Local Coverage Determination (LCD): Botulinum Toxins (L33274)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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LCD Information

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for botulinum toxins. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for botulinum toxins and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

Internet Only Manual (IOM) Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
    - Chapter 1, Section 30 Drugs and Biologicals
    - Chapter 6, Section 20.5.2 Coverage of Outpatient Therapeutic Services Incident to a Physician’s Service Furnished on or After January 1, 2010

- Chapter 15, Section 50 Drugs and Biologicals, Section 60 Services and Supplies
- Chapter 16, Section 120 Cosmetic Surgery

- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1862(a)(10) excludes coverage for cosmetic surgery.
- Title XVIII of the Social Security Act, Section 1861(t). This section addresses drugs and biologicals definitions.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Clostridium botulinum toxin describes a family of neurotoxins produced by the anaerobic bacteria of the species C. botulinum. There are seven distinct serotypes of botulinum toxin: A, B, C, D, E, F and G. All botulinum neurotoxin serotypes are understood to produce their clinical effect by blocking the release of the neurotransmitters, principally acetylcholine, from nerve endings.[1] There are four distinct serotype A botulinum toxin products, onabotulinumtoxinA (Botox®), abobotulinumtoxinA (Dysport®), incobotulinumtoxinA (Xeomin®), and prabotulinumtoxinA-xvfs (Jeuveau®), and one serotype B botulinum toxin product, rimabotulinumtoxinB (Myobloc®) that have been approved by the U.S. Food and Drug Administration (FDA). Jeuveau® is indicated for cosmetic use only.[2]

Whether a botulinum toxin is produced from the same or a different serotype producing strain, they undergo different manufacturing processes which yield differences in the size and weight of the molecules. Because of this, Botox®, Dysport®, Xeomin® and Myobloc®, as well as other botulinum toxin products available internationally, are not interchangeable. They are chemically, pharmacologically and clinically distinct.[1]

Botulinum toxin injections are commonly used to treat a wide variety of conditions in which the main therapeutic effect is to decrease undesired or excessive contraction of striated or smooth (involuntary) muscle. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings.[1] The resulting chemical-denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively.

The overall coverage of drugs is addressed in the CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Sections 50.4.1 and 50.4.2 and includes coverage for FDA-approved drugs and unlabeled use of a drug.

Covered Indications

NOTE: The four botulinum therapies are not interchangeable and are only covered as listed below.

Botulinum toxins (Botox®, Dysport®, Xeomin® and Myobloc®), will be considered medically reasonable and necessary when administered for treatment of FDA-labeled indications and Off-label indications (as applicable) below:

1. FDA[3] indications for onabotulinumtoxinA (Botox®) as noted on the FDA website: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=103000

2. Off-Label indications for onabotulinumtoxinA (Botox®) may be considered medically reasonable and necessary in patients for the following conditions:
   - Esophageal achalasia in adults who are considered poor surgical candidates[4]
   - Chronic anal fissure for patients with inadequate response to conservative or pharmacologic treatment[5]
   - Essential hand tremor for patients with a high amplitude tremor that disrupts activities of daily living and have had inadequate response to oral pharmacotherapy such as propranolol and primidone[6]
   - Focal limb dystonia[6]
   - Hemifacial spasm in adults (cranial nerve VII disorder)[6]
   - Isolated oromandibular dystonia in adults[7]
   - Laryngeal dystonia (spastic dysphonia) for adductor type (ADSD)[6]
   - Bothersome simple motor tics in adolescents and adults when the benefits of treatment outweigh the risks[8]
   - Severely disabling or aggressive vocal tics in older adolescents and adults when the benefits of treatment outweigh the risks[8]

3. FDA[9] indications for abobotulinumtoxinA (Dysport®) as noted on the FDA website: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125274

4. Off-label indications for abobotulinumtoxinA (Dysport®) may be considered medically reasonable and necessary in patients for the following conditions:
   - Blepharospasm in adults[6,7]
   - Hemifacial spasm in adults (cranial nerve VII disorder)[6]
   - Isolated oromandibular dystonia in adults[7]

5. FDA[10] indications for incobotulinumtoxinA (Xeomin®) as noted on the FDA website: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125360

6. FDA[11] indications for rimabotulinumtoxinB (Myobloc®) as noted on the FDA website: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=103846

Limitations

1. Localization procedures would not be expected for easily targeted muscles and, therefore, would not be considered medically reasonable and necessary.[7]

2. Cosmetic procedures are not a covered benefit under Medicare.
   - Treatment of wrinkles, also referred to as glabellar lines, smoker's lines, crow's feet, laugh lines and aging neck, using botulinum toxins is considered to be a cosmetic procedure, and is not covered under Medicare.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

Off-Label Indications Supported by Evidence-Based Guidelines

Botulinum toxin is used therapeutically to reduce pathologic muscle contraction. Health outcomes of interest are improved function and improved quality of life.

Gastrointestinal

Achalasia
The American College of Gastroenterology has provided evidence based clinical practice guidelines for the diagnosis and management of achalasia. Achalasia is a condition where the muscles in the lower part of the esophagus do not relax and prevent the passage of food. Botulinum toxin has a strong recommendation based on moderate quality evidence in patients who are not candidates for pneumatic dilation (PD) or surgical myotomy.[4] Serious side effects are rare. In comparative effectiveness studies, PD was found to be superior to botulinum toxin, demonstrating PD is more effective in the long term, and therefore only patients who are not candidates for pneumatic dilation, or surgical myotomy, are eligible for botulinum toxin.

