



Drugs and Biologicals: Botulinum Toxins

Revision: 1

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OnabotulinumtoxinA (Botulinum Toxin A) (Botox[®])
AbobotulinumtoxinA (Botulinum Toxin A) (Dysport[®])
IncobotulinumtoxinA (Botulinum Toxin A) (Xeomin[®])
RimabotulinumtoxinB (Botulinum Toxin B) (Myobloc[®])

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

OnabotulinumtoxinA (Botox[®]):

FDA

1. Blepharospasm, Associated with dystonia
2. Cervical dystonia
3. Headache; Prophylaxis - Migraine (Chronic)
4. Hyperhidrosis of axilla (Severe), In cases of primary disease that are inadequately managed by topical agents
5. Incontinence due to detrusor instability, Associated with a neurologic condition
6. Strabismus
7. Upper limb spasticity
8. Wrinkled face, Hyperfunctional

Off-Label

1. Achalasia
2. Anal fissure, chronic
3. Auriculotemporal syndrome
4. Backache
5. Benign prostatic hyperplasia



6. Bladder muscle dysfunction - overactive, Neurogenic
7. Cerebral palsy – Spasticity
8. Cervicogenic headache
9. Congenital esotropia
10. Detrusor and sphincter dyssynergia
11. Difficulty speaking - Disturbance in speech
12. Disorder of esophagus
13. Disorder of nervous system - Excessive salivation
14. Epicondylitis
15. Essential tremor
16. Excessive salivation - Parkinson's disease, Advanced
17. Excessive tear production
18. Fibromyalgia
19. Gilles de la Tourette's syndrome
20. Hemifacial spasm
21. Hemorrhoidectomy - Postoperative pain
22. Idiopathic trigeminal neuralgia, Refractory
23. Injury to oculomotor nerve (Acute)
24. Isolated oromandibular dystonia
25. Lower limb spasticity
26. Migraine, Episodic; Prophylaxis
27. Pelvic floor dyssynergia
28. Tardive dyskinesia
29. Temporomandibular joint disorder
30. Tension-type headache
31. Thoracic outlet syndrome
32. Whiplash injury to neck

AbobotulinumtoxinA (Dysport®):

FDA:

1. Spasmodic torticollis
2. Wrinkled face (Moderate to Severe), Hyperfunctional



Off-Label:

1. Achalasia, In patients who are surgical candidates
2. Blepharospasm
3. Cerebral palsy – Spasticity
4. Hemifacial spasm
5. Spasticity

IncobotulinumtoxinA (Xeomin[®]):

FDA:

1. Blepharospasm
2. Cervical dystonia
3. Rhytide of glabellar skin (Moderate to Severe)

RimabotulinumtoxinB (Myobloc[®]):

FDA

1. Spasmodic torticollis

Off-Label

1. Bladder muscle dysfunction – overactive
2. Excessive salivation, Medical condition-associated; Prophylaxis
3. Hyperhidrosis
4. Incontinence - Spinal cord injury
5. Migraine; Prophylaxis
6. Spastic dysphonia
7. Upper limb spasticity
8. Wrinkled face, Hyperfunctional

Coding Information:

HCPCS Code(s)

J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
J0586	INJECTION, ABOBOTULINUMTOXINA, 5 UNITS



J0587	INJECTION, RIMABOTULINUMTOXINB, 100 UNITS
J0588	INJECTION, INCOBOTULINUMTOXIN A, 1 UNIT

ICD-9 Codes that Support Medical Necessity

The correct use of an ICD-9-CM code listed in the "ICD-9 Codes that Support Medical Necessity" section does not guarantee coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this LCD.

ICD-9 codes must be coded to the highest level of specificity. Consult the 'Official ICD-9-CM Guidelines for Coding and Reporting' in the current ICD-9-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

Please Note: For HCPCS codes J0585 and J0586

333.6	GENETIC TORSION DYSTONIA
333.71	ATHETOID CEREBRAL PALSY
333.79	OTHER ACQUIRED TORSION DYSTONIA
333.81 - 333.85	BLEPHAROSPASM - SUBACUTE DYSKINESIA DUE TO DRUGS
333.89	OTHER FRAGMENTS OF TORSION DYSTONIA
334.1	HEREDITARY SPASTIC PARAPLEGIA
340	MULTIPLE SCLEROSIS
341.0	NEUROMYELITIS OPTICA
341.1	SCHILDER'S DISEASE

