Botulinum Toxin

Disclaimer

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The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member’s plan contracts, state laws, and federal laws. Please reference the member’s plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Botulinum toxins are injectable medications that block the nerves controlling muscle function. Paralysis of the targeted muscles typically occurs within 2 to 5 days and lasts for 2 to 3 months. There are seven different types (A-G) of Botulinum toxin, but only types A and B are approved for clinical use. This medication class can be used to treat muscle spasms or muscle overactivity seen in a number of neurological conditions, such as cerebral palsy, stroke, and spinal cord disorders. Botulinum toxins can also be used for cosmetic purposes, such as for decreasing wrinkles, however cosmetic use is not covered by Oscar. Botulinum toxin preparations must be prescribed and administered by a licensed physician or medical provider.

Definitions

“Botulinum Toxins” refer to the seven serologically distinct neurotoxins derived from the bacterium Clostridium botulinum. These agents differ in their synthesis and the specific bacterium strain from which they are isolated. Botulinum toxins function by inhibiting acetylcholine release at the neuromuscular junction to cause flaccid paralysis of muscles. The four preparations that are currently approved for clinical use are:

1. “AbobotulinumtoxinA” (Dysport) - a type A botulinum toxin
2. “OnabotulinumtoxinA” (Botox) - a type A botulinum toxin
3. “IncobotulinumtoxinA” (Xeomin) - a type A botulinum toxin
“RimabotulinumtoxinB” (Myobloc) - a type B botulinum toxin

“Muscle Spasms” refer to the involuntary contractions of one or more muscles.

“Sialorrhea” (also known as “Ptyalism”) refers to excess salivation or drooling.

“Cervical Dystonia” (also known as “Spasmodic Torticollis”) refers to painful contraction of the neck muscles causing twisting or tilting of the head to one side.

“Hyperhidrosis” refers to inappropriate, excessive sweating.

“Blepharospasm” refers to uncontrolled blinking or spasms of the eyelids.

“Detrusor Hyperactivity” (also known as “Bladder Overactivity”) refers to spasms of the bladder muscles resulting in pain or incontinence.

“Achalasia” is failed relaxation of the lower esophageal sphincter resulting in painful spasms and/or regurgitation of food.

Clinical Indications and Coverage

OnabotulinumtoxinA (Botox) (J0585)
Oscar covers OnabotulinumtoxinA (Botox) for the following indications when the disease-specific criteria below are met:

A. Achalasia, when ALL of the following are met:
   a. Confirmed diagnosis with esophageal manometry; and
   b. Presence of progressive dysphagia to solids and liquids; and
   c. Pneumatic dilation or surgical myotomy has been attempted but was unsuccessful, or the member was not a good candidate for the procedure, or the member refused treatment; and
   d. Contraindication or lack of response to appropriate pharmacologic treatment (e.g. calcium channel antagonists, long-acting nitrates); and
   e. Alternative causes of the symptoms (e.g. esophageal stricture, carcinoma, schatzki’s ring, or extrinsic compression), have been ruled out by upper endoscopy and/or adequately treated.
B. Chronic anal fissure, when ALL of the following are met:
   a. At least 2 months of symptoms, including ONE or more of the following:
      i. Nocturnal pain and bleeding; or
      ii. Post-defecation pain.
   b. Failure of topical nitrates or contraindication to their use; and
   c. The member is not a surgical candidate or has refused surgery; and
   d. None of the following features are present:
      i. Anal fistula; or
      ii. Hemorrhoids; or
      iii. HIV; or
      iv. Inflammatory bowel disease; or
      v. Perianal abscess; or
      vi. Perianal cancer; or
      vii. Prior perianal surgical intervention.

C. Blepharospasm, when ALL of the following are met:
   a. Documented diagnosis of ONE or more of the following:
      i. Benign essential blepharospasm; or
      ii. Blepharospasm associated with dystonia; or
      iii. Blepharospasm associated with facial nerve disorders such as Bell palsy.
   b. Alternative causes of the symptoms have been ruled out or adequately treated,
      including but not limited to neuromuscular diseases (e.g. myasthenia gravis).

D. Hemifacial spasm, when ALL of the following are met:
   a. Documented diagnosis of hemifacial spasm in muscles innervated by the facial nerve
      (cranial nerve VII); and
   b. Alternative causes of the symptoms have been ruled out or adequately treated,
      including but not limited to neuromuscular diseases (e.g. myasthenia gravis).