Technical Assessments
A Cochrane database review of 6 studies included 178 patients and discovered no significant difference in remission between PD and botulinum toxin treatment within 4 weeks of the initial intervention. Three studies included in the review had 12-month data with remission in 33 of 47 PD patients compared with 11 of 43 botulinum toxin patients (relative risk of 2.67, 95% confidence interval 1.58–4.52). These outcomes provide strong evidence that PD is more successful than botulinum toxin in the long term for patients with achalasia.

Chronic Anal Fissure
Anal fissure is defined as an ulcer-like, longitudinal tear in the midline of the anal canal, distal to the dentate line. Treatments for anal fissure lean heavily on adaptation from the American Society of Colon and Rectal Surgeons Practice Parameters from the most recent published guidelines in 2010 and 2011 and are supplemented with subsequent publications through 2013.[5] Generally, treatment for chronic anal fissure is targeted at reducing the sphincter spasms caused by this condition. Recommended therapy includes topical medications like calcium channel blockers or nitrates. For patients who do not respond to conservative or pharmacologic treatment, local injections of botulinum toxin are strongly recommended for relief of painful spasms. Surgery (internal anal sphincterotomy) is recommended for medically refractory situations.

Wald et al.[5] released the American College of Gastroenterology practice guideline for management of benign anorectal disorders which discuss the definitions, diagnostic criteria, differential diagnoses, and treatments of a set of benign disorders of anorectal function and/or structure. Studies[5] show that injection of botulinum toxin into the internal anal sphincter allows healing in 60% to 80% of fissures, and at a greater rate than a placebo. Usual side effects include temporary incontinence of flatus in up to 18%, and of stool in 5%. Relapse may occur in up to 42%, however patients have shown similar outcomes to initial therapy.

Currently, a consensus has not been reached on dosage, exact site of administration, number of injections, or effectiveness. Greater doses may increase healing and are considered as safe as lower doses. The effects of botulinum toxin may be potentiated by topical nitrate medications in patients with refractory anal fissure. Botulinum toxin is reserved for patients who fail pharmacologic treatment with nitrates or calcium channel blockers. Lateral internal sphincterotomy (LIS) is recommended for patients who have failed botulinum toxin injection therapy.

Other benign anorectal disorders which include defecatory disorders, fecal incontinence and chronic proctalgia lack evidence for botulinum toxin administration.

Neurology

The American Academy of Neurology (AAN)[12] has produced a clinical practice guideline process manual that includes a discussion regarding elements of recommendations and levels of evidence (see tables below).

Level (Quality) of Evidence		
Level A (High)	**Level B (Moderate)**	**Level C (Low)**
• High quality evidence from more than 1 random controlled trial (RCT) • Meta-analyses of high-quality RCTs • Several high-quality studies with consistent results	• Moderate quality evidence from 1 or more RCTs • Meta-analyses of moderate quality RCTs • Moderate quality evidence from 1 or more well designed nonrandomized studies or meta-analyses of such studies	• Randomized or nonrandomized observational or registry studies with limitations of design • Meta-analyses of such studies • Consensus of expert opinion • Case studies • Practice guidelines • Reviews
Note: When there is insufficient evidence to support an inference for the use of an intervention (i.e., the balance of benefits and harms is unknown), a Level U is appropriate. A Level U indicates that the available evidence is insufficient to support or refute the efficacy of an intervention.[12]		

Class (Strength) of Recommendation **Measures the Risk of Bias**	
Class I Studies (Strong)	Studies are judged to have a low risk of bias; randomization of patients is effectively balanced between treatment and comparison groups for important confounding baseline differences.
	Treatment is recommended/is indicated/useful/effective/beneficial.

Class IIa Studies (Moderate)	Studies have a moderate risk of bias; patients in different treatment groups match on all known baseline confounders.
	Recommendation is reasonable/can be useful/effective/beneficial.
Class IIb Studies (Weak)	Studies have a moderate to high risk of bias; patients in different treatment groups may not match on all important confounders.
	Additional studies needed. Usefulness/effectiveness is unknown/unclear/uncertain or not well established.
Class III Studies (No Benefit)	Studies have a moderately high risk of bias; patients in different treatment groups do not match on all important confounders.
	Therapy is not recommended/not useful/effective and may be harmful.[12]

Blepharospasm
The American Academy of Neurology has provided recommendations for the use of botulinum neurotoxin in blepharospasm based on the following studies:

One Class II and one Class III study[6] compared two different serotype A botulinum neurotoxins (Botox® and Dysport®). In the Class II study, 212 participants were assessed in a crossover design using a 4:1 dose ratio of Dysport® to Botox®. The primary clinical outcome, duration of effect, was similar for the two botulinum neurotoxins. The Class III trial, a parallel design of 42 patients without blinded raters, used a dose ratio of 4:1. Duration of action was the primary clinical outcome, and this outcome and others including number of booster doses needed, latency of effect, clinical efficacy, and adverse reactions were comparable for the two botulinum toxin products. A Class I trial performed a comparison of Xeomin® and Botox® injecting equal doses in 300 study participants (256 participants finished the trial). Results showed identical effectiveness and side effects.