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341.20 - 341.22	ACUTE (TRANSVERSE) MYELITIS NOS - IDIOPATHIC TRANSVERSE MYELITIS
341.8	OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM
341.9	DEMYELINATING DISEASE OF CENTRAL NERVOUS SYSTEM UNSPECIFIED
342.10 - 342.12	SPASTIC HEMIPLEGIA AND HEMIPARESIS AFFECTING UNSPECIFIED SIDE - SPASTIC HEMIPLEGIA AND HEMIPARESIS AFFECTING NONDOMINANT SIDE
343.0 - 343.9	CONGENITAL DIPLEGIA - INFANTILE CEREBRAL PALSY UNSPECIFIED
344.00 - 344.5	QUADRIPLEGIA UNSPECIFIED - UNSPECIFIED MONOPLÉGIA
346.70 - 346.73	CHRONIC MIGRAINE WITHOUT AURA, WITHOUT MENTION OF INTRACTABLE MIGRAINE WITHOUT MENTION OF STATUS MIGRAINOSUS - CHRONIC MIGRAINE WITHOUT AURA, WITH INTRACTABLE MIGRAINE, SO STATED, WITH STATUS MIGRAINOSUS
351.8	OTHER FACIAL NERVE DISORDERS
378.00 - 378.08	ESOTROPIA UNSPECIFIED - ALTERNATING ESOTROPIA WITH OTHER NONCOMITANCIES
378.10 - 378.18	EXOTROPIA UNSPECIFIED - ALTERNATING EXOTROPIA WITH OTHER NONCOMITANCIES
378.20 - 378.24	INTERMITTENT HETEROTROPIA UNSPECIFIED - INTERMITTENT EXOTROPIA ALTERNATING
378.30 - 378.35	HETEROTROPIA UNSPECIFIED - ACCOMMODATIVE COMPONENT IN ESOTROPIA

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378.40 - 378.45	HETEROPHORIA UNSPECIFIED - ALTERNATING HYPERPHORIA
378.50 - 378.54	PARALYTIC STRABISMUS UNSPECIFIED - SIXTH OR ABDUCENS NERVE PALSY
378.60 - 378.63	MECHANICAL STRABISMUS UNSPECIFIED - LIMITED DUCION ASSOCIATED WITH OTHER CONDITIONS
378.71	DUANE'S SYNDROME
378.81 - 378.85	PALSY OF CONJUGATE GAZE - ANOMALIES OF DIVERGENCE
378.87	OTHER DISSOCIATED DEVIATION OF EYE MOVEMENTS
378.9	UNSPECIFIED DISORDER OF EYE MOVEMENTS
438.20 - 438.22	HEMIPLEGIA AFFECTING UNSPECIFIED SIDE - HEMIPLEGIA AFFECTING NONDOMINANT SIDE
438.30 - 438.32	MONOPLÉGIA OF UPPER LIMB AFFECTING UNSPECIFIED SIDE - MONOPLÉGIA OF UPPER LIMB AFFECTING NONDOMINANT SIDE
438.40 - 438.42	MONOPLÉGIA OF LOWER LIMB AFFECTING UNSPECIFIED SIDE - MONOPLÉGIA OF LOWER LIMB AFFECTING NONDOMINANT SIDE
478.75	LARYNGEAL SPASM
527.7	DISTURBANCE OF SALIVARY SECRETION
530.0	ACHALASIA AND CARDIOSPASM
564.6	ANAL SPASM
565.0	ANAL FISSURE

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705.21	PRIMARY FOCAL HYPERHIDROSIS
705.22	SECONDARY FOCAL HYPERHIDROSIS
723.5	TORTICOLLIS UNSPECIFIED
728.85	SPASM OF MUSCLE
754.1	CONGENITAL MUSCULOSKELETAL DEFORMITIES OF STERNOCLEIDOMASTOID MUSCLE
780.8	GENERALIZED HYPERHIDROSIS
784.40 - 784.42	VOICE AND RESONANCE DISORDER, UNSPECIFIED - DYSPHONIA
784.49	OTHER VOICE AND RESONANCE DISORDERS
V72.85*	OTHER SPECIFIED EXAMINATION
*V72.85 is to be used to code for 'intractable headache due to tension'	

