Effective Date: 12/2009
Last Reviewed: 12/2019, 8/2020, 3/2021, 5/2021, 3/2023, 12/2023, 01/2024 Pharmacy Scope: Medicaid (Pharmacy Benefit ONLY) Medical Scope: Commercial, Medicare-Medicaid Plan (MMP)

Botox® (onabotulinumtoxinA)
(Intramuscular/Intradetrusor/Intradermal)

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)**

****Effective 01/01/2022: Medication will only be covered on the Pharmacy Benefit for Medicaid Members**

I. Length of Authorization

- Coverage will be provided for six months and may be renewed for 12 months
- Preoperative use in Ventral Hernia may NOT be renewed.

II. Dosing Limits

A. **Quantity Limit (max daily dose) [Medical Benefit]:**

- Botox 100 unit powder for injection: 1 vial per 84 days
- Botox 100 unit powder for injection: 5 vials once (for Ventral Hernia only)
- Botox 200 unit powder for injection: 2 vials per 84 days
- **Max Units (per dose and over time) [HCPCS Unit]:**

Indication	Billable Units	Per # days
Blepharospasm	200	84
Cervical Dystonia	300	84
Strabismus	100	84
Esophageal Achalasia	100	168
Adult Upper Limb Spasticity	400	84
Adult Lower Limb Spasticity	400	84
Chronic Migraine	200	84
Severe Primary Axillary Hyperhidrosis	100	112
Sialorrhea	100	84
Neurogenic Bladder/Detrusor Overactivity	200	84
Overactive Bladder	100	84
Chronic Anal Fissures	100	84
Palmar Hyperhidrosis	200	168
Pediatric Upper Limb Spasticity	200	84
Pediatric Lower Limb Spasticity	300	84
Laryngeal Dystonia	100	84
Hemifacial Spasms	100	84
Oromandibular Dystonia	200	84
Ventral Hernia	500	N/A
All other indications	400	90

B. Quantity Limit (max daily dose) [Medicaid Pharmacy Benefit]:

- Botox 1 fill per 84 days

III. Summary of Evidence

Botox is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for several conditions such as overactive bladder, neurogenic detreuser overactivity, prophylaxis of headaches, cervical dystonia, and others. For chronic migraine, the PREEMPT studies, have shown that Botox injections administered at specified intervals lead to a significant reduction in the number of headache days per month and improve quality of life in chronic migraine patients. Botox has demonstrated a favorable safety profile in long-term studies, with the most common adverse events being mild to moderate and transient, such as neck pain and muscle weakness.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria

- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, daxibotulinumtoxina-lanm, etc.); **AND**

Blepharospasms [1]† Φ

- Patient is at least 12 years of age

Cervical Dystonia [1]† Φ

- Patient is at least 16 years of age ; **AND**
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Patient has sustained head tilt; **OR**
  - Patient has abnormal posturing with limited range of motion in the neck

Strabismus [1]† Φ

- Patient is at least 12 years of age

Spastic Conditions [1,8,9,10,11,12,13,14, 22,23,24,25,26,46]

- Patient has one of the following:
  - Upper/Lower limb spasticity in adults (i.e., used post-stroke for spasms) †
  - Pediatric upper limb spasticity in patients aged 2 years or greater (i.e., used post-stroke for spasms or for spasms related to cerebral palsy) † Φ
  - Pediatric lower limb spasticity in patients aged 2 years or greater †
  - Spasticity due to multiple sclerosis or Schilder's disease ‡
  - Acquired spasticity secondary to spinal cord or brain injuries ‡
  - Spastic Plegic conditions including Monoplegia, Diplegia, Hemiplegia, Paraplegia (including Hereditary spastic paraplegia) and Quadriplegia ‡
  - Hemifacial Spasm [26,32,33,49,50,51] ‡

Severe Primary Axillary Hyperhidrosis [1,15,52,59]†

- Patient has tried and failed ≥ 1 month trial of a topical agent *(e.g., aluminum chloride, glycopyrronium, etc); **AND**
  - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc)