E. Cervical dystonia (i.e. spasmodic torticollis), when ALL of the following are met:
   a. Neck pain or abnormal head positioning adversely affects daily functioning; and
   b. There are documented involuntary contractions in the neck muscles (e.g. splenius,
      trapezius, posterior cervical, or sternocleidomastoid); and
   c. Alternative causes of the symptoms have been ruled out or adequately treated,
      including but not limited to:
      i. Neuromuscular disease (e.g. myasthenia gravis); or
      ii. Chronic neuroleptic treatment; or
      iii. Fixed muscle contractures.
   d. Symptoms have been present for at least 6 months.
F. Axillary hyperhidrosis, when ALL of the following are met:
   a. Conservative treatment has failed, is contraindicated, or was not tolerated. Conservative treatment included both topical and oral therapy:
      i. Topical aluminum chloride or extra-strength antiperspirants; and
      ii. Appropriate pharmacotherapy (e.g. beta blockers, anticholinergics, and/or benzodiazepines).
   b. Significant disruption in professional and/or social functioning has occurred because of excessive sweating; and
   c. Alternative causes of the symptoms (e.g. hyperthyroidism, lifestyle factors), have been ruled out or adequately treated.

G. Laryngeal dystonia, when ALL of the following are met:
   a. Moderate to severe phonation difficulties; and
   b. Adductor-type spasmodic dysphonia confirmed by fiberoptic laryngoscopy.

H. Migraine headache prophylaxis, when ALL of the following are met:
   a. Diagnosis of migraine headache per International Classification of Headache Disorders criteria, defined as meeting ALL of the following criteria:
      i. Headache is characterized by at least TWO of the following:
         1. Pulsating quality; or
         2. Unilateral; or
         3. Moderate to severe pain; or
         4. Aggravated by physical activity.
      ii. Symptoms are associated with at least ONE of the following:
         1. Nausea and/or vomiting; or
         2. Photobobia (sensitivity to light) and phonophobia (sensitivity to sound).
      iii. Other potential causes of headache have been ruled out.
   b. The migraine headaches meet the definition of chronic, defined as occurring for at least 4 hours per day, at a minimum of 15 days per month, and for 3 or more months; and
   c. There is no neuromuscular disease (e.g. myasthenia gravis); and
   d. Failure of at least 3 total medications from two different classes of migraine prophylaxis medications and at least 60 days duration for each medication. Classes include:
      i. Beta blockers
      ii. Tricyclic antidepressants
      iii. Antiepileptics
      iv. Calcium channel blockers
      v. ACE- or ARB-inhibitors.
I. Motor tics, when ALL of the following are met:
   a. Failure to respond to conservative therapy with at least two different neuroleptics; and
   b. The tics are severe enough to interfere with daily functioning.

J. Neurogenic urinary incontinence, neurogenic detrusor overactivity, or detrusor sphincter dyssynergia, when ALL of the following are met:
   a. The condition is secondary to spinal cord injury or neurologic disease (e.g. multiple sclerosis); and
   b. Conservative therapy with at least one appropriately dosed anticholinergic medications has failed or was contraindicated; and
   c. Documented failure of behavioral therapy; and
   d. No acute urinary retention unless the patient is receiving intermittent catheterization as part of the overall treatment plan; and
   e. No acute urinary tract infection; and
   f. Balloon sphincter dilation or surgical treatment has been attempted but was unsuccessful, or the member was not a candidate due to comorbidities, or the member refused surgery.

K. Overactive bladder with urge incontinence, when ALL of the following are met:
   a. Conservative therapy with at least three appropriately dosed, prescription anticholinergic medications has failed or was contraindicated; and
   b. Documented failure of behavioral therapy; and
   c. No acute urinary retention; and
   d. No acute urinary tract infection; and
   e. Urodynamic testing confirms urge urinary incontinence.

L. Raynaud’s syndrome, when ALL of the following are met:
   a. Non-pharmacologic treatment including behavioral intervention, avoidance of sympathomimetic medications, and smoking cessation have failed to resolve symptoms; and
   b. Medical treatment with an adequate trial oral (e.g. calcium channel blockers, PDE5 inhibitors) and topical agents (e.g. nitrates) has failed to improve symptoms; and
   c. IV prostaglandin therapy has failed to improve symptoms of digital ischemia.

M. Sialorrhea, when ALL of the following are met:
   a. Caused by neurological disease (such as Amyotrophic Lateral Sclerosis or Parkinson’s disease or Cerebral Palsy); and
   b. Refractory to two months of continuous, appropriate pharmacotherapy (e.g. oral anticholinergics); and
c. Documented complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications.

N. Spasticity, when BOTH of the following criteria are met:
   a. The member is characterized by ONE of the following:
      i. Children greater than the age of 2 with spasticity due to cerebral palsy who are receiving ongoing rehabilitation; or
      ii. Adult members with spasticity secondary to my multiple sclerosis or other demyelinating diseases of the central nervous system; or
      iii. Adults members with post-stroke spasticity of the upper or lower extremity.
   b. The member meets ALL of the following:
      i. Documentation of abnormal muscle tone that interferes with daily functioning or is expected to result in joint contracture with further growth; and
      ii. Surgical intervention is the only alternative option; and
      iii. Appropriate non-surgical medical treatment has failed; and
      iv. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation.