The conclusion for these studies indicate Botox® and Xeomin® have level B evidence, Dysport® has level C evidence. These studies signify that following dose modifications, Botox® and Xeomin® may be equal and Botox® and Dysport® may be comparable for the treatment of blepharospasm.

Hemifacial Spasm
Hemifacial spasm is illustrated by a combination of unilateral clonic and tonic spasms of the muscles innervated by the facial nerve. Treatment choices include oral pharmacologic treatments (including carbamazepine, baclofen, and

benzodiazepine) that have limited effectiveness, and microvascular decompression of the facial nerve, which is a highly invasive technique.

A Class II study[6] comprised of 11 patients was a prospective, blinded trial with four arms: a random dose based on clinical experience of between 2.5 and 10 units of BoNT-A (Botox®), half the dose, double the dose, and saline placebo. Patients went through the four treatment arms in random order. Utilization of a clinical scale to rate videotapes and a patient subjective scale, 84% had objective improvement with a minimum of one of the active doses with a tendency for an improved response with higher dose; only one participant improved on placebo. Seventy-nine percent described subjective improvement lasting an average of 2.8 months with active treatment. The principal side effect was weakness of the face, generally mild (97%). Other side effects included bruising, diplopia, ptosis, and headache.

A Class III study[6], a double-blind, prospective, parallel design including only four participants per group used individualized therapy (dose range 2.5 to 40 units) with BoNT-A (Botox®) in the active arm. In addition, 93 patients studied in an open label fashion were reported. More improvement was shown on a clinical scale with BoNT than with a saline placebo. Improvement continued an average of 3.8 months. Side effects, reported in 63% of participants, were usually mild and involved dry eye, mouth droop, and ptosis.

One Class II study[6] contrasted Botox® and Dysport® in a parallel design without placebo control or blinded raters. A dose ratio of 4:1 was used for Dysport® to Botox®. The primary clinical outcome (duration of action) and other clinical outcomes (number of booster doses needed, latency of effect, clinical efficacy, and frequency of adverse reactions) were comparable for the two products. Therapeutic effects lasted 2.6–3.0 months.

The conclusion for these studies signifies botulinum neurotoxin may be considered as a treatment for hemifacial spasm. Botox® and Dysport® have level C evidence and after dosage modification, are comparable in effectiveness.

Focal limb dystonia
Focal hand dystonia is also referred to as writer's cramp, other occupational hand dystonia, and non-task-specific hand dystonia. Currently, no effective alternative medical or proven surgical therapies have been established for focal limb dystonia.

A Class I trial[6] randomized 40 study participants with writer's cramp in a double-blind design for botulinum neurotoxin (BoNT) or an equal amount of saline placebo. Clinical assessment was utilized in selecting the muscle to be injected. Study participants with insufficient or no response were offered a second injection one month later. The chief outcome measure was the patient's indicated request to continue injection therapy. In patients randomized to BoNT, 70% requested to maintain treatment in comparison to 32% of those who received a placebo ($p = 0.03$). Patients injected with BoNT also had considerable improvement in comparison to patients who had been given a placebo in secondary clinical outcome measures including a visual analog scale, symptoms severity scale, writer's cramp rating scale, and assessment of writing speed, but not in the functional status scale. The only side effects reported were temporary weakness and pain at the injection site.

One Class II trial, a prospective, double-blind, crossover study[6] comprised 17 study participants with several forms of limb dystonia, including lower extremity (3 patients) and secondary dystonia (4 patients). Study participants were given a series of four injections in arbitrary order, one with a dose of BoNT that the investigators judged to be "optimal," one at half the optimal dose, one at double the dose, and one with saline placebo. Per a patient subjective scale, 82% of patients who received BoNT experienced improvement compared to 6% (one patient) who received placebo. Using physician rating of videotapes, 59% of patients experienced improvement with active treatment and 38% with placebo (not significant). A dose-response association for improvement was not evident. A considerable degree of inter-observer inconsistency was shown, which was attributed to an inadequate outcome evaluation. The

principal side effect after BoNT injections was focal weakness (53%) with increased probability with higher doses. Weakness was experienced with 13% of placebo injections and additional adverse effects involved muscle stiffness, pain, and malaise.

Another Class II study[6] utilized a placebo-controlled, double-blind, crossover design for 20 individuals with writer's cramp. Clinical assessment was utilized in selecting the muscle to be injected and the dose of BoNT-A was founded on investigator experience. Outcome evaluations included assessment of writing speed, accuracy, writing samples, and patients' subjective report. There was substantial improvement with BoNT therapy in the objective measures, but not in patients' own evaluations. The only adverse effect was focal weakness, although this was severe enough to worsen pen control in one participant. This study only evaluated the first active therapy session for study participants; therefore, the therapeutic effects achieved were not optimal.

An additional Class II trial[6] was a double-blind, placebo-controlled, crossover design with 10 study participants with focal hand dystonia. Muscles and BoNT-A (Botox®) doses were selected and optimized during a time of open treatment before the trial. Outcome measures were based on study participant's subjective ratings and observer ratings of videotapes taken during actions relevant to the individual dystonia. Eight participants had improved subjective ratings and six had improved videotape ratings with BoNT in comparison with placebo. Weakness was noted in the injected muscles of 80% of study participants with active treatment.

