



July 12, 2024

VIA ELECTRONIC MAIL cmd.inquiry@cgsadmin.com

Meredith Loveless, MD, Medical Director,
CGS Administrators LLC
Attn: Medical Review 26 Century Blvd., Ste ST610
Nashville, TN 37214-3685

Re: Proposed LCD - Botulinum Toxin Injections (DL39857)

Dear Dr. Loveless,

On behalf of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)¹, the American Laryngological Association (ALA) and the American Broncho-Esophagological Association (ABEA) we are contacting you regarding **CGS Administrators LLC's Proposed Local Coverage Determination (LCD) – Botulinum Toxin Injections (DL 39857)**.

This Proposed LCD has been developed to address the off-label uses of Botulinum Toxins in the Medicare population. As Botulinum toxin is a versatile tool utilized in daily practice of medicine, it has become standard of care for many specialties. Otolaryngologist-Head and Neck Surgeons are no exceptions. As the specialty most involved with the upper aerodigestive tract, our specialists treat patients benefiting from botulinum toxin injections to improve their ability to communicate, to work, to swallow and to breathe. We are concerned that the LCD as written, inappropriately limits otolaryngologist-head and neck surgeons from giving “best care” treatment options to our patients. In many cases, the use of Botulinum toxin is critical to returning to employment or safely eating a meal or simply talk to their family.

As otolaryngologist-head and neck surgeons we would like to address our specific concerns and provide information that we believe will be helpful as you construct the final LCD to ensure that all patients have access to the full armamentarium of treatment options to effectively treat their medical problem and improve their day to day living conditions.

Our concerns are listed below and are accompanied by literary references as supporting documentation.

General Indications and Limitations of Coverage

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Many conditions which are commonly and successfully treated with botulinum toxin chemodenervation have not received explicit Food and Drug Administration (FDA) approval for treatment. Many of these conditions have historically responded favorably to botulinum toxin have been reimbursed accordingly. These include laryngeal dystonia/spasmodic dysphonia¹, vocal tremor²⁻⁴, facial dystonia, facial and laryngeal synkinesis, temporomandibular joint disorders, palatal myoclonus⁵, first-bite syndrome, Frey's syndrome⁶, salivary fistula, chronic cough⁷⁻⁸, laryngeal spasm, laryngeal granuloma, muscle tension dysphonia, radiation induced muscle spasm, torticollis, inducible laryngeal obstruction, cricopharyngeal dysfunction⁹⁻¹¹, phonic tics¹²⁻¹⁴.

The Proposed LCD references that Botulinum toxin administration must not be given more frequently than every 12 weeks, regardless of diagnosis, unless specifically addressed in the policy. There is ample literature to support that many disorders significantly benefit from more frequent chemodenervation than every 12 weeks based on an individual's response to treatment. Lagos-Villaseca et. al. describes that 27.5% of patients among a multi-institutional cohort benefited from injection intervals of less than 90 days⁴. The effect of botulinum toxin chemodenervation also has a plateau effect followed by dissipation of effect with return of spasm/symptoms. For laryngeal dystonia the mean plateau is 38 days¹⁵. Furthermore, for other dystonia/hyperfunctional disorders of the head and neck, the duration of effect is reported as less than 3 months: blepharospasm (73.3 days), cervical dystonia (81.2 days) and hemifacial spasm (81 days)¹⁶.

Item 10 in the policy references that injections are not considered reasonable and necessary for patients with existing medical conditions which could affect the neuromuscular function; Botulinum toxin is often used in neurologic states when neuromuscular function is affected and thus this statement seems broad and will exclude many individuals that would benefit from treatment. Such conditions might include stroke, cerebral palsy, muscular dystrophy, mitochondrial myopathies, etc.

Item 12 states that Botulinum toxin injections are not considered reasonable and necessary for patients with severe clotting disorders. However, botulinum toxin chemodenervation can and have been used safely in patients with clotting disorders, and in patients that are on anticoagulation with appropriate medical supervision.

Regarding Item 14 which references that both conscious sedation and monitored anesthesia care (MAC) are not medically necessary for botulinum toxin injections, we respectfully disagree. In most cases, botulinum toxin chemodenervation may not require sedation but in pediatric patients, individuals with underlying anxiety disorders, or other medical conditions, sedation is critical and necessary for the procedure to be performed

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accurately, safely and effectively. Inclusion of this statement as written in the final policy will exclude these patients from safe and effective treatment. Furthermore, in select patients and situations, injections into the laryngeal muscles and cricopharyngeus muscle may require direct laryngoscopy under general anesthesia in cases where these muscles are technically not accessible due to patient anatomy, provider experience, or availability of specialized equipment. Additionally, or for certain patients who are unable to cooperate with injection into highly sensitive areas (e.g. pediatric patients, hyperactive gag reflex, severe laryngospasm). For the pediatric patient population, sedation is standard of care for salivary gland chemodenervation for sialorrhea and for chemodenervation for spasticity and muscular hyperfunction.