Prophylaxis for Chronic Migraines [1,6,7,53,54,56,58]†

- Patient is utilizing prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.); **AND**
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months; **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; **AND**
  - On at least 8 days per month for at least 3 months:
    - Headaches have characteristics and symptoms consistent with migraine§; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of migraine-prophylactic medications below for examples)

Esophageal Achalasia [2,3,4,5]‡

- Patient is at high risk of complication from pneumatic dilation, surgical myotomy or peroral endoscopic myotomy (POEM); **OR**
- Patient has had treatment failure with pneumatic dilation, surgical myotomy, or POEM; **OR**
- Patient has had perforation from pneumatic dilation; **OR**

- Patient has an epiphrenic diverticulum or hiatal hernia; **OR**
- Patient has esophageal varices

Focal Dystonias [34,35,36,37,38,39,40,41]‡

- Focal upper limb dystonia
  - Patient has functional impairment; **OR**
  - Patient has pain as a result
- Laryngeal dystonia
- Oromandibular dystonia
  - Patient has functional impairment; **OR**
  - Patient has pain as a result

Sialorrhea associated with Neurological Disorders [15,16,17,18,19,20,42,43]‡

- Patient has a history of troublesome sialorrhea for at least a 3 month period; **AND**
  - Patient has Parkinson's disease; **OR**
  - Patient has severe developmental delays; **OR**
  - Patient has cerebral palsy; **OR**
  - Patient has amyotrophic lateral sclerosis

Incontinence due to Detrusor Overactivity [1,55, 67]†

- Patient is at least 5 years of age; **AND**
- Patient does not have a current, untreated urinary tract infection; **AND**
- Patient has detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes

Overactive Bladder (OAB) [1,55]†

- Patient does not have a current, untreated urinary tract infection; **AND**
- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) and/or beta-adrenergic (i.e., mirabegron) classes

Severe Palmar Hyperhidrosis [15,21,52]‡

- Patient has tried and failed ≥ 1 month trial of a topical agent* (i.e., aluminum chloride, etc); **AND**
- Patient has failed with iontophoresis; **AND**
  - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant impact to activities of daily living due to condition

Chronic Anal Fissure [27,28,29,30,31,47,61,62,63]‡

- Other causes of disease have been ruled out (i.e., Crohn's Disease, etc); **AND**
- Patient has failed on non-pharmacologic supportive measures (i.e., sitz baths, psyllium fiber, bulking agents, etc.); **AND**
- Patient has tried and failed a ≥ 1 month trial of conventional pharmacologic therapy (i.e., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)

Ventral Hernia [65,66]‡

- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

*** This requirement does not apply to MMP members**

† FDA Approved Indication; ‡ Literature Supported Indication; **Φ** Orphan Drug

Migraine-Prophylaxis Oral Medications *(list not all-inclusive)*
• Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc)
Migraine Features §
Migraine without aura • At least five attacks have the following: o Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) o Headache has at least two of the following characteristics: – Unilateral location – Pulsating quality – Moderate or severe pain intensity – Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** o During headache at least one of the following:

– Nausea and/or vomiting – Photophobia and phonophobia
Migraine with aura • At least two attacks have the following: o One or more of the following fully reversible aura symptoms: – Visual – Sensory – Speech and/or language – Motor – Brainstem – Retinal; **AND** o At least three of the following characteristics: – At least one aura symptom spreads gradually over ≥5 minutes – Two or more symptoms occur in succession – Each individual aura symptom lasts 5 to 60 minutes – At least one aura symptom is unilateral – At least one aura symptom is positive (e.g., scintillations and pins and needles) – The aura is accompanied, or followed within 60 minutes, by headache

V. Renewal Criteria [1-66]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and indication specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (i.e., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, swallowing/breathing difficulties, etc.), severe hypersensitivity reactions, severe pulmonary effects (i.e., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, and urinary retention, etc.; **AND**
- Disease response as evidenced by the following:

Blepharospasms

- Improvement of severity and/or frequency of eyelid spasms

Cervical Dystonia

- Improvement in the severity and frequency of pain; **AND**
- Improvement of abnormal head positioning

Strabismus

- Improvement in alignment of prism diopters compared to pre-treatment baseline

Focal Upper/Lower Limb Spasticity

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (i.e., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Hemifacial Spasms

- Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face

Severe Primary Axillary Hyperhidrosis

- Significant reduction in spontaneous axillary sweat production; **AND**
- Patient has a significant improvement in activities of daily living

Prophylaxis for Chronic Migraines

- Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Improvement in function; **AND**
- Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.)

Esophageal achalasia

- Improvement and/or relief in symptoms (i.e., dysphagia, pain, etc.); **OR**
- Improvement in esophageal emptying as evidenced by functional testing

Focal Dystonias

- Focal upper limb dystonia
  - Improvement in pain and/or function
- Laryngeal dystonia
  - Improvement in voice function or quality
- Oromandibular dystonia
  - Improvement in pain and function

Sialorrhea associated with Neurological Disorders

- Significant decrease in saliva production

Incontinence due to Detrusor Overactivity

- Patient does not have a current, untreated urinary tract infection; **AND**

- Significant improvements in weekly frequency of incontinence episodes; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Overactive Bladder (OAB)

- Patient does not have a current, untreated urinary tract infection; **AND**
- Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Severe Palmar Hyperhidrosis

- Significant reduction in spontaneous palmar sweat production; **AND**
- Patient has a significant improvement in activities of daily living

Chronic Anal Fissure

- Complete healing of anal fissure; **OR**
- Symptomatic improvement of persistent fissures

Spastic Conditions, Other (Plegias, etc.)

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (i.e., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Ventral Hernia

- May not be renewed

Dosage/Administration

Indication	Dose
Blepharospasm	1.25-2.5 Units (0.05—0.1 ml per site) injected into each of 3 sites per affected eye every three months. There appears to be little benefit obtainable from injecting more than 5 Units per site. The effect of treatment lasts an average of 12 weeks. Cumulative dose in 30 days should not exceed 200 units
Cervical Dystonia	198 Units to 300 Units divided among the affected muscles. No more than 50 Units per site. May re-treat in 12 weeks.
Strabismus	Based on muscle(s) affected, 1.25-2.5 Units in any one muscle initially. Subsequent doses may be increased up to two-fold compared to previously administered dose. No more than 25 Units in any one muscle for recurrent cases. The effect of treatment usually lasts about 12 weeks.
Esophageal Achalasia	100 Units (20-25 Units per quadrant) per administration, dose may be repeated in 6 months (24 weeks)
Upper Limb Spasticity	Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of

