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SANTA BARBARA • SANTA CRUZ

David Geffen School of Medicine at UCLA
Department of Head and Neck Surgery
10833 Le Conte Avenue, 62-132 CHS
Los Angeles CA 90095-1624
E-mail: gberke@mednet.ucla.edu
GERALD S. BERKE, MD

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RE: Proposed LCD- Botulinum Toxin Injections

To whom it may concern,
Thank you for allowing the Dysphonia International, formally the National Spasmodic Dysphonia Association (NSDA) to comment on the new guidelines of use and payment of Botulinum toxin to treat vocal dystonia's of the head and neck. As way of introduction I am currently the Chair of the Dysphonia International (NSDA) Scientific Advisory Board and have been in this position for over 10 years. My current academic title is Chair Emeritus and Professor of Otolaryngology / Head and Neck Surgery at the UCLA School of Medicine, and Director and founder of the UCLA Voice Center for Medicine and the Arts. I was the former president of the American Laryngological Association as well as the Tribological Society, the nations oldest sub-specialty society and I have published extensively on studies of laryngeal physiology and was a member of National Deafness and Other Communications Disorders Advisory Council from June 2010 to May 2014 as the only Laryngologist on the council. I have reported on and used botox to treat laryngeal disorders since 1985 and developed the Point-Touch Technique for injection. Moreover, I was the co-chair of the re-write of the 1995 National Strategic Research Plan of Voice Disorders and Swallowing.

As a matter of information, I would certainly like to call your attention to the letter from Michael Johns, MD the president of the American Laryngological Association, the letter from Robert Bastian MD, of the Bastian Voice Institute in IL, who is nationally considered an expert in the diagnosis and management of laryngeal (spasmodic) dysphonia and also Clark Rosen MD, who is the Chief in the Division of Laryngology as well as the Director of the UCSF Voice and Swallowing Center at the University of California. Their comments are pertinent to the points raised and need to be carefully considered within the context of indications and treatment coverage for patients with Botox responsive neurologic disorders affecting the larynx. With respect to these continuing and new criteria, under indications of coverage where is says:

"Initial botulinum toxin injections for laryngeal dystonia will be considered reasonable and necessary when the following requirements are met:

1. *Objective documentation of the clinical features consistent with the diagnosis of adductor or abductor laryngeal dystonia; AND*
2. *Objective assessment and documentation to rule out non-organic voice disorders;"*

Currently there are no standard "objective" documentation methodologies. While the Voice Handicap Index and Voice Performance Questionnaire have been useful in identifying improvement in patients for the treatment of laryngeal disorders, they are self-reported subjective questionnaires. Dystonia International along with the Dystonia Coalition have funded an objective severity measure of patients with Spasmodic Dysphonia using machine learning analysis of videoscope laryngeal images, https://pubmed.ncbi.nlm.nih.gov/36130065/. This is one of the first objective studies showing relationship

of analysis to perceptual severity, the computer algorithm is currently not available to the public, and the methodologies are still undergoing longitudinal verification of therapeutic improvement. In the meantime, initial documentation of the hallmarks related to both tremor, adductor spasmodic dysphonia, and abductor spasmodic dysphonia should be required as well as description of video laryngeal imaging with qualitative observations of severity, including sidedness, tremor, and lack of other non-neurological causes of dysphonia. It is of course reasonable and necessary to document at baseline as well as before each treatment procedure.

Unfortunately under initial dosing guidelines the sentence was incorrect, the correct sentence should read:

1. The initial injection of onabotulinumtoxinA for Adductor Laryngeal Dystonia may be placed unilaterally or bilaterally into the thyroarytenoid and lateral cricoarytenoid muscles.
2. For Adductor laryngeal dystonia a dose ranging from 1/16 of a unit up to 5 units on each side.
3. For Abductor dysphonia the posterior cricoarytenoid muscle on one or both side may be injected with a dose between 1 to 5 units of toxin.

Under subsequent Botulinum toxin injections shall be deemed reasonable and necessary when:

1. Documentation of informed clinical decision regarding repeat Botulinum toxin injections and reassessment of the degree of persistent and or recurrent laryngeal dystonia and assessment of previous response to Botulinum toxin is present and documented.

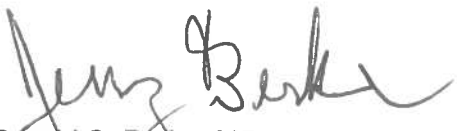
Under subsequent dosing guidelines, the sentence should read:

1. Additional injections of onabotulinumtoxinA on one or both sides, subsequent injections are usually are given at 12 week intervals but may be given more or less frequently depending upon on the documented degree of breathiness, what the individual patient can manage and the response to the previous dose.

Under limitations of coverage, it is agreed that Medicare should allow payment of one injection per side, regardless of the number of injections made into the site. It should be noted that the dose response curve for each individual patient is quite variable with dose responses from 1/16 of a unit up to 5 or even 10 units need to be required for maximum beneficial effects.

With respect to my comments, I would refer you to Dr. Michael Johns and the American Laryngological Association letter for bullet items 1-4 and bullet for item 5. I would like to thank the committee for seriously considering the corrections to the LCD and additional relevant information.

Sincerely,



Gerald S. Berke, MD
Professor and Chair Emeritus
UCLA Department of Head and Neck Surgery
David Geffen School of Medicine at UCLA