Item 16 states that image guidance is not considered reasonable and necessary for injection of Botulinum toxin. While this is true for some conditions, there is robust literature indicating that in patients with sialorrhea, image guidance (US guided needle placement) is appropriate and routinely used. Additionally, for chemodenervation of laryngeal disorders, endoscopic approaches are routinely used such that needle placement is confirmed via rigid or flexible endoscopy.

Item 17 indicates that Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as one area. These procedure codes are billed unilaterally or bilaterally. Thus, we request revision of this coverage criteria in the final LCD.

Clinical Rating Scales

Clinical rating scales are useful for research and for quantification of symptoms but routine use in longitudinal clinical practice is not necessary. We respectfully request that all requirements to use a clinical rating scale be removed from this Proposed LCD.

Blepharospasm

Blepharospasm can cause functional blindness and thus it is important to maintain a more even treatment effect to avoid recurrence of visual in facial functional impairment. Clinicians provide treatment when symptoms begin to reoccur to avoid the blepharospasm to reach peak intensity. The LCD as currently written requires persistence or reoccurrence of moderate to severe blepharospasm for subsequent treatment.

The limitation of no more than 5 units per eye is inadequate for patients with more severe blepharospasm which may require up to 30 – 50 units per eye. Under Summary of Evidence (pg 37) –although onabotulinumtoxin is not listed as Level A – it is currently the most commonly used preparation and the most studied preparation.

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Cervical Dystonia

Cervical dystonia is a clinical diagnosis supported by history and a clinical exam, there is not necessarily an “etiology” of the Central Nervous System (CNS) impairment to document separate from what would be documented in cases of idiopathic or primary cervical dystonia. Patients with long-standing cervical dystonia can receive up to 400+ units of onabotulinumtoxin A and thus the upper limits of toxin administration need to be greater in the final LCD.

The Proposed LCD details that pain disorders such as temporomandibular disorders (TMD) and severe bruxism are not medically necessary indications for Botulinum toxin injections. Many patients benefit from injection for hyperfunction of cervical muscles and muscles of mastication and these patients with positive responses should have their treatment appropriately covered.

In the final LCD, it is critical to address that patients who travel a long distances to receive medical care, who are working, those with transportation or financial barriers, be allowed to receive multiple procedures in the same visit. Not allowing such coordination of care is financially burdensome and, in many cases, may prevent patients from receiving necessary and appropriate care. Stipulating that a patient cannot receive multiple procedures on the same day effectively serves as an exclusionary barrier to these patients receiving appropriate care.

Summary of Evidence

In the Summary of Evidence section, Onabotulinumtoxin (Botox) is not included as “level A –” but should be, given it is most commonly used Botulinum toxin. At times it is very difficult to procure abo(Dysport). Rima(Myobloc) has a shorter duration of action than many of the other toxins and has significant side effects at high doses and diffuses more easily to other muscle sites causing dry mouth, dry eyes, dysphagia etc. For these reasons, Onabotulinumtoxin (Botox) is the most commonly used toxin type and should be listed as the first line treatment of choice with a related A- grading level.

Chronic Migraine

The Initial dosing guidelines listed only allow 5 units per site divided among the following muscles: frontalis, corrugator, procerus, occipitalis, temporalis, trapezius, and cervical paraspinal muscle group. The masseter muscle is excluded but should be added to the final LCD as it is a commonly treated site.

The upper limit dose should be 400+ units. For many patients, both the muscles of mastication which can routinely be treated in doses up to 200 units (50 units to each of

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the four muscles)] and the cervical paraspinal muscles (which can also take large doses of toxin) when treated.

Hemifacial Spasm/ Facial Dystonia

The Initial dose of 30 units is reasonable but may need to increase by more than 5-15 units over time.

Hyperhidrosis

The Proposed LCD only considers the diagnosis of axillary hyperhidrosis. The LCD as finalized should also include Frey syndrome (also known as auriculotemporal syndrome), a postoperative phenomenon following salivary gland surgery and less commonly neck dissection, facelift procedures, and trauma that is characterized by gustatory sweating and flushing in the preauricular area in response to mastication or a salivary stimulus. It is a common occurrence after salivary gland surgery, occurring in 4% to 62% of post parotidectomy patients to some degree. For patients with severe Frey syndrome, treatment with Botulinum Toxin injections significantly improves quality of life⁶.