Indication	Dose
	local muscle weakness, the patient's response to previous treatment, or adverse event history with Botox. For pediatrics, localization of the involved muscles with techniques such as needle electromyographic guidance, nerve stimulation, or ultrasound is recommended. Adults – In clinical trials, doses ranging from 75 Units to 400 Units were divided among selected muscles at a given treatment session. Re-treat,,no sooner than every 12 weeks. Pediatrics – The recommended dose for treating pediatric upper limb spasticity is 3 Units/kg to 6 Units/kg divided among the affected muscles. The total dose of Botox administered per treatment session in the upper limb should not exceed 6 Units/kg or 200 Units, whichever is lower. The maximum cumulative dose should not exceed the lower of 10 Units/kg body weight or 340 Units, in a 3-month interval.
Lower Limb Spasticity	Adults – 300 to 400 Units divided among 5 muscle groups (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).Re-treat,, no sooner than every 12 weeks. Pediatrics (Excluding Spasticity Caused by Cerebral Palsy) – The recommended dose for treating pediatric lower limb spasticity is 4 Units/kg to 8 Units/kg divided among the affected muscles. The total dose of Botox administered per treatment session in the lower limb should not exceed 8 Units/kg or 300 Units, whichever is lower. The maximum cumulative dose should not exceed the lower of 10 Units/kg body weight or 340 Units, in a 3-month interval.
Chronic Migraine	155 Units administered intramuscularly (IM) as 0.1 mL (5 Units) injections per each site. Injections should be divided across 7 specific head/neck muscle areas. The recommended re-treatment schedule is every 12 weeks.
Severe Primary Axillary Hyperhidrosis	50 Units intradermally per axilla every 16 weeks
Sialorrhea	15-40 Units in the parotid gland injected in two places and 10-15 Units in the submandibular glands (total dose from 50-100 Units per patient/administration), repeated in 3 months (12 weeks), if needed.
Neurogenic Bladder/Detrusor Overactivity	Adults 200 Units per treatment injected into the detrusor muscle using 30 injections (6.7 units each). Pediatrics Weight ≥ 34kg: 200 Units per treatment injected into the detrusor muscle using 20 injections. Weight < 34kg: 6 Units/kg per treatment injected into the detrusor muscle using 20 injections. ** Re-inject no sooner than 12 weeks from the prior bladder injection.
Overactive Bladder (OAB)	100 Units per treatment injected into the detrusor muscle using 20 injections (5 units each). Re-inject no sooner than 12 weeks from the prior bladder injection.
Palmar Hyperhidrosis	50-100 units per hand, repeated every 6 months (24 weeks), as needed
Hemifacial Spasms	Recommended dose of 12 to 40 U, divided among affected muscles. Retreatment within 12 weeks

Indication	Dose
Oromandibular Dystonia	80 units per side(~40 units injected into both the masseter and submentalis complex muscles) every 12 weeks.
Laryngeal Dystonia	Starting dose of 1.25-5 units into affected muscles. Dose may be titrated up to 25 units based on response and side effects.. Retreat every 3 months (12 weeks).
Chronic Anal Fissures	Recommended doses of up to 25 units, injected into the anal sphincter. Retreat every 3 months (12 weeks).
Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. *May not be renewed.*
All other indications (unless otherwise specified)	Not to exceed a cumulative dose of 400 Units (for one or more indications) every 12 weeks
– When initiating treatment, the lowest recommended dose should be used. – In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 Units, in a 3-month (12-week) interval (unless used for Ventral Hernia). – In treating pediatric patients, the total should not exceed the lower of 10 Units/kg body weight or 340 Units, in a 3-month (12-week) interval. – Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.	

VI. Billing Code/Availability Information

HCPCS Code:

- J0585 – Injection, onabotulinumtoxinA, 1 unit; 1 billable unit = 1 unit

NDC:

-
- Botox 100 unit powder for injection; single-dose vial: 00023-1145-xx
- Botox 200 unit powder for injection; single-dose vial: 00023-3921-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G11.4	Hereditary spastic paraplegia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.9	Dystonia, unspecified
G25.89	Other specified extrapyramidal and movement disorders
G35	Multiple sclerosis
G37.0	Diffuse sclerosis of central nervous system
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus

ICD-10	ICD-10 Description
G43.E19	Chronic migraine with aura, intractable, without status migrainosus
G51.3	Clonic hemifacial spasm
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.4	Ataxic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
G83.0	Diplegia of upper limbs
G83.10	Monoplegia of lower limb affecting unspecified side
G83.11	Monoplegia of lower limb affecting right dominant side
G83.12	Monoplegia of lower limb affecting left dominant side
G83.13	Monoplegia of lower limb affecting right nondominant side
G83.14	Monoplegia of lower limb affecting left nondominant side
G83.20	Monoplegia of upper limb affecting unspecified side
G83.21	Monoplegia of upper limb affecting right dominant side