O. Strabismus, when ALL of the following are met:
   a. The deviation is a maximum of 50 prism diopters; and
   b. The strabismus is not primarily due to any of the following:
      i. Duane syndrome with lateral rectus muscle weakness; or
      ii. Restrictive strabismus; or
      iii. Prior surgical over-recession of antagonist orbital musculature.

P. Upper extremity focal dystonia (e.g. writer’s cramp), when ALL of the following are met:
   a. No prior surgical intervention; and
   b. Conservative therapy and/or lifestyle modification has failed; and
   c. Significant pain and/or abnormal hand or forearm positioning that adversely affects daily functioning.

AbobotulinumtoxinA (Dysport) (J0586)
Oscar covers AbobotulinumtoxinA (Dysport) for the following indications when the disease-specific criteria below are met:

A. Blepharospasm or hemifacial spasms, when ALL of the following are met:
   a. Documented diagnosis of ONE or more of the following:
      i. Benign essential blepharospasm; or
      ii. Blepharospasm associated with dystonia; or
      iii. Hemifacial spasm involving the orbicularis oculi muscle.
b. Alternative causes of the symptoms have been ruled out or adequately treated, including, but not limited to, neuromuscular diseases (e.g. myasthenia gravis).

B. Cervical dystonia (i.e. spasmodic torticollis) when ALL of the following are met:
   a. Neck pain or abnormal head positioning adversely affects daily functioning; and
   b. There are documented involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); and
   c. Alternative causes of the symptoms have been ruled out or adequately treated, including, but not limited to:
      i. Neuromuscular disease (e.g. myasthenia gravis); or
      ii. Chronic neuroleptic treatment; or
      iii. Fixed muscle contractures.
   d. Symptoms have been present for at least 6 months.

C. Axillary hyperhidrosis, when ALL of the following are met:
   a. Conservative treatment has failed, is contraindicated, or was not tolerated. Conservative treatment included both topical and oral therapy:
      i. Topical aluminum chloride or extra-strength antiperspirants; and
      ii. Appropriate pharmacotherapy (e.g. beta blockers, anticholinergics, and/or benzodiazepines).
   b. Significant disruption in professional and/or social functioning has occurred because of excessive sweating; and
   c. Alternative causes of the symptoms (e.g. hyperthyroidism, lifestyle factors), have been ruled out or adequately treated.

D. Sialorrhea, when ALL of the following are met:
   a. Caused by neurological disease (e.g. Amyotrophic Lateral Sclerosis or Parkinson’s disease or Cerebral Palsy); and
   b. Refractory to two months of continuous, appropriate pharmacotherapy (e.g. oral anticholinergics); and
   c. Documented complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents and/or lifestyle modifications.

E. Spasticity, when BOTH of the following criteria are met:
   a. The member can be characterized into ONE of the following:
      i. Children greater than the age of 2 with spasticity due to cerebral palsy who are receiving ongoing rehabilitation; or
      ii. Adult members with spasticity secondary to multiple sclerosis or other demyelinating diseases of the central nervous system; or
      iii. Adults members with post-stroke spasticity of the upper or lower extremity.
b. The member meets **ALL** of the following:
   i. Documentation of abnormal muscle tone that interferes with daily functioning or is expected to result in joint contracture with further growth; **and**
   ii. Surgical intervention is the only alternative option; **and**
   iii. Appropriate non-surgical medical treatment has failed; **and**
   iv. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation.

F. Upper extremity focal dystonia (e.g. writer’s cramp), when **ALL** of the following are met:
   a. No prior surgical intervention; **and**
   b. Failure of at least two months of conservative therapy and/or lifestyle modification; **and**
   c. Significant pain and/or abnormal hand or forearm positioning that adversely affects daily functioning.

RimabotulinumtoxinB (Myobloc) (J0587)
Oscar covers RimabotulinumtoxinB (Myobloc) for the following indications when the disease-specific criteria below are met:

A. Cervical dystonia (i.e. spasmodic torticollis), when **ALL** of the following are met:
   a. Neck pain or abnormal head positioning adversely affects daily functioning; **and**
   b. There are documented involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); **and**
   c. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
      i. Neuromuscular disease (e.g. myasthenia gravis); **or**
      ii. Chronic neuroleptic treatment; **or**
      iii. Fixed muscle contractures.
   d. Symptoms have been present for at least 6 months.