Laryngeal Dysphonia

We respectfully suggest that this condition be more appropriately referenced as Laryngeal Dystonia (LD) rather than Laryngeal Dysphonia, as currently written in the draft policy. Under the section addressing Initial Botulinum Toxin Injections, the Proposed LCD indicates that there will be “objective” documentation of the clinical features. The use of the term “objective” is not appropriate. The diagnosis of Laryngeal Dystonia of any type including adductor, abductor, mixed or respiratory¹⁷ is made by a combination of clinician perceptual analysis, flexible laryngoscopy and exclusion of other disorders. Textbook: Bailey’s Head & Neck Surgery, 6ed, 2022, Chapter 70, “Neurologic Disorders of the Larynx”, pages 1070-1080. Wolters Kluwer provides an accurate description.

Also, it is not standard of practice to measure the response of vocal improvement due to botulinum toxin chemodenervation for laryngeal dystonia with an objective clinical scale. In fact, no validated scale currently exists for laryngeal dystonia (encompassing all types as described above). Additionally, the Voice Handicap Index (VHI) and the Vocal Performance Questionnaire (VPQ) are neither objective nor diagnostic and there are no studies showing utility of these patient reported scales in differentiating LD from other voice disorders or in the longitudinal care of patients with LD. These scales are examples of patient reported outcome measures (PROMs) used in voice care. These tools are patient reported and capture the patient’s opinion of their perceived vocal dysfunction. Furthermore, the questions included in these PROMs do not capture the specific physical and phenomenological communication abnormalities experienced by laryngeal dystonia patients. The use of these PROMs is not a standard of care in assessing quantitatively or

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qualitatively response to botulinum toxin treatment for those physicians treating these patients. We respectfully request that this requirement for “objective clinical scale” be removed. A

The initial injection guideline describes the use of onabotulinumtoxin - while this is likely the most commonly used preparation, there are several other types and preparations available. Patients that may have used botulinum toxin chemodenervation for other disease processes, may have utilized a different preparation, most commonly Incobotulinumtoxin -Xeomin. We suggest that in these scenarios other preparations of Botulinum toxin be allowed.

The initial dosing guidelines describe injections in “two separate sites of one posterior cricoarytenoid muscle on one side to a total dose between 1.5 to 3.5 units.” Although this does capture a possible initial dosing strategy for Abductor laryngeal dystonia, a rarer subtype of laryngeal dystonia, it does not address initial treatment for Adductor laryngeal dystonia which accounts for greater than 95% of laryngeal dystonia.

For the Adductor laryngeal dystonia sub-type, an average starting dose would be up to 2.5 units into each TA-LCA (bilateral injections) muscle for a total starting dose of up to 5 units total. Furthermore, these muscles are small and expert clinicians do not routinely inject into two separate sites on each muscle. Importantly, some clinicians utilize endoscopic false vocal fold injections with excellent results¹⁸ and these injections tend to have higher doses of 5-10 units bilaterally with a total starting dose of up to 20 units total.

A 12-week interval is required in the proposed LCD. Many patients require more frequent botulinum toxin dosing to control symptoms⁴ and subsequently recommend that a shorter interval be allowed if the clinician determines that more frequent treatments are medically necessary. Additionally, there is a subset of patients who require a higher dose than 7 units. There is no literature describing a maximum dose for laryngeal dystonia.

The proposed LCD limits coverage payment to only one injection per site. Many patients with laryngeal dystonia are injected bilaterally, which is a different billing code than unilateral injections. There are also some patients that require injections for facial or cervical dystonia in addition to laryngeal dystonia. Up to 17% of laryngeal dystonia patients can eventually develop additional dystonia of other anatomical areas such as craniocervical and other sites¹.

Sialorrhea

Although Rima and Incobotulinum toxin are mentioned in the initial dosing guidelines at appropriate doses, Onabotulinum toxin Is still the most commonly used toxin for this

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disorder. These patients often have neurologic dysfunction such as cerebral palsy, stroke, closed head injury with swallowing dysfunction as the underlying etiology of the sialorrhea and thus receive chemodenervation for trunk or limb spasticity/dystonia or other facial, laryngeal, cervical spasticity/dystonia with onabotulinumtoxin. It is important that both indications are covered and allowed treatment with chemodenervation, and to allow chemodenervation with the same serotype of toxin.

For subsequent dosing there is no allowance to increase the dose. The Proposed LCD additionally references subsequent dosing for Incobotulinumtoxin at 16 weeks – which should be shortened to 12 weeks.

Conclusion

We appreciate the opportunity to provide comments on CGS Administrators' proposed LCD Botulinum Toxin Injections (DL39857). We respectfully request that the final coverage policy adopted by CGS include the suggestions included in this correspondence and would welcome the opportunity to discuss our feedback. Should you have any questions, please contact healthpolicy@entnet.org.

Sincerely,

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Executive Vice President and CEO
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