ICD-10	ICD-10 Description
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
G83.4	Cauda equina syndrome
H49.00	Third [oculomotor] nerve palsy, unspecified eye
H49.01	Third [oculomotor] nerve palsy, right eye
H49.02	Third [oculomotor] nerve palsy, left eye
H49.03	Third [oculomotor] nerve palsy, bilateral
H49.10	Fourth [trochlear] nerve palsy, unspecified eye
H49.11	Fourth [trochlear] nerve palsy, right eye
H49.12	Fourth [trochlear] nerve palsy, left eye
H49.13	Fourth [trochlear] nerve palsy, bilateral
H49.20	Sixth [abducent] nerve palsy, unspecified eye
H49.21	Sixth [abducent] nerve palsy, right eye
H49.22	Sixth [abducent] nerve palsy, left eye
H49.23	Sixth [abducent] nerve palsy, bilateral
H49.30	Total (external) ophthalmoplegia, unspecified eye
H49.31	Total (external) ophthalmoplegia, right eye
H49.32	Total (external) ophthalmoplegia, left eye
H49.33	Total (external) ophthalmoplegia, bilateral
H49.40	Progressive external ophthalmoplegia, unspecified eye
H49.41	Progressive external ophthalmoplegia, right eye
H49.42	Progressive external ophthalmoplegia, left eye
H49.43	Progressive external ophthalmoplegia, bilateral
H49.881	Other paralytic strabismus, right eye
H49.882	Other paralytic strabismus, left eye
H49.883	Other paralytic strabismus, bilateral
H49.889	Other paralytic strabismus, unspecified eye
H49.9	Unspecified paralytic strabismus
H50.00	Unspecified esotropia
H50.011	Monocular esotropia, right eye
H50.012	Monocular esotropia, left eye
H50.021	Monocular esotropia with A pattern, right eye
H50.022	Monocular esotropia with A pattern, left eye

ICD-10	ICD-10 Description
H50.031	Monocular esotropia with V pattern, right eye
H50.032	Monocular esotropia with V pattern, left eye
H50.041	Monocular esotropia with other noncomitancies, right eye
H50.042	Monocular esotropia with other noncomitancies, left eye
H50.05	Alternating esotropia
H50.06	Alternating esotropia with A pattern
H50.07	Alternating esotropia with V pattern
H50.08	Alternating esotropia with other noncomitancies
H50.10	Unspecified exotropia
H50.111	Monocular exotropia, right eye
H50.112	Monocular exotropia, left eye
H50.121	Monocular exotropia with A pattern, right eye
H50.122	Monocular exotropia with A pattern, left eye
H50.131	Monocular exotropia with V pattern, right eye
H50.132	Monocular exotropia with V pattern, left eye
H50.141	Monocular exotropia with other noncomitancies, right eye
H50.142	Monocular exotropia with other noncomitancies, left eye
H50.15	Alternating exotropia
H50.16	Alternating exotropia with A pattern
H50.17	Alternating exotropia with V pattern
H50.18	Alternating exotropia with other noncomitancies
H50.21	Vertical strabismus, right eye
H50.21	Vertical strabismus, right eye
H50.22	Vertical strabismus, left eye
H50.30	Unspecified intermittent heterotropia
H50.311	Intermittent monocular esotropia, right eye
H50.312	Intermittent monocular esotropia, left eye
H50.32	Intermittent alternating esotropia
H50.331	Intermittent monocular exotropia, right eye
H50.332	Intermittent monocular exotropia, left eye
H50.34	Intermittent alternating exotropia
H50.40	Unspecified heterotropia
H50.411	Cyclotropia, right eye
H50.412	Cyclotropia, left eye