B. Sialorrhea, when **ALL** of the following are met:
   a. Caused by neurological disease (e.g. Amyotrophic Lateral Sclerosis or Parkinson's disease or cerebral palsy); **and**
   b. Refractory to two months of continuous, appropriate pharmacotherapy (e.g. oral anticholinergics); **and**
   c. Documented complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications.
IncobotulinumtoxinA (Xeomin) (J0588)

Oscar covers IncobotulinumtoxinA (Xeomin) for the following indications when the disease-specific criteria below are met:

A. Blepharospasm or hemifacial spasms, when ALL of the following are met:
   a. Documented diagnosis of benign essential blepharospasm, dystonia, or hemifacial spasm involving the orbicularis oculi muscle; and
   b. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to neuromuscular diseases (e.g. myasthenia gravis).

B. Cervical dystonia (i.e. spasmodic torticollis), when ALL of the following are met:
   a. Neck pain or abnormal head positioning adversely affects daily functioning; and
   b. There are documented involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); and
   c. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
      i. Neuromuscular disease (e.g. myasthenia gravis); or
      ii. Chronic neuroleptic treatment; or
      iii. Fixed muscle contractures.
   d. Symptoms have been present for at least 6 months.

C. Spasticity of the upper limb in adults when ALL of the following are met:
   a. Documentation of abnormal muscle tone that interferes with daily functioning; and
   b. Surgical intervention is the only alternative option; and
   c. Appropriate non-surgical medical treatment has failed; and
   d. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation.

Continued Care

Criteria for Continuing Treatment After Initial Trial

Continuing treatment with botulinum toxin, except as outlined for specific conditions elsewhere, is considered medically necessary and covered by Oscar when, at the end of the initial trial period:

A. There is a documented positive response in the medical record (the response should generally last 3 months); and

B. The member continues to meet the clinical criteria for the specific botulinum toxin agent; and

C. The prescribing clinician provides an expected duration and frequency of ongoing treatment, which may require ongoing approval (Note: It is generally NOT considered medically necessary to provide botulinum toxin treatments more frequently than every 3 months for a covered condition, regardless of diagnosis).
**General Recommendations for Time to Retreatment**

Assuming all other clinical criteria continue to be met, the following are general recommendations for time to retreatment with botulinum toxin agents. These durations may vary by individual member but should not occur more frequently than every 3 months. Requests for injection frequency more often than specified below should be accompanied with documentation of medical necessity:

1. **Botox:**
   - a. Blepharospasm - 3 months
   - b. Cervical dystonia - 3 months
   - c. Spasticity in children with cerebral palsy - 3 months
   - d. Axillary hyperhidrosis - 4 months
   - e. Spasmodic dysphonia - 3 months
   - f. Strabismus - 3 months
   - g. Upper limb spasticity - 3 months
   - h. Chronic migraine - 3 months
   - i. Hemifacial spasm - 3 months
   - j. Achalasia - 3 months
   - k. Focal hand dystonia - 3 months
   - l. Sialorrhea - 3 months
   - m. Urinary incontinence due to detrusor overactivity secondary to neurologic condition - 6-12 months
   - n. Overactive bladder - 3-6 months

2. **Dysport:**
   - a. Cervical dystonia - 3 months
   - b. Upper limb spasticity - 3 months
   - c. Pediatric lower limb spasticity - 3 months

3. **Mybloc**
   - a. Cervical dystonia - 3-4 months

4. **Xeomin**
   - a. Blepharospasm - 3 months
   - b. Upper limb spasticity - 3 months

*Note*: when not specifically mentioned above, frequency should not exceed 3 months regardless of the indication.

**Criteria for Discontinuing Treatment**

Botulinum toxin treatment is generally no longer covered and should be discontinued, except as outlined for specific conditions elsewhere, when the following criteria are met:
A. Lack of documented clinical response after initial trial; or
B. In cases where initial trial was successful, lack of documented clinical response to two consecutive treatments precludes treatment at that site for a period of at least one year.

For botulinum toxin injection for migraine headaches meeting the above clinical criteria, continuing treatment is considered medically necessary and covered by Oscar when, at the end of the initial trial period:

A. The frequency of migraine headaches was reduced by at least 7 days over a one month period compared to the pre-treatment average; or
B. The duration of migraine headaches was reduced by at least 100 hours total over a one month period compared to the pre-treatment average.

*Note: the trial period for migraine headaches is defined as 6 months or a maximum of 2 treatments.