Three Class II studies[6] assessed technical issues of BoNT administration. In one trial, a blinded, randomized, crossover design was utilized to contrast continuous muscle activation to immobilization immediately following BoNT injection. Blinded assessment of handgrip strength and writing showed a substantial increase in focal weakness with continuous muscle activity, but no subjective or objective improvement in writing. In a different Class II study, participants were randomized to one of two muscle localization methods; electromyography (EMG) recording or electrical stimulation. Injections guided by both techniques were similarly effective in producing weakness in the target muscle. In a third trial, the precision of muscle localization with and without EMG was assessed. In needle placements established on surface anatomy, 37% were localized in the targeted muscle.

The therapy for focal limb dystonia with BoNT is challenging, especially in reaching adequate neuromuscular blockade to relieve dystonic movements without initiating excessive muscle weakness.

The conclusion for these studies signifies Botox® has level B evidence and should be considered as a treatment option for focal limb dystonia.

Laryngeal dystonia

Laryngeal dystonia (spasmodic dysphonia) commonly presents as adductor type (ADSD) and less commonly as abductor type (ABSD). The voice of an individual with ADSD is described as strained or strangled, while ABSD generates a weak and breathy voice. Currently, no effective alternative medical or surgical therapies have been established for spasmodic dysphonia.

One Class I trial[6] of botulinum neurotoxin (BoNT) for 13 study participants with ADSD, a double-blind, randomized, parallel group study, compared seven patients who received BoNT with six patients who received saline. Outcome measures comprised instrumental quantitative measures of voice function and patient ratings. Substantial benefit was achieved in the study participants who received BoNT ($p = 0.01$).

One Class III trial[6] discovered that adding voice therapy after BoNT therapy in ADSD patients extended improvements from the BoNT treatment. Another study discovered that resting the voice for 30 minutes following the BoNT injection extended the therapeutic effects of BoNT. One Class III study of 15 participants with ABSD did not observe a noteworthy distinction between using percutaneous or endoscopic injection technique.

The conclusion for these studies signifies Botox® has level B evidence and should be recommended as a treatment option for adductor spasmodic dysphonia (ADSD); however, there is inadequate evidence to support the effectiveness for botulinum neurotoxin in abductor spasmodic dysphonia (ABSD).

Chronic tics

Tics, generally linked with Tourette syndrome, are characterized as short, sporadic movements (motor tics) or sounds (vocal or phonic tics), generally led by a premonitory sensation. Current treatment includes anti-dopaminergic drugs (neuroleptics) which are normally successful for multifocal tics. However, the side effects are considered unfavorable especially in individuals with focal tics like blinking, blepharospasm, head jerking, neck twisting, and loud vocalizations, including the involuntary and repetitive use of obscene language.

In preliminary open label Class IV trials,[6] the muscles involved in the motor and phonic tics were injected with botulinum neurotoxin (BoNT) and showed an adequate to significant decrease in the strength and occurrence of the tics, and almost full elimination of the premonitory sensation. In a Class IV trial of 35 study participants treated in 115 sessions for bothersome or incapacitating tics, the average peak effect response was 2.8 (range 0=no effect, 4=marked improvement in both severity and function). The average length of improvement was 3.4 months (up to 10.5). Dormancy to start of improvement was 3.8 days (up to 10). Twenty-one participants out of 25 (84%) with significant premonitory sensory symptoms obtained noticeable relief of these symptoms with BoNT (average improvement 70.6%).

A class II trial[6] with 18 study participants with simple motor tics achieved a 39% decrease in the number of tics per minute in 2 weeks following BoNT injection in comparison to a 6% rise in the placebo participants (p=0.004). Also, a 0.46 decrease in "urge scores" with BoNT in comparison to a 0.49 rise in the placebo participants (p=0.02). This underpowered study was unable to reveal sufficient differences in measured variables like severity score, tic suppression, pain, and patient global impression. The maximum results derived from BoNT may not have been realized at 2 weeks. Also, it was noted that the study participants did not score themselves as considerably compromised because of their tics, so their symptoms may have been reasonably mild at baseline.

The conclusion for these studies indicates Botox® has level C evidence and may be effective for the treatment of motor tics (one Class II study). There is insufficient data to conclude the effectiveness of BoNT in phonic tics (one Class IV study).

Pringsheim et al[8] provided a systematic review of the literature to make recommendations on the assessment and management of tics in individuals with Tourette syndrome (TS) and chronic tic disorders. A multidisciplinary panel consisting of 9 physicians, 2 psychologists, and 2 patient representatives developed practice recommendations, integrating findings from a systematic review and following an Institute of Medicine–compliant process to ensure transparency and patient engagement. Recommendations were supported by structured rationales, integrating evidence from the systematic review, related evidence, principles of care, and inferences from evidence.

The systematic review integrates the evidence supporting the effectiveness and detriments of medical, behavioral, and neurostimulation treatments for tics. The treatment of tics must be personalized and based on collaborative determinations among patients, caregivers, and clinicians. Many individuals with tic disorders have psychiatric comorbidities, which require clinicians to set treatment priorities. The management of comorbid conditions is of chief concern in determining treatment options for tics in individuals with TS. Medications, behavioral therapy, and neurostimulation have been shown to significantly decrease tics; however, these treatments seldom fully terminate tics.

