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Regarding: Proposed LCD – Botulinum Toxin Injections

To Whom It May Concern:

As medical providers to individuals with both hyperfunctional muscular, secretory and nociception disorders of the upper aerodigestive tract we would like to raise several concerns regarding the new LCD proposed guidelines (Proposed LCD – Botulinum Toxin Injections). We have identified several errors and omissions in the guidelines as written such that it significantly undermines the confidence of the medical and lay community in the medical expertise of the individuals developing these proposals. We have concerns that these proposals are not being vetted by professionals familiar with these disease processes/treatments or experienced with the treatments. We strongly oppose these changes that at best limit providers from giving the most appropriate care and at worst prevent patients from receiving necessary care. We have listed our concerns below with page numbers to the LCD for reference. We have included relevant literature.

On behalf of the Otolaryngology community, we strongly request that the information in the proposed LCD is changed to reflect the published literature regarding the treatment with chemodenervation of the described craniocervical disorders to allow safe and effective treatment of our patients.

Sincerely,

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Key Points Summary

- In the treatment of disorders of the aerodigestive tract, botulinum toxin chemodenervation is commonly used to treat a variety of disorders that include but are not limited to laryngeal dystonia (spasmodic dysphonia), blepharospasm, facial dystonia, cervical dystonia (spasmodic torticollis), orolinguomandibular dystonia, facial and laryngeal synkinesis, neurogenic laryngeal stridor, hyper-functional voice disorders, tic disorders, temporomandibular joint dysfunction, palatal myoclonus, first-bite syndrome, Frey syndrome, sialorrhea, and cricopharyngeus muscle dysfunction.
- The frequency of use of botulinum toxin chemodenervation injection procedures is largely dependent on the patient's specific clinical needs and physiologic response and more frequent treatment is often required. Having set limits on these is arbitrary and not supported by the literature.
- Similarly, limitations on starting dosage and maximal dosage fail to recognize the variety of effective treatment plans tailored to the needs of our patients.
- Diagnostic criteria for laryngeal dystonia include the evaluation of voice quality changes such as alterations in pitch, loudness, or vocal effort that impair communication or reduce the quality of life. A thorough history and physical examination are crucial to identify underlying causes of dysphonia and to differentiate Laryngeal dystonia from other voice disorders. Laryngoscopy is recommended when dysphonia fails to resolve or improve within 4 weeks or when a serious underlying cause is suspected, irrespective of the duration of symptoms.
- Laryngeal dystonia botulinum toxin chemodenervation is often performed bilaterally for optimal patient response.
- For the more common adductor form of the disorder the thyroarytenoid (TA)/lateral cricoarytenoid (LCA) muscle complex is targeted. For the rarer abductor form and mixed-type the posterior cricoarytenoid muscle is targeted.
- Onabotulinumtoxin is the most common form of botulinum toxin used for treatment of laryngeal dystonia in clinical practice and in the medical literature

Pg4: General Indications and Limitations of Coverage

- For items 1-4 we raise the concern that many important conditions which are commonly and successfully treated with botulinum toxin chemodenervation, do not hold a FDA approval standing for treatment. This includes many conditions that have historically been covered such as Laryngeal dystonia/spasmodic dysphonia[1], vocal tremor[2-4], facial dystonia, facial and laryngeal synkinesis, TMJ, palatal myoclonus[5], first-bite syndrome, Frey syndrome[6], salivary fistula, chronic cough[7, 8], laryngeal spasm, laryngeal granuloma, muscle tension dysphonia, radiation induced muscle spasm, inducible laryngeal obstruction, cricopharyngeal dysfunction[9-11], phonic tics[12-14].
- For item 5, we would like to provide literature to support that many disorders significantly benefit from more frequent chemodenervation than every 12 weeks. Lagos-Villaseca et. al. describes that 27.5% of patients among a multi-institutional cohort benefited from injection intervals of less than 90 days[4]. 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 days[15]. 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].