Coverage Exclusions

General Exclusions
All botulinum toxin preparations (regardless of type) are considered contraindicated, experimental, investigational, or unproven, and thus not covered, in the following cases:

1. Infection at the proposed injection site
2. Known hypersensitivity to any botulinum toxin preparation or the components in the formulation
3. Retreatment of a condition with the same or different agent after a failed initial trial, regardless of if the member continues to meet clinical criteria. Note: If the member initially failed therapy due to an agent-specific intolerance or reaction, rather than a clinical feature, then this statement may not apply
4. **ALL** cosmetic purposes

Botulinum toxin antibody assays are considered experimental, investigational, or unproven, and thus not covered by Oscar.

AbobotulinumtoxinA (Dysport) (J0586)
The use of AbobotulinumtoxinA (Dysport) for any other indication not listed above is **not covered** by Oscar, as it is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

A. Anal fissure
   a. **Rationale for non-coverage:** A study comparing 100 patients randomized to Dysport/Botox versus topical nitrates for anal fissures demonstrated greater rates of healing in the botulinum toxin group, however the efficacies for the two types of toxins
were not individually reported. The current evidence is insufficient to support Dysport for this indication.¹

B. Benign prostatic hypertrophy (BPH)
   a. *Rationale for non-coverage:* A 2011 review article on abobotulinumtoxinA for lower urinary tract symptoms related to BPH concluded that the level of evidence is low and further randomized controlled trials are necessary.²

C. Charcot-Marie-Tooth disease³

D. Chronic musculoskeletal and myofascial pain
   a. *Rationale for non-coverage:* A systematic review of the available randomized trials found lack of efficacy for Dysport in myofascial pain syndromes.⁴

E. Headaches, including migraines, tension headaches, or headaches secondary to cranial neuralgia
   a. *Rationale for non-coverage:* A prospective, multi-center, randomized, double-blind placebo-controlled trial found no significant difference between placebo and Dysport in headache free days (primary outcome) among patients suffering from chronic migraine.⁵⁻⁶

F. Hyperhidrosis, other than axillary hyperhidrosis
   a. *Rationale for non-coverage:* An expert review by the American Academy of Neurology concluded that the evidence for Dysport in palmar hyperhidrosis was inadequate to guide clinical decision making.⁷

G. Sialorrhea in children
   a. *Rationale for non-coverage:* A Cochrane review and a separate systematic review on children with excessive salivation/drooling associated with cerebral palsy concluded that the evidence is insufficient to determine the efficacy of AbobotulinumtoxinA in this patient group.⁸⁻⁹

H. Lateral epicondylitis²²
I. Obesity²³
J. Plantar fasciitis²⁴
K. Postnatal brachial plexus injury²⁵
L. Refractory interstitial cystitis²⁶
M. Shoulder pain
N. Strabismus²⁷⁻²⁸
O. Tardive dyskinesia
P. Carpal tunnel syndrome²⁹
Q. Trigeminal neuralgia³⁰
R. Achalasia or upper esophageal sphincter dysfunction³¹
S. AbobotulinumtoxinA (Dysport) is contraindicated in members with allergy to cow’s milk protein, per FDA guidelines.

OnabotulinumtoxinA (Botox) (J0585)
The use of OnabotulinumtoxinA (Botox) for any other indication not listed above is not covered by Oscar, as it is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

A. Hyperhidrosis, other than axillary
   a. Rationale for non-coverage: An expert review by the American Academy of Neurology concluded that the evidence for Botox in palmar hyperhidrosis was inadequate to guide clinical decision making. For craniofacial hyperhidrosis, an UpToDate review on “Primary Focal Hyperhidrosis” highlights an overall lack of randomized evidence for botulinum toxin therapy in craniofacial hyperhidrosis. Further evidence on hyperhidrosis for non-axillary sites is limited and insufficient to guide clinical decision making.1-12

B. Sialorrhea in children
   a. Rationale for non-coverage: A Cochrane review and a separate systematic review on children with excessive salivation/drooling associated with cerebral palsy concluded that the evidence is insufficient to determine the efficacy of botulinum toxin therapy in this patient group.13-14

C. Anal sphincter achalasia
   a. Rationale for non-coverage: A 2012 meta-analysis on 16 nonrandomized studies examining Botox for internal anal sphincter achalasia revealed significantly higher rates of non-response and adverse outcomes when compared to myectomy. Further evidence is required to determine a potential benefit of Botox therapy in this patient population.15

D. BPH with lower urinary tract symptoms
   a. Rationale for non-coverage: A randomized trial on 380 men with BPH and lower urinary tract symptoms who were assigned to either Botox or placebo revealed no significant difference between the two groups. Multiple reviews have found a lack of randomized evidence demonstrating efficacy for this indication.16-19