ICD-10	ICD-10 Description
H50.42	Monofixation syndrome
H50.43	Accommodative component in esotropia
H50.50	Unspecified heterophoria
H50.51	Esophoria
H50.52	Exophoria
H50.53	Vertical heterophoria
H50.54	Cyclophoria
H50.55	Alternating hyperphoria
H50.60	Mechanical strabismus, unspecified
H50.611	Brown's sheath syndrome, right eye
H50.612	Brown's sheath syndrome, left eye
H50.621	Inferior oblique muscle entrapment, right eye
H50.622	Inferior oblique muscle entrapment, left eye
H50.629	Inferior oblique muscle entrapment, unspecified eye
H50.631	Inferior rectus muscle entrapment, right eye
H50.632	Inferior rectus muscle entrapment, left eye
H50.639	Inferior rectus muscle entrapment, unspecified eye
H50.641	Lateral rectus muscle entrapment, right eye
H50.642	Lateral rectus muscle entrapment, left eye
H50.649	Lateral rectus muscle entrapment, unspecified eye
H50.651	Medial rectus muscle entrapment, right eye
H50.652	Medial rectus muscle entrapment, left eye
H50.659	Medial rectus muscle entrapment, unspecified eye
H50.661	Superior oblique muscle entrapment, right eye
H50.662	Superior oblique muscle entrapment, left eye
H50.669	Superior oblique muscle entrapment, unspecified eye
H50.671	Superior rectus muscle entrapment, right eye
H50.672	Superior rectus muscle entrapment,left eye
H50.679	Superior rectus muscle entrapment, unspecified eye
H50.681	Extraocular muscle entrapment, unspecified, right eye
H50.682	Extraocular muscle entrapment, unspecified, left eye
H50.689	Extraocular muscle entrapment, unspecified, unspecified eye
H50.811	Duane's syndrome, right eye
H50.812	Duane's syndrome, left eye

ICD-10	ICD-10 Description
H50.89	Other specified strabismus
H50.9	Unspecified strabismus
H51.0	Palsy (spasm) of conjugate gaze
H51.11	Convergence insufficiency
H51.12	Convergence excess
H51.20	Internuclear ophthalmoplegia, unspecified eye
H51.21	Internuclear ophthalmoplegia, right eye
H51.22	Internuclear ophthalmoplegia, left eye
H51.23	Internuclear ophthalmoplegia, bilateral
H51.8	Other specified disorders of binocular movement
H51.9	Unspecified disorder of binocular movement
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.041	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.042	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.043	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.044	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side

ICD-10	ICD-10 Description
I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified site
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side
I69.349	Monoplegia of lower limb following cerebral infarction affecting unspecified site
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side

ICD-10	ICD-10 Description
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site
I69.841	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side
I69.842	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side
I69.843	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side
I69.844	Monoplegia of lower limb following other cerebrovascular disease affecting left non-dominant side
I69.849	Monoplegia of lower limb following other cerebrovascular disease affecting unspecified site
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
I69.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
I69.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
I69.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side

ICD-10	ICD-10 Description
J38.3	Other diseases of vocal cords
K43.6	Other and unspecified ventral hernia with obstruction, without gangrene
K43.7	Other and unspecified ventral hernia with gangrene
K43.9	Ventral hernia without obstruction or gangrene
K11.7	Disturbances of salivary secretions
K22.0	Achalasia of cardia
K60.1	Chronic anal fissure
L74.510	Primary focal hyperhidrosis, axilla
L74.512	Primary focal hyperhidrosis, palms
M43.6	Torticollis
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder

Dual coding requirements:

- Primary G and M codes require a secondary G or I code in order to be payable

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): 6; K	**NCD/LCD/LCA Document (s):** A52848
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&bc=gAAAAAAAAAAA	

Jurisdiction(s): F	**NCD/LCD/LCA Document (s):** A57186
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57186&bc=gAAAAAAAAAAA&	

Jurisdiction(s): E	**NCD/LCD/LCA Document (s):** A57185
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57185&bc=gAAAAAAAAAAA&	

Jurisdiction(s): 5, 8	**NCD/LCD/LCA Document (s):** A57474
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&bc=gAAAAAAAAAAA	

Jurisdiction(s): 15	**NCD/LCD/LCA Document (s):** A56472
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56472&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): J & M	**NCD/LCD/LCA Document (s):** A56646
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56646&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): J & M	**NCD/LCD/LCA Document (s):** A56389
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56389&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 9; N	**NCD/LCD/LCA Document (s):** A57715
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57715&bc=gAAAAAAAAAAA&	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Botox was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Botox according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.