Comprehensive Behavioral Intervention for Tics (CBIT) is recommended as an initial treatment option for individuals with tics causing psychosocial or physical impairment provided that the individual is motivated to participate in treatment (Level B). Other behavioral interventions may be recommended if CBIT is not available, such as exposure

and response prevention (Level C).

The literature shows that botulinum toxin injections with onabotulinumtoxinA are probably more likely than a placebo to reduce tic severity in adolescents and adults. Botulinum toxin injections may also improve premonitory urges. OnabotulinumtoxinA is associated with greater rates of weakness relative to placebo. Also, a common side effect of injecting botulinum toxin in the laryngeal muscles for vocal tics is hypophonia. Botulinum toxin effects generally last for 12-16 weeks, after which injections would need to be repeated.

Recommendations based on this study include: 1) Botulinum toxin injections are recommended for the treatment of adolescents and adults with localized and bothersome simple motor tics when the benefits of treatment outweigh the risks (Level C). 2) Botulinum toxin injections are recommended for the treatment of older adolescents and adults with severely disabling or aggressive vocal tics when the benefits of treatment outweigh the risks (Level C). In addition, providers must advise patients with tics that treatment with botulinum toxin may cause temporary weakness and hypophonia.

Essential hand tremor

Tremor, an involuntary, rhythmic movement generated by alternating or synchronous contractions of antagonistic muscles is a common movement disorder. While propranolol and primidone normally improve mild or moderate essential tremor, pharmacotherapy is typically not adequate to control a high-amplitude tremor that disrupts activities of daily living. In patients with disabling tremor, local injection of botulinum neurotoxin (BoNT) may be utilized prior to contemplating more aggressive intervention such as thalamic deep brain stimulation.

A Class II placebo-controlled trial[6] assessed 25 study participants with hand tremor of 2 (moderate) to 4 (severe) on the tremor severity rating scale. Patients were randomized to be given either 50 units of BoNT-A (Botox®) or placebo injections into the wrist flexors and extensors of the dominant limb. If study participants failed to respond to the first injection, another injection of 100 units could be administered 4 weeks later. Rest, postural, and kinetic tremor were assessed at 2 to 4-week intervals over a 16-week period, using tremor severity rating scales, accelerometry, and evaluations of improvement and disability. There was substantial improvement on the tremor severity rating scale 4 weeks following injection in participants treated with BoNT as compared to placebo, and this improvement was maintained for the length of the study. Four weeks following injection, 75% of BoNT-treated study participants versus 27% of placebo-treated patients ($p < 0.05$) conveyed mild to moderate improvement. While trends were observed for some elements, functional rating scales did not improve. Postural accelerometry measurements revealed a 30% decrease in amplitude in 9 of 12 BoNT-treated patients and in 1 of 9 placebo-treated patients ($p < 0.05$). While all patients treated with BoNT reported some degree of finger weakness, no severe, irreversible, or unexpected adverse events transpired.

Comparable results occurred in another Class II multicenter, double-blind, controlled study[6] that used a comparable protocol and included 133 study participants with essential tremor. Participants were randomized to have 50 or 100 units of Botox® injected into wrist flexors and extensors and were then followed for 4 months. The trial revealed substantial improvement in postural tremor, however only minimal improvement in kinetic tremor and functional evaluations.

The study design of both Class II studies restricts their applicability to clinical practice. Both studies utilized a rigid treatment protocol that employed a fixed BoNT dose and a predetermined set of muscles. In practice, dosages and injected muscles are frequently tailored for a patient based on their tremor pattern.

A Class II study[6] of only 10 patients with head tremor failed to demonstrate a statistically significant benefit in BoNT-treated patients. Two Class IV open-label studies in voice tremor showed modest improvement from baseline in objective acoustic and subjective measures following unilateral or bilateral BoNT injection.

The conclusion for these studies indicates BoNT injection of forearm muscles may be helpful in reducing the tremor amplitude in patients with essential hand tremor. The benefits must be considered in conjunction with the common adverse effect of muscle weakness associated with BoNT injection. Existing data is insufficient to draw a conclusion on the use of BoNT in the treatment of head and voice tremor. Botox® has level C evidence and should be considered as a treatment option for essential hand tremor in patients with a high amplitude tremor that disrupts activities of daily living and have had an inadequate response to oral agents including propranolol and primidone.

Oromandibular Dystonia

Hassel and Charles[7] conducted a systematic literature review to give a summary of the history of oromandibular dystonia, botulinum neurotoxin (BoNT), and the utilization of BoNT to treat this focal cranial dystonia. Oromandibular dystonia (OMD) has various treatment choices consisting of BoNT therapy, medication, and surgical intervention. Botulinum neurotoxin is commonly recognized as a first-line therapy.

The effectiveness of medication therapy is limited and does not show the same level of value when compared to BoNT. Oral medication treatments are also restricted by systemic side effects that are not typically experienced with botulinum toxin. Benzodiazepine use is also problematic due to potential tolerance and addiction.