Please Note: For HCPCS code J0585 only

596.54	NEUROGENIC BLADDER NOS
596.55	DETRUSOR SPHINCTER DYSSYNERGIA
788.31	URGE INCONTINENCE

Please Note: For HCPCS code J0587

333.83	SPASMODIC TORTICOLLIS
723.5	TORTICOLLIS UNSPECIFIED

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754.1	CONGENITAL MUSCULOSKELETAL DEFORMITIES OF STERNOCLEIDOMASTOID MUSCLE
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Please Note: For HCPCS code J0588

333.6	GENETIC TORSION DYSTONIA
333.71	ATHETOID CEREBRAL PALSY
333.79	OTHER ACQUIRED TORSION DYSTONIA
333.81	BLEPHAROSPASM
333.83	SPASMODIC TORTICOLLIS
333.85	SUBACUTE DYSKINESIA DUE TO DRUGS
333.89	OTHER FRAGMENTS OF TORSION DYSTONIA
334.1	HEREDITARY SPASTIC PARAPLEGIA
340	MULTIPLE SCLEROSIS
341.20- 341.22	ACUTE (TRANSVERSE) MYELITIS NOS - IDIOPATHIC TRANSVERSE MYELITIS
341.8	OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM
341.9	DEMYELINATING DISEASE OF CENTRAL NERVOUS SYSTEM UNSPECIFIED
342.10- 342.12	SPASTIC HEMIPLEGIA AND HEMIPARESIS AFFECTING UNSPECIFIED SIDE - SPASTIC HEMIPLEGIA AND HEMIPARESIS AFFECTING NONDOMINANT SIDE
343.0- 343.9	CONGENITAL DIPLEGIA - INFANTILE CEREBRAL PALSY UNSPECIFIED
344.00- 344.5	QUADRIPLEGIA UNSPECIFIED - UNSPECIFIED MONOPLÉGIA
438.20- 438.22	HEMIPLEGIA AFFECTING UNSPECIFIED SIDE - HEMIPLEGIA AFFECTING NONDOMINANT SIDE
438.30- 438.32	MONOPLÉGIA OF UPPER LIMB AFFECTING UNSPECIFIED SIDE - MONOPLÉGIA OF UPPER LIMB AFFECTING NONDOMINANT SIDE
438.40- 438.42	MONOPLÉGIA OF LOWER LIMB AFFECTING UNSPECIFIED SIDE - MONOPLÉGIA OF LOWER LIMB AFFECTING NONDOMINANT SIDE
527.7	DISTURBANCE OF SALIVARY SECRETION
705.21	PRIMARY FOCAL HYPERHIDROSIS
705.22	SECONDARY FOCAL HYPERHIDROSIS

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723.5	TORTICOLLIS UNSPECIFIED
728.85	SPASM OF MUSCLE
754.1	CONGENITAL MUSCULOSKELETAL DEFORMITIES OF STERNOCLEIDOMASTOID MUSCLE
780.8	GENERALIZED HYPERHIDROSIS

Diagnoses that Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity

Any ICD-9-CM code that is not listed in the "ICD-9 Codes that Support Medical Necessity" section of this LCD.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

N/A

Diagnoses that DO NOT Support Medical Necessity

Any diagnoses that are not listed in the "ICD-9 Codes that Support Medical Necessity" section of this LCD.

Indications and Limitations:

Because Botulinum Toxins (BT) are invasive, their use should be reserved for patients in whom a diagnosis has been established with reasonable certainty.

For most patients with these conditions BT promises significant but variable relief of symptoms that last for varying periods of time. Often times repeated injections are required for sustained relief of symptoms. Long-term effects of chronic BT therapy are unknown. Loss of response to repeated injections is seen and immunoresistance is thought to be one mechanism.

