ASHA
American
Speech-Language-Hearing
Association

Submitted electronically to policycomments@wpsic.com

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RE: Draft Local Coverage Determination DL39909: Botulinum Toxin Injections

To whom it may concern:

On behalf of the American Speech-Language-Hearing Association (ASHA), I write to offer comments on the draft local coverage determination (LCD) for botulinum toxin injections (BTIs).[1]

ASHA is the national professional, scientific, and credentialing association for 234,000 members, certificate holders, and affiliates who are audiologists; speech-language pathologists (SLPs); speech, language, and hearing scientists; audiology and speech-language pathology assistants; and students.

SLPs treat patients with laryngeal spasmodic dysphonia (SD) as members of multidisciplinary care teams that include the physicians who provide these injections. SLPs recognize the tremendous value BTIs have for these patients and are concerned with numerous provisions of the draft LCD. **Therefore, ASHA opposes the draft LCD in its current form and encourages WPS to engage clinicians with expertise in the treatment of patients with SD.**

SD is a neurological voice condition (focal laryngeal dystonia) that impacts every aspect of a person's life because it significantly impairs their ability to communicate functional daily needs. Treatment of SD using BTIs varies greatly in dosing, site of injection, and unilateral or bilateral dosing intervals depending on the different forms of this voice condition and the patient's age and sex.[2,3] The proposed guidelines limit a physician's ability to determine the appropriate course of treatment. For example, injections are limited to once every 12 weeks. However, it is generally accepted in the medical community that some patients with SD may need to receive more than one course of BTIs within a three-to-four-month period.

Additionally, focal laryngeal dystonia is similar to other forms of dystonia such as blepharospasm and cervical dystonia. The coverage guidelines for blepharospasm and cervical dystonia allow for variation in dosing based on the patient's response to treatment. It is clinically inappropriate to establish different coverage guidelines based on the form of dystonia.

The proposed LCD requires the same dosing over the course of treatment. But the medical literature indicates that the amount of BTI needed to effectively provide symptom improvement may decrease over time. Maintaining consistent or higher dosing over the course of treatment may be clinically contraindicated because it places patients at risk for swallowing impairment or aspiration because the airway does not have appropriate protection. Therefore, the proposed LCD would undermine the current treatment for these patients.

We are concerned the coverage guidelines included in the draft LCD are not based on commonly accepted practices by the physicians treating these patients or on current peer-reviewed published articles. For example, the muscle mentioned for the initial injection—

posterior cricoarytenoid (PCA)—is never injected for people with adductor SD. The posterior PCA is injected primarily for patients with abductor SD, the least common type of SD. In adductor SD, the thyroarytenoid (TA) muscle is the primary muscle injected, as it creates a strained, strangled vocal quality. The muscle injected is dictated by which muscle(s) are spasming. Unfortunately, the muscles that are injected for adductor SD are not mentioned anywhere in the guidelines, which calls into question coverage for patients with this form of SD. Thus, the criteria outlined in the LCD cannot be applied to all people with SD.

The diagnosis guidelines fail to address coverage for patients with mixed (both adductor and abductor) SD. Coverage is also restricted to moderate to severe SD. However, there is no "objective clinical scale" for this condition and no criteria that would place a patient in a mild, moderate, or severe category. Moreover, due to vocal demands, a patient with mild symptoms could benefit greatly—and possibly even more so—than someone with more significant dysphonia.

Finally, the diagnosis guidelines state:

> "The objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment. For example, the Voice Handicap Index (VHI) and the Vocal Performance Questionnaire (VPQ)."

Although the VHI and VPQ are useful patient reported outcome measures, they are not objective clinical outcome measures upon which coverage should be based.

This proposal, if finalized, would essentially leave the majority of people with SD voiceless, depriving them of access to medically necessary care. **ASHA strongly believes WPS should not finalize this LCD until coverage guidelines can address all types of SD based on current treatment protocols.**

Thank you for your consideration of this request. ASHA stands ready to assist as you consider our comments. If you or your staff have any questions, please contact Sarah Warren, MA, ASHA's director of health care policy for Medicare, at swarren@asha.org.

Sincerely,

Tena L. McNamara, AuD, CCC-A/SLP
2024 ASHA President

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[1] Centers for Medicare & Medicaid Services. (n.d.). *Proposed LCD Botulinum Toxin Injections* (DL39836). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39835&ver=10&contractorName=2&contractorNumber=all&proposedStatus=all&sortBy=title&bc=10

[2] Heyes, R., Adler, C.H., Zhang, N., Lott, D.G., and Bansberg, S.F. (2023, January 29). *Significance of age and sex in botulinum neurotoxin dosing for adductor spasmodic dysphonia*. World J Otorhinolaryngol Head Neck Surg. 2023;9:168-173. https://doi.org/10.1002/wjo2.88

[3] Kang, M.S., Lee, S.J., Choi, H-S, and Lim, J-Y. *Factors influencing long-term treatment response to botulinum toxin injection for spasmodic dysphonia*. Clin Otolaryngol. 2021;46:436–444. https://doi.org/10.1111/coa.13678