First Coast Service Options, Inc.

JN Open Meeting

Thursday, October 24, 1 p.m.

Topics:

DL33274 – Botulinum Toxins

CORPORATE PARTICIPANTS

Patrick Mann, MD - Novitas Executive Contractor Medical Director

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PRESENTER

Jonathan Bouchard- Director of Health Economics and Outcomes Research, IPSEN

PRESENTATION

Dr. Patrick Mann

Thank you, Monica. Good morning all. I would like to welcome everyone to First Coast's open October meeting. My name is Dr. Patrick Mann. And joining me today are my Novitas and First Coast colleagues, Dr. Anitra Graves, Dr. David Sommers, Dr. Benita Jackson, Dr. Jennifer Davis, and Dr. Vishnu Potini. Please be aware that First Coast is recording this virtual open meeting to comply with the CMS guidelines. By remaining logged in and connected