1. OnabotulinumtoxinA (Botulinum Toxin A) (Botox[®]) (J0585):

FDA: Treatment of:

- A. Upper limb spasticity in adult patients;
- B. Cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain;
- C. Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients;



- D. Blepharospasm associated with dystonia in patients ≥ 12 years of age;
- E. Strabismus in patients ≥ 12 years of age;
- F. Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer);
- G. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication

Off Label Use:

- H. Facial Spasm;
- I. Hemifacial Spasm;
- J. Spasmodic Dysphonia;
- K. Focal hand dystonia (Writers' Cramp);
- L. Chronic anal fissure refractory to conservative treatment;
- M. Esophageal achalasia patients in whom surgical treatment is not indicated;
- N. Frey's syndrome;
- O. Spasticity resulting from brain, spinal cord and other neurological diseases (e.g. Cerebral Palsy, CVA, traumatic brain injury, anoxic brain injury, Multiple Sclerosis, etc.) that results in pain and/or impaired activities of daily living (ADLs);
- P. Headache - Coverage for carefully-selected patients with intractable headache due to tension who have been refractory to standard and usual conventional therapy will be allowed. The medical literature now has more negative than positive studies for the use of botulinum toxin in the treatment of tension headache, however, research is ongoing. Reports in the literature, and from experienced clinicians, note response to therapy in some patients refractory to other standard therapy. For continuing botulinum toxin therapy, the patient must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin. *Note:* This indication is to be coded with ICD-9 code V72.85.
- Q. Sialorrhea

2. AbobotulinumtoxinA (Botulinum Toxin A) (Dysport[®]) (J0586):

FDA:



Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients

Off Label Use:

- A. Upper limb spasticity in adult patients;
- B. Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients;
- C. Blepharospasm associated with dystonia in patients ≥ 12 years of age;
- D. Strabismus in patients ≥ 12 years of age.
- E. Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
- F. Facial Spasm;
- G. Hemifacial Spasm;
- H. Spasmodic Dysphonia;
- I. Focal hand dystonia (Writers' Cramp);
- J. Chronic anal fissure refractory to conservative treatment;
- K. Esophageal achalasia patients in whom surgical treatment is not indicated;
- L. Frey's syndrome;
- M. Spasticity resulting from brain, spinal cord and other neurological diseases (e.g. Cerebral Palsy, CVA, traumatic brain injury, anoxic brain injury, Multiple Sclerosis, etc.) that results in pain and/or impaired activities of daily living (ADLs);
- N. Headache - Coverage for carefully-selected patients with intractable headache due to tension who have been refractory to standard and usual conventional therapy will be allowed. The medical literature now has more negative than positive studies for the use of botulinum toxin in the treatment of tension headache, however, research is ongoing. Reports in the literature, and from experienced clinicians, note response to therapy in some patients refractory to other standard therapy. For continuing botulinum toxin therapy, the patient must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin. Note: This indication is to be coded with ICD-9 code V72.85.
- O. Sialorrhea

3. IncobotulinumtoxinA (Botulinum Toxin A) (Xeomin[®]) (J0588)

FDA: Treatment of



- A. Adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients;
 - B. Blepharospasm in adults previously treated with onabotulinumtoxinA (Botox[®]).
4. RimabotulinumtoxinB (Botulinum Toxin B) (Myobloc[®]) (J0587):
- FDA:**
Treatment of adults with cervical dystonia to reduce the severity of abnormal Head position and neck pain associated with cervical dystonia.
- Off Label Use:**
Myobloc[®] will be covered for the same indications as Botox[®]/Dysport[®] when documentation supports the patient is unresponsive to Botox[®]/Dysport[®].

Limitations

- 1. Treatment for cosmetic reasons such as craniofacial wrinkles will not be covered.
- 2. Medicare will allow payment for one injection per each functional muscle group/anatomical site regardless of the number of injections made into each group/site or the number of muscles that comprise the functional group.
- 3. Botulinum toxin treatment is not indicated for patients:
 - A. receiving aminoglycosides, which may interfere with neuromuscular transmission; or
 - B. with chronic paralytic strabismus, except to reduce antagonist contractor in conjunction with surgical repair.
- 4. Botulinum toxin is not recommended for patients with:
 - A. strabismus, when angles are over 50 prism diopters;
 - B. restrictive strabismus;
 - C. Duane's syndrome with lateral rectus weakness; or
 - D. secondary strabismus caused by prior surgical over-recession of the antagonist.
- 5. OnabotulinumtoxinA (Botulinum Toxin A) (Botox[®]) and AbobotulinumtoxinA (Botulinum Toxin A) (Dysport[®]) are not indicated for patients with new onset headache. Please refer to FDA Indications and Off Label Use for these products.

Background:

Botulinum toxin, a protein and neurotoxin produced by *Clostridium botulinum*, blocks release of acetylcholine from nerve endings.



Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

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8. Myobloc[®] [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc; 2009.
9. Xeomin[®] [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; 2011.

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