- For item 10 – 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 – botulinum toxin chemodenervation can be used safely in patients with clotting disorders, and in patients that are on anticoagulation with appropriate medical supervision
- Item 14 – in most cases, botulinum toxin chemodenervation may not require sedation but for pediatric patients, individuals with underlying anxiety disorders or other medical conditions sedation is critical and necessary for the procedure to be performed accurately, safely and effectively. This statement will exclude these patients from safe and effective treatment. Furthermore, 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, or in the case of a patient who is unable to cooperate with injection into highly sensitive area (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, We would like to bring up that for sialorrhea image guidance (US guided needle placement) is 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: here it is specified that medicare will allow payment for one injection per site regardless of the number of injections made into the site with a site being defined as one area. We would like to point out that these procedure codes are billed unilaterally or bilaterally.

Pg8: Blepharospasm

- Clinical rating scales are useful for research and for quantification of symptoms but routine use in longitudinal clinical practice is not necessary. We advocate that the requirement for a clinical rating scale to be used be removed from this LCD.
- For the subsequent treatment this document requires persistence or reoccurrence of moderate to severe blepharospasm – clinicians treat when symptoms begin to reoccur and avoid allowing the blepharospasm to reach peak intensity. Blepharospasm can cause functional blindness and thus it is important to maintain a more even treatment effect to avoid recurrence of visual impairment.
- Limitation of no more than 5 units per eye is too low a dose for more significant blepharospasm which may go 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

Pg 10: Blepharospasm associated with Orofacial Dystonia

- Clinical rating scales are useful for research and for quantification of symptoms but routine use in longitudinal clinical practice is not necessary. We advocate that the requirement for a clinical rating scale to be used be removed from this LCD.

Pg 12: Cervical Dystonia

- Clinical rating scales are useful for research and for quantification of symptoms but routine use in longitudinal clinical practice is not necessary. We advocate that the requirement for a clinical rating scale to be used be removed from this LCD.
- Cervical dystonia is a clinical diagnosis supported by history and a clinical exam thus for point #2 there is not necessarily an "etiology" of CNS impairment to document separate from what we would document in point #1
- For patients that travel a long distance to receive medical care, who are working, or who have transportation or financial barriers, it is critical that they can have multiple procedures in the same visit. Not allowing such coordination of care both is financially burdensome for the patients and in many cases may prevent them from receiving necessary care. Stipulating that a patient can not receive multiple procedures on the same day is placing unnecessary barriers to these patients receiving appropriate care.
- Patients with long-standing cervical dystonia can receive up to 400+ units of onabotulinumtoxinA and thus the upper limits of toxin administration needs to be higher
- On page 13 it is called out that pain disorders such as TMD and severe bruxism are not medically necessary indications for botulinum toxin injections - we have many patients that benefit from injection for hyperfunction of cervical muscles and muscles of mastication and these patients should be allowed treatment.
- Under Summary of Evidence (p. 38): Onabotulinumtoxin (Botox) is not listed as level A - but is most commonly used. It is very difficult to get abo(Dysport) in the United states. Rima(Myobloc) has a significant side effect profile at these high doses and diffuses more easily to other muscle sites (dry mouth, dry eyes, dysphagia). Rima(Myobloc) also has a shorter duration of action than many of the other toxins. For the above reasons, Onabotulinumtoxin (Botox) is the most commonly used toxin type and should be listed as first line.

Pg 14: Chronic Migraine

- For initial dosing guidelines (pg 16 point #1) the initial dosing guideline only allows 5 units per site divided among the following muscles: frontalis, corrugator, procerus, occipitalis, temporalis, trapezius, and cervical paraspinal muscle group. The masseter is not called out among these muscles and is commonly treated.
- Under limitations of coverage (pg 16 point #1) it states that it is not reasonable nor necessary for multiple procedures to be provided on the same day. For patients that travel a long distance to receive medical care, who are working, or who have transportation or financial barriers, it is critical that they can have multiple procedures in the same visit. Not allowing such coordination of care both is financially burdensome for the patients and in many cases may prevent them from

receiving necessary care. Stipulating that a patient can not receive multiple procedures on the same day is placing unnecessary barriers to these patients receiving appropriate care.

- The upper limit of dose should be higher than 195 units - and should go up to 400+ units. The rationale is that for many of these patients both the muscles of mastication [which can routinely be treated in doses up to 200 units (50 units to each of the four muscles)] and the cervical paraspinal muscles (which can also take large doses of toxin) are treated.