E. Chronic pain, including, but not limited to: myofascial pain syndrome, inflammatory pain, musculoskeletal pain (including acute shoulder and back pain), post-herpetic neuralgia, gynecologic pain syndromes
   a. Rationale for non-coverage: Multiple systematic reviews and meta-analyses have concluded that the current evidence is inadequate to support the use of Botox in chronic pain syndromes.20-27
F. Club foot (e.g. talipes equinovarus)
   a. **Rationale for non-coverage:** The existing evidence consists of a small (n=20) randomized trial showing no benefit with Botox in reducing cast time, need for further procedural intervention, or risk for relapse. A separate, larger study with 239 patients found some evidence of efficacy for Botox, however the study was designed as a retrospective case series. Further randomized, prospective evidence is needed to determine a potential benefit of Botox for this indication.\(^{28,29}\)

G. Trigeminal neuralgia
   a. **Rationale for non-coverage:** The current evidence is either uncontrolled or nonrandomized with small patient samples. Review articles have suggested there may be some efficacy for Botox in trigeminal neuralgia but indicate that further study is needed.\(^{30-32}\)

H. Gastroparesis
   a. **Rationale for non-coverage:** Systematic review and expert consensus has concluded that there is minimal evidence for Botox in gastroparesis.\(^{33-34}\)

I. Frey Syndrome (i.e. Gustatory sweating)
   a. **Rationale for non-coverage:** A 2013 evidence-based review concluded that the lack of randomized clinical evidence for Botox in Frey’s syndrome limits the support for clinical use.\(^{35-36}\)

J. Migraines or other headaches (e.g. tension, cluster, chronic daily) that do not meet the above criteria
   a. **Rationale for non-coverage:**
      i. A 2012 meta-analysis found that botulinum toxin A was not associated with fewer episodic migraines or chronic tension headaches.\(^{92}\)
      ii. Per the 2016 American Academy of Neurology guidelines on botulinum neurotoxin for headaches:\(^{11}\)
         1. No conclusions could be made for chronic daily headache;
         2. “OnaBoNT-A should not be offered as a treatment option for episodic migraine (Level A).” Episodic migraine is defined as fewer than 15 episodes per month.
         3. “OnaBoNT-A should not be considered as a treatment option for tension-type headache (Level B).”

K. Obesity\(^{93-94}\)
L. Phonic tics\(^{95}\)
M. Acute and chronic back pain
N. Cosmetic strabismus, defined as adults with congenital strabismus without binocular fusion.
O. Chronic idiopathic constipation (CIC)

P. Plantar fasciitis

Q. Depression

R. Postnatal brachial plexus injury

S. Refractory interstitial cystitis

T. Carpal tunnel syndrome

U. Tremor, including benign essential tremor of the hands, head and vocal tremors

V. Tardive dyskinesia

W. Thoracic outlet syndrome

X. Upper esophageal sphincter dysfunction

Y. Painful bruxism

Z. Acute and chronic shoulder pain

AA. First-bite syndrome, with or without pain that has failed traditional analgesics

BB. Palatal myoclonus

CC. Post-radiation myokymia, including facial myokymia and trismus

**IncobotulinumtoxinA (Xeomin) (J0588)**

The use of IncobotulinumtoxinA (Xeomin) for any other indication not listed above is not covered by Oscar, as it is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

A. Hyperhidrosis, including axillary, palmar, and craniofacial
   a. **Rationale for non-coverage:** Xeomin and Botox were compared in a double-blind trial in treating palmar hyperhidrosis. There were no significant differences in short- or long-term efficacy outcomes, however only 25 patients were included in the study. Given the small sample size and lack of confirmatory studies, further evidence is required. Similar limitations are present in comparable studies on axillary hyperhidrosis. Further evidence is needed to determine a potential benefit of Xeomin for this indication.

B. Migraine prophylaxis
   a. **Rationale for non-coverage:** The evidence for Xeomin in migraine prophylaxis comes from small, retrospective case series and poster presentations, indicating further prospective, randomized evidence is required to guide any potential clinical application.

C. Detrusor hyperactivity (e.g. bladder overactivity)
   a. **Rationale for non-coverage:** There is limited evidence on Xeomin in patients with overactive bladder. Preliminary results on 95 patients from a double-blinded study on Xeomin and Botox in bladder overactivity were presented at the 27th Annual Congress of the European Association of Urology. However, further peer-reviewed randomized evidence is currently lacking, limiting guidance for clinical application.
D. Post-stroke lower limb spasticity
   a. Rationale for non-coverage: A prospective, open label study on 71 patients demonstrated safety and efficacy of Xeomin in post-stroke lower limb spasticity, however further randomized studies are required to establish clinical use. Furthermore, the 2016 American Academy of Neurology Guidelines state that there “is insufficient evidence to support or refute the use of incosBoNT-A for the treatment of lower limb spasticity.” 8, 22