For the treatment of OMD, OnaBoNT/A (Botox®) and aboBoNT/A (Dysport®) carry the highest evidence (level of evidence C for both). While IncoBoNT/A (Xeomin®) and RimaBoNT/B (Myobloc®) have insufficient evidence to support therapy for OMD (level of evidence U for both).

Analysis of Evidence
(Rationale for Determination)

Botulinum toxin can improve quality of life through reducing muscle rigidity and contraction and is a treatment for voluntary and involuntary muscle dysfunction. Reduction of painful contractions is important for an improved quality of life.

Dosing and frequency are important considerations. While botulinum toxins have a fairly wide therapeutic window, all botulinum toxin products have a black box warning regarding the potential for distant spread of toxin effect. These symptoms can occur hours to weeks after administration. Symptoms may include swallowing and breathing difficulties which can be life threatening and can lead to death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults, particularly in those patients who have an underlying condition that would predispose them to these symptoms.[9,10,11] Therefore, the lowest effective dose that produces the desired clinical effect should be used. Treatment effect can last from twelve to sixteen weeks, with labeled use suggesting a minimum interval of twelve weeks. Dosing frequency should be at the longest interval that produces the desired clinical effect.

Medical utilization of botulinum toxins has increased in the past 30 years with an extensive track record of safety and efficacy.[1] The mechanism of action is well understood. However, the benefits of botulinum toxin must be balanced with the risk. Professional societies have evidence based guideline recommendations to assist providers in maximizing patient outcomes.

There are important differences between the botulinum toxin preparations that include potency and duration of effect. They are chemically, pharmacologically and clinically distinct and are not interchangeable.

Achalasia
Current evidence based guidelines indicate that botulinum toxin therapy for achalasia is confined to circumstances where pneumatic dilation (PD) and surgical myotomy are not considered suitable options due to inherent patient-related risks. In addition to the current guidelines, the IBM Micromedex® compendium DrugDex® lends support for Botox® as an off-label treatment of achalasia in adults.[13] Therefore, off-label coverage has been extended for Botox® consistent with current evidence based guidelines.

Chronic anal fissure
Current evidenced-based recommendations indicate chronic anal fissure should be treated with topical medications like calcium channel blockers or nitrates. In situations where patients do not respond to conservative or pharmacologic treatment, local injections of botulinum toxin have been shown to be as effective in healing fissures and are therefore recommended as an alternative treatment. Thus, consistent with evidence based guidelines, off-label coverage has been extended for Botox® as a treatment option for chronic anal fissure in patients with inadequate response to conservative or pharmacologic treatment.

Blepharospasm
Studies show Botox® and Xeomin® may be comparable for the treatment of blepharospasm following dose modification. Studies signify Botox® and Dysport® may be equivalent for the treatment of blepharospasm. Dysport® has backing in the IBM Micromedex® compendium DrugDex® for off-label treatment of blepharospasm in adults.[13] Accordingly, off-label coverage has been extended for Dysport® for the treatment of blepharospasm in adults.

Hemifacial spasm
The literature indicates botulinum neurotoxin may be considered as a treatment for hemifacial spasm with minimal side effects. Studies show Botox® and Dysport®, after dosage modification, may be equal in effectiveness. Botox® and Dysport® have additional support in the IBM Micromedex® compendium DrugDex® for off-label treatment of hemifacial spasm in adults.[13] Subsequently, off-label coverage has been extended for Botox® and Dysport® as a treatment of hemifacial spasm in adults.

Focal limb dystonia
Currently, no effective alternative medical or proven surgical therapies have been established for focal limb dystonia. Studies signify botulinum neurotoxin should be considered as a treatment option for focal hand dystonia, also referred to as writer's cramp. Therefore, consistent with evidence based guidelines, off-label coverage has been extended for Botox® as a treatment of focal limb dystonia.

Laryngeal dystonia
Laryngeal dystonia (spasmodic dysphonia) commonly presents as adductor type (ADSD) and less commonly as abductor type of spasmodic dysphonia (ABSD). Presently, no effective alternative medical or surgical therapies have been established for spasmodic dysphonia. Studies show botulinum neurotoxin should be recommended as a treatment option for adductor spasmodic dysphonia (ADSD); however, there is inadequate evidence to support the effectiveness for botulinum neurotoxin in abductor spasmodic dysphonia (ABSD). Botox® has support in the IBM Micromedex® compendium DrugDex® for off-label treatment of spastic dysphonia in adults.[13] Consequently, consistent with evidence based guidelines, off-label coverage has been extended for Botox®.

Essential hand tremor
Studies indicate botulinum neurotoxin injection of forearm muscles may be helpful in reducing the tremor amplitude in patients with a high amplitude essential hand tremor that disrupts activities of daily living and have had an inadequate response to oral agents including propranolol and primidone. Therefore, consistent with evidence based guidelines, off-label coverage has been extended for Botox® as a treatment for essential hand tremor for patients

with a high amplitude tremor that disrupts activities of daily living and have had an inadequate response to oral pharmacotherapy such as propranolol and primidone.