Pg 18: Hemifacial Spasm/ Facial Dystonia

- Clinical rating scales are useful for research and for quantification of symptoms but routine use in longitudinal clinical practice is not necessary. We advocate that the requirement for a clinical rating scale to be used be removed from this LCD.
- Initial dose of 30 units is reasonable but may need to increase much more than 5-15 units over time.

Pg 19: Hyperhidrosis

- Only axillary hyperhidrosis is considered in the LCD and we would like to call out Frey Syndrome as an important diagnosis to cover.
- Frey syndrome (also known as auriculotemporal syndrome) is 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 significantly improves QoL[6].

P21: Laryngeal Dysphonia

- Diagnostic title should be changed from Laryngeal Dysphonia to Laryngeal Dystonia
- Under Initial Botulinum Toxin Injections point #1 (pg 22)- In this statement it is described that there will be objective documentation of the clinical features. The frequent use of the term objective is not appropriate. The diagnosis of Laryngeal Dystonia (any type including adductor, abductor, mixed or respiratory[17]) is made by a combination of clinician perceptual analysis, flexible laryngoscopy and exclusion of other disorders. Please see the description in the following textbook: Bailey's Head & Neck Surgery, 6ed, 2022, Chapter 70, "Neurologic Disorders of the Larynx", pages 1070-1080. Wolters Kluwer.
- Under Initial Botulinum Toxin Injections point #3 (pg 22) - 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, and no validated scale currently exists for laryngeal dystonia (encompassing all types as

described above). The VHI and 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 among many 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. This is the patient's opinion, not an objective assessment. Furthermore the questions included in these PROMs do not capture the specific physical and phenomenological communication abnormalities experienced by laryngeal dystonia patients. None of the current large academic neurolaryngology practices utilize these scales for diagnosis or longitudinal care of patients with LD (personal communication with Dr. Andrew Blitzer, and USC, UCSF, University of Washington, University of Michigan). We request that this requirement for "objective clinical scale" be removed as it is not currently part of clinical use and has not been recommended to be incorporated into clinical use by any treatment guideline

- The initial injection guideline describes the use of onabotulinumtoxin - while this is likely the most commonly used preparation currently, there are several other types and preparations available - and in patients that may have used botulinum toxin chemodenervation for other disease processes they may be using a different preparation (most commonly incobotulinumtoxin -Xeomin). We recommend that in these scenarios other preparations of botulinumtoxin are allowed.
- The initial dosing guidelines (pg 22) describe injection 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, which is the more rare 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 even expert clinicians do not routinely inject into two separate sites into each muscle. It may be that the authors of this LCD are referring to bilateral injections which are common in ADductor LD treatment but less common in ABductor LD treatment. Finally, some clinicians utilize endoscopic false vocal fold injections with excellent results[18] - and these injections tend to have higher doses of 5-10 units bilaterally with a total starting dose of up to 20 units total.
- The subsequent dosing guidelines (pg 22) point #1 describes a second injection 2-4 weeks later into the contralateral side which is appropriate for ABductor LD. Additionally, another injection in the 2-4 week time frame may also be appropriate for patients that require a booster for an injection with minimal response- although booster injections are most often bilateral.
- Subsequent dosing guidelines (pg 22) point #2 - A 12-week interval is noted – we know that many patients require more frequent botulinum toxin dosing to control symptoms[4] and subsequently advocate that a shorter interval is 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 max dose for laryngeal dystonia.

- In the heading under limitations of coverage (pg 23) – it describes that medicare will allow payment for only one injection per site. Many patients with laryngeal dystonia are injected bilaterally, which is a different billing code than unilateral injections. Additionally, some patients 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 (both craniocervical and other sites)[1].

Pg 27: 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 disorder. These patients often have neurologic dysfunction (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. Additionally subsequent dosing for incobotulinumtoxin Is at 16 weeks – which should be shortened to 12 weeks.

Pg 32: Provider Qualifications

- Otolaryngologists are qualified as part of their residency training process for botulinum toxin chemodenervation of craniocervical sites. Injection may be guided via EMG, endoscopically, ultrasound, or performed without specific image guidance.

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