E. Sialorrhea
   a. Rationale for non-coverage: A recent meta-analysis and randomized double-blind placebo-controlled cross-over study on sialorrhea in Parkinson’s disease patients revealed minimal efficacy, and the authors concluded that further studies should be conducted. The clinical evidence for Xeomin in sialorrhea is insufficient to determine any potential clinical benefit. 9

F. Atrial fibrillation 10

G. Spasticity in children with cerebral palsy
   a. Rationale for non-coverage: A single randomized, double-blind trial assessing safety of Xeomin in 35 children with spasticity due to cerebral palsy demonstrated a similar safety profile to Botox, however further studies with greater patient populations are indicated to determine potential clinical benefit. 11

RimabotulinumtoxinB (Myobloc) (J0587)
The use of RimabotulinumtoxinB (Myobloc) for any other indication not listed above is not covered by Oscar, as it is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

A. Bladder dysfunction (e.g. overactive bladder, detrusor hyperreflexia)
   a. Rationale for non-coverage: The evidence has been contradictory or inconclusive, with some studies showing RimabotulinumtoxinB efficacy while others have demonstrated a lack of benefit. A 2011 Cochrane review (updating the previous 2007 review) identified 19 studies meeting inclusion criteria, and found that the efficacy of RimabotulinumtoxinB was inferior to that of type A toxins with a substantially shorter duration of benefit across randomized trials for bladder dysfunction. 1-4

B. Hyperhidrosis;
   a. Rationale for non-coverage: The clinical evidence for RimabotulinumtoxinB (type B agent) is substantially limited compared to type A agents. The literature consists primarily of one randomized trial comparing RimabotulinumtoxinB and OnabotulinumtoxinA in 24 patients with axillary hyperhidrosis that shows comparable anhidrotic effect. Other studies are similarly limited in sample size and the general
consensus indicates that long-term, larger studies are needed to determine potential clinical benefit.\textsuperscript{5-9}

C. Spasticity in adults, including post-stroke spasticity and spasticity of the upper and/or lower extremities associated with other neurological disorders
   a. Rationale for non-coverage: The clinical evidence for RimabotulinumtoxinB (type b agent) is substantially limited compared to type A agents. A single randomized trial on 24 patients showed possible improvements with RimabotulinumtoxinB but concluded that larger studies with long-term follow up were needed for further evidence. The US Pharmacopeial Convention has stated that off-label use of RimabotulinumtoxinB for spasticity secondary to stroke or brain injury may be indicated, however updated data has failed to demonstrated the statistically significant benefit seen in earlier studies. The American Academy of Neurology currently states (per 2016 guidelines), that the data is insufficient to determine the efficacy of Myobloc in lower limb spasticity, and the evidence is limited to a single Class I study for upper limb spasticity.\textsuperscript{10-13}

D. Spasticity in children with cerebral palsy (CP)
   a. Rationale for non-coverage: A review by the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society concluded that the evidence was limited in children with CP, and that the existing evidence on RimabotulinumtoxinB showed inferior efficacy compared to type A toxins.\textsuperscript{14}

E. Upper esophageal dysfunction or achalasia
   a. Rationale for non-coverage: A 2014 Cochrane review revealed no randomized clinical trials on RimabotulinumtoxinB for upper esophageal dysfunction.\textsuperscript{15}

F. Migraine prophylaxis

G. Incontinence after spinal cord injury

H. Blepharospasm\textsuperscript{33}

I. Hemifacial spasm\textsuperscript{32}

J. Spasmodic dysphonia

\textbf{Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)}

Codes covered if clinical criteria are met:

\begin{center}
\begin{tabular}{|l|l|}
\hline
\textbf{CPT/HCPCS Codes covered if criteria are met:} \\
\hline
\textbf{Code} & \textbf{Description} \\
\hline
J0585 & Injection, onabotulinumtoxinA, 1 unit (Botox®) \\
\hline
\end{tabular}
\end{center}
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0586</td>
<td>Injection, abobotulinumtoxinA, 5 units (Dysport®)</td>
</tr>
<tr>
<td>J0587</td>
<td>Injection, rimabotulinumtoxinB, 100 units (Myobloc®)</td>
</tr>
<tr>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, 1 unit (Xeomin®)</td>
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</tbody>
</table>

**ICD-10 codes covered if criteria are met for onabotulinumtoxinA (J0585):**

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<td>Spasmodic torticollis</td>
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<td>Blepharospasm</td>
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<td>Multiple sclerosis</td>
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<td>G43.419</td>
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<td>G43.601</td>
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<td>Contracture of muscle, other site</td>
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<td>Description</td>
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**ICD-10 codes covered if criteria are met for abobotulinumtoxinA (J0586):**