Oromandibular dystonia (OMD)
Oromandibular dystonia (OMD) has various treatment choices consisting of botulinum toxin therapy, medication, and surgical intervention. Medications, like anticholinergics (trihexyphenidyl and benztropine), benzodiazepines, VMAT2 inhibitors (tetrabenazine), levodopa, and baclofen, have been utilized with varying success. The effectiveness of medication therapy is limited and does not show the same level of value when compared to botulinum toxin. Oral medication treatments are also restricted by systemic side effects that are not typically experienced with botulinum toxin.

Current practice guidelines for botulinum toxins show support for Botox® and Dysport® for the treatment of OMD. In addition to the literature, Botox® has support in the IBM Micromedex® compendium DrugDex® for off-label treatment of isolated oromandibular dystonia in adults.[13] Thus, consistent with evidence based guidelines, off-label coverage has been extended for Botox® and Dysport® as a treatment for isolated oromandibular dystonia in adults.

Motor tics and disabling or aggressive vocal tics
The treatment of tics must be personalized and based on collaborative determinations among patients, caregivers, and clinicians. Many individuals with tic disorders have psychiatric comorbidities, which require clinicians to set treatment priorities. The management of comorbid conditions is of chief concern in determining treatment options for tics in individuals with TS. Medications, behavioral therapy, and neurostimulation have been shown to significantly decrease tics; however, these treatments seldom fully terminate tics. Evidence based guidelines indicate: 1) OnabotulinumtoxinA (Botox®) injections are recommended for the treatment of adolescents and adults with localized and bothersome simple motor tics when the benefits of treatment outweigh the risks; and 2) OnabotulinumtoxinA (Botox®) injections are recommended for the treatment of older adolescents and adults with severely disabling or aggressive vocal tics when the benefits of treatment outweigh the risks. In addition to the current guidelines, the IBM Micromedex® compendium DrugDex®[13] lends support for Botox® as an off-label treatment of Gilles de la Tourette's syndrome in adults. Therefore, off-label coverage has been extended for Botox® consistent with current evidence based guidelines.

The quality of evidence in the literature is insufficient to support botulinum toxin injection for the treatment of defecatory disorders (DD), chronic proctalgia, phonic tics, head tremor, and voice tremor at this time. Further research is needed to clarify the utility and efficacy of botulinum toxin therapy for these conditions.

General Information

Associated Information

Please refer to the related Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715) for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

