treatment of painful bruxism when the member has had an inadequate response to a night guard and has had an inadequate response to pharmacologic therapy such as diazepam.

Palatal Myoclonus
Authorization of 12 months may be granted for the treatment of palatal myoclonus when the member has disabling symptoms (e.g., intrusive clicking tinnitus) who had an inadequate response to clonazepam, lamotrigine, carbamazepine or valproate.

First Bite Syndrome
Authorization of 12 months may be granted for the treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants.

CONTINUATION OF THERAPY

- All members (including new members) requesting authorization for continuation of therapy for approvable conditions other than migraine prophylaxis must meet all requirements in coverage criteria and be experiencing benefit from therapy.

- Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the member has achieved or maintained a reduction in monthly headache frequency since starting therapy with Botox.

DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines**.**

Adults: Dosing should not exceed a cumulative dose of 400 units every 84 days

Pediatric (patients less than 18 years of age): Dosing should not exceed the lessor of 10 units/kg or 340 units every 84 days.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Botox (OnabotulinumtoxinA)	Other ~~All~~	<18years 10units/kg ~~mg/kg~~ up to a maximum of 340 units is the maximum cumulative dose allowed ~~permitted~~ in a 12-week interval when treating one or more indications. ≥18years 400 units is the maximum cumulative dose allowed ~~permitted when treating one or more indications~~ in a 12 week interval when treating one or more indications.
Botox (OnabotulinumtoxinA)	Achalasia	Route of Administration: Intramuscular 100Units per treatment. May re-treat no sooner than every 6 months. ~~<18year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks.~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Adult Urinary Incontinence Associated with a Neurologic Condition	Route of Administration: Intramuscular ≥18 year(s) 200Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Blepharospasm	Route of Administration: Intramuscular ≥12 to <18 year(s) 200Units per treatment. May re-treat no sooner than every 12 weeks.

		≥18 year(s) 200Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Cervical Dystonia	Route of Administration: Intramuscular ≥18 year(s) 400Units divided among the affected muscles. No more than 50 Units per site. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Chronic Anal Fissures	Route of Administration: Intramuscular 100Units per treatment. May re-treat no sooner than every 12 weeks. ~~<18year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Chronic Migraine Prophylaxis	Route of Administration: Intramuscular ≥18 year(s) 155Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Essential Tremor	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Excessive Salivation (Chronic Sialorrhea or Ptyalism)	Route of Administration: Injection 100Units per treatment. May re-treat no sooner than every 12 weeks. ~~<18year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks.~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Facial Myokymia	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max~~ ~~340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks.≥18 year(s)

		400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Focal Hand Dystonia	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	First Bite Syndrome	Route of Administration: Injection <18year(s) <34kg 10Units/kg per treatment. May re-treat no sooner than every 12 weeks. ~~up to max 340 Units per 12 week period~~ ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Hemifacial Spasm	Route of Administration: Intramuscular 100Units per treatment. May re-treat no sooner than every 12 weeks. ~~<18year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks.~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Hirschsprung Disease with Internal Sphincter Achalasia	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Myofascial Pain Syndrome	Route of Administration: Intramuscular <18year(s) <34kg

		10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Orofacial Tardive Dyskinesia	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Oromandibular Dystonia	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Overactive Bladder	Route of Administration: Intramuscular ≥18 year(s) 100Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Painful Bruxism	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg ~~up to max 340 Units~~ per treatment. May re-treat no sooner than every 12 weeks. ≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Palatal Myoclonus	Route of Administration: Intramuscular <18year(s) <34kg 10Units/kg per treatment. May re-treat no sooner than every 12 weeks. ~~10Units/kg up to max 340 Units per 12 week period~~

		≥34kg 340Units per treatment. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Palmar or Gustatory (Frey's Syndrome) Hyperhidrosis	Route of Administration: Injection ≥18 year(s) 400Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Pediatric Urinary Incontinence Associated with a Neurologic Condition	Route of Administration: Intramuscular ≥5 to <18 year(s) <34kg 6Units/kg per treatment. May re-treat no sooner than every 12 weeks. ≥5 to <18 year(s) ≥34kg 200Units per treatment. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Primary Axillary Hyperhidrosis	Route of Administration: Intradermal ≥18 year(s) 50 Units per axilla. May re-treat no sooner than every 12 weeks.
Botox (OnabotulinumtoxinA)	Spasmodic Dysphonia (Laryngeal Dystonia)	Route of Administration: Intramuscular 100Units per treatment. May re-treat no sooner than every 12 weeks. ~~<18year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks.~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Strabismus	Route of Administration: Intramuscular ≥12 year(s) 100Units per treatment. May re-treat no sooner than every 12 weeks. ~~≥12 to <18 year(s)~~ ~~10Units/kg up to max 340 Units per treatment. May re-treat no sooner than every 12 weeks.~~ ~~≥18 year(s)~~ ~~400Units per treatment. May re-treat no sooner than every 12 weeks.~~
Botox (OnabotulinumtoxinA)	Upper or Lower Limb Spasticity	Route of Administration: Intramuscular ≥2 to <18 year(s) <34kg 10Units/kg ~~up to max 340 Units~~ divided among the affected muscles when treating both upper and lower limbs or both lower limbs. The total dose per treatment session should not exceed 6 Units/kg up to max 200 Units in the upper limb and 8 Units/kg up to max 300

		Units in the lower limb. May re-treat no sooner than every 12 weeks. ≥34kg 340Units divided among the affected muscles when treating both upper and lower limbs or both lower limbs. The total dose per treatment session should not exceed 6 Units/kg up to max 200 Units in the upper limb and 8 Units/kg up to max 300 Units in the lower limb. May re-treat no sooner than every 12 weeks. ≥18 year(s) 400Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE

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