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<th>Code</th>
<th>Description</th>
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<td>Spasmodic torticollis</td>
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<td>Contracture of muscle, unspecified ankle and foot</td>
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<td>M62.48</td>
<td>Contracture of muscle, other site</td>
</tr>
<tr>
<td>M62.49</td>
<td>Contracture of muscle, multiple sites</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if criteria are met for rimabotulinumtoxinB (J0587):**

- G12.21 Amyotrophic lateral sclerosis
- G20  Parkinson's disease
- G24.3  Spasmodic torticollis
- 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
- K11.7  Disturbances of salivary secretion

**ICD-10 codes covered if criteria are met for incobotulinumtoxinA (J0588):**

- G24.3  Spasmodic torticollis
- G24.4  Idiopathic orofacial dystonia
- G24.5  Blepharospasm
- G51.3  Clonic hemifacial spasm
- G51.8  Other disorders of facial nerve
- G51.9  Disorder of facial nerve, unspecified
- M62.40 Contracture of muscle, unspecified site
- M62.411 Contracture of muscle, right shoulder
- M62.412 Contracture of muscle, left shoulder
- M62.419 Contracture of muscle, unspecified shoulder
M62.421  Contracture of muscle, right upper arm
M62.422  Contracture of muscle, left upper arm
M62.429  Contracture of muscle, unspecified upper arm
M62.431  Contracture of muscle, right forearm
M62.432  Contracture of muscle, left forearm
M62.439  Contracture of muscle, unspecified forearm
M62.441  Contracture of muscle, right hand
M62.442  Contracture of muscle, left hand
M62.449  Contracture of muscle, unspecified hand
M62.451  Contracture of muscle, right thigh
M62.452  Contracture of muscle, left thigh
M62.459  Contracture of muscle, unspecified thigh
M62.461  Contracture of muscle, right lower leg
M62.462  Contracture of muscle, left lower leg
M62.469  Contracture of muscle, unspecified lower leg
M62.471  Contracture of muscle, right ankle and foot
M62.472  Contracture of muscle, left ankle and foot
M62.479  Contracture of muscle, unspecified ankle and foot
M62.48   Contracture of muscle, other site
M62.49   Contracture of muscle, multiple sites

**CPT/HCPCS Codes covered but may be subject to medical necessity review:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
</tr>
<tr>
<td>46505</td>
<td>Chemodenervation of internal anal sphincter [covered for anal fissure only]</td>
</tr>
<tr>
<td>52287</td>
<td>Cystourethroscopy, with injection(s) for chemodenervation of the bladder</td>
</tr>
<tr>
<td>64611</td>
<td>Chemodenervation of parotid and submandibular salivary glands, bilateral</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td>64612</td>
<td>Chemodenervation of muscles(s); muscles(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)</td>
</tr>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
</tr>
<tr>
<td>64616</td>
<td>Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)</td>
</tr>
<tr>
<td>64617</td>
<td>Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed</td>
</tr>
<tr>
<td>64642 - 64645</td>
<td>Chemodenervation of one extremity</td>
</tr>
<tr>
<td>64646 - 64647</td>
<td>Chemodenervation of trunk muscle(s)</td>
</tr>
<tr>
<td>64650</td>
<td>Chemodenervation of eccrine glands; both axillae</td>
</tr>
<tr>
<td>67345</td>
<td>Chemodenervation of extraocular muscle</td>
</tr>
<tr>
<td>S2340</td>
<td>Chemodenervation of abductor muscle(s) of vocal cord</td>
</tr>
<tr>
<td>S2341</td>
<td>Chemodenervation of adductor muscle(s) of vocal cord</td>
</tr>
<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
</tr>
<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope</td>
</tr>
<tr>
<td>31571</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope</td>
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**CPT/HCPCS codes not covered:**

<table>
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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>64653</td>
<td>Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day</td>
</tr>
<tr>
<td>86609</td>
<td>Antibody; bacterium, not elsewhere specified [neutralizing antibodies to botulinum toxin]</td>
</tr>
</tbody>
</table>
References

AbobotulinumtoxinA (Dysport)


OnabotulinumtoxinA (Botox)


**IncobotulinumtoxinA (Xeomin)**


RimabotulinumtoxinB (Myobloc)


32. Trosch RM, Adler CH, Pappert EJ. Botulinum toxin type B (Myobloc(R)) in subjects with hemifacial spasm: Results from an open-label, dose-escalation safety study.

Clinical Guideline Revision / History Information

<table>
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<tr>
<th>Original: Review/Revise Dates</th>
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<tr>
<td>Original Date:</td>
<td>8/7/2017</td>
</tr>
<tr>
<td>Reviewed/Revised:</td>
<td>1/18/2018</td>
</tr>
<tr>
<td>Signed:</td>
<td>Sean Martin, MD, Medical Director</td>
</tr>
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