First Coast Service Options, Inc. reference LCDs: L28790, L29088 , L29103

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
03/21/2021	R11	LCD posted for notice on 02/04/2021. LCD becomes effective for dates of service on and after 03/21/2021. 09/24/2020 DL33274 Draft LCD posted for comment.	• Creation of Uniform LCDs With Other MAC Jurisdiction
01/08/2019	R10	Revision Number: 8 Publication November 2019 Connection LCR A/B2019-075 Explanation of Revision: Based on Change Request (CR) 10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions ("Bill Type Codes," "Revenue Codes," "CPT/HCPCS Codes," "ICD-10 Codes that Support Medical Necessity," "Documentation Requirements" and "Utilization Guidelines" sections of the LCD) and place them into a newly created billing and coding article. During the process of moving the ICD-10-CM diagnosis codes to the billing and coding article, the ICD-10-CM diagnosis code ranges were broken out and listed individually. In addition, the Social Security Act and IOM reference sections were updated. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018.	• Other (Revision based on CR 10901)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	
11/15/2018	R9	Revision Number: 7 Publication: November 2018 Connection LCR A/B2018-085 Explanation of Revision: Based on a LCD reconsideration request, the "Coverage Indications, Limitations, and/or Medical Necessity" section of the LCD under "FDA indications for Xeomin®:" was revised to add the FDA indication "chronic sialorrhea in adult patients". Also, the "ICD-10 Codes that Support Medical Necessity" section of the LCD was revised to add ICD-10-CM diagnosis code K11.7 to the "Group 4 Codes" that support medical necessity for procedure code J0588 (Injection, incobotulinumtoxin A, 1 unit). In addition, the "Sources of Information" section of the LCD was updated to include the published source from the reconsideration request. This revision to the LCD is effective for claims processed on or after 11/15/2018, for dates of service on or after 07/03/2018. 11/15/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Reconsideration Request
10/01/2018	R8	Revision Number: 6 Explanation of Revision: Based on CR 10847 (Annual 2019 ICD-10-CM Update), the LCD was revised to indicate that diagnosis codes were added and deleted within existing diagnosis code ranges. The effective date of this revision is based on date of service.	• Revisions Due To ICD-10-CM Code Changes
05/03/2018	R7	Revision Number: 5 Publication: May 2018 Connection LCR A/B2018-041	• Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Explanation of revision: Based on an LCD reconsideration request, this LCD was revised in the "Coverage Indications, Limitations, and/or Medical Necessity" section to include the FDA indications for Dysport® –the treatment of spasticity in adults and the treatment of lower limb spasticity in pediatric patients 2 years of age and older. In addition, the accompanying diagnosis codes (G11.4, G80.8, G82.21-G82.22, G82.51-G82.52, G83.11-G83.14, I69.041-I69.044, I69.141-I69.144, I69.241-I69.244, I69.341-I69.344, I69.841-I69.844, M62.451-M62.452, M62.461-M62.462, M62.471-M62.472, M62.48, M62.49, M62.831, and M62.838) for these indications were added to the "ICD-10 Codes that Support Medical Necessity" section under "Group 2 Codes:" and the "Sources of Information and Basis for Decision" has also been updated. The LCD revision to include the treatment of lower limb spasticity in pediatric patients 2 years of age and older is effective for claims processed on or after May 3, 2018, for dates of service on or after 07/29/2016. The LCD revision to include the treatment of spasticity in adults is effective for claims processed on or after May 3, 2018, for dates of service on or after June 14, 2017. 05/03/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	
02/08/2018	R6	Revision Number: 4 Publication: February 2018 Connection LCR A/B2018-012 Explanation of revision: This LCD has been revised to include an explanation that all the codes within the asterisked range from the first code to the last code apply for ICD-10 code ranges in the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure codes J0585, J0586 and J0588. In addition, the procedure codes in the "CPT/HCPCS Codes" section of the LCD were put in groups to be consistent with the groups in the "ICD-10 Codes that Support Medical Necessity" section of the LCD. The effective date of this revision is based on process date.	• Provider Education/Guidance • Public Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		02/08/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	
06/09/2016	R5	Revision Number: 3 Publication: June 2016 Connection LCR A/B2016-066 Explanation of revision: Based on an LCD reconsideration request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0586. Additionally, language clarifying the asterisked diagnoses was also added to this section. Also, "spasticity of the arm in patients following a stroke" was removed from the "Off-label Indications" section for Dysport™. The effective date of this revision is for dates of service on or after 06/09/16. This LCD was also revised to add ICD-10-CM code range G81.11-G81.14 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for claims processed on or after 06/09/16, for dates of service on or after 12/22/2015. In addition, based on an LCD reconsideration request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for dates of service on or after 06/09/16.	• Typographical Error
06/09/2016	R4	Revision Number: 3 Publication: June 2016 Connection LCR A/B2016-066 Explanation of revision: Based on an LCD reconsideration	• Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0586. Additionally, language clarifying the asterisked diagnoses was also added to this section. Also, "spasticity of the arm in patients following a stroke" was removed from the "Off-label Indications" section for Dysport™. The effective date of this revision is for dates of service on or after 06/09/16. This LCD was also revised to add ICD-10-CM code range G81.11-G81.14 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for claims processed on or after 06/09/16, for dates of service on or after 12/22/2015. In addition, based on an LCD reconsideration request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for dates of service on or after 06/09/16.	
06/09/2016	R3	Revision Number: 3 Publication: June 2016 Connection LCR A/B2016-066 Explanation of revision: Based on an LCD reconsideration request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0586. Additionally, language clarifying the asterisked diagnoses was also added to this section. Also, "spasticity of the arm in patients following a stroke" was removed from the "Off-label Indications" section for Dysport™. The effective date	• Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		of this revision is for dates of service on or after 06/09/16. This LCD was also revised to add ICD-10-CM code range G81.11-G81.14 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for claims processed on or after 06/09/16, for dates of service on or after 12/22/2015. In addition, based on an LCD reconsideration request, this LCD was revised to add ICD-10-CM codes G80.0, G80.1, G80.2, G82.53, G82.54, G83.0*, and ICD-10-CM code ranges G83.21-G83.24*, I69.031-I69.034, I69.051-I69.054, I69.131-I69.134, I69.151-I69.154, I69.231-I69.234, I69.251-I69.254, I69.331-I69.334, I69.351-I69.354, I69.831-I69.834, and I69.851-I69.854 under the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure code J0588. The effective date of this revision is for dates of service on or after 06/09/16.	
03/29/2016	R2	Revision Number: 2 Publication: March 2016 Connection LCR A/B2016-053 Explanation of revision: Based on an LCD reconsideration request, this LCD was revised to include the FDA indication for Xeomin® –upper limb spasticity in adult patients under the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD. The effective date of this revision is for claims processed on or after 3/29/2016, for dates of service on or after 12/22/2015. This LCD was also revised based on LCD reconsideration request to include the FDA indication for Botox® - lower limb spasticity in adult patients under the "Indications and Limitations of Coverage and/or Medical Necessity" section. In addition "spastic hemiplegia", and "spasticity related to stroke" were removed from the "Off label Indications for Botox®" and added to the "FDA Indications for Botox®" section of the LCD. Also, the ICD-10-CM codes G80.1, I69.061-I69.065, I69.161- I69.165, I69.261-I69.265 and I69.361-I69.365 were added under "ICD-10 Codes that Support Medical Necessity" for procedure code J0585. The effective date of this revision is for claims processed on or after 03/29/2016, for dates of service on or after 01/21/2016.	• Reconsideration Request
02/23/2016	R1	Revision Number: 1 Publication: March 2016 Connection LCR A/B2016-044	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Explanation of revision: Based on an LCD reconsideration request, this LCD was revised to include FDA indication for Dysport— upper limb spasticity in adult patients under the Indications and Limitations of Coverage and/or Medical Necessity section of the LCD. The effective date of this revision is for claims processed on or after 02/23/2016, for dates of service on or after 07/15/15	• New/Updated Technology

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57715 - Billing and Coding: Botulinum Toxins
A58585 - Response to Comments: Botulinum Toxins
LCD(s)
DL33274 - Botulinum Toxins

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2021 with effective dates 03/21/2021 - N/A
Updated on 11/21/2019 with effective dates 01/08/2019 - 03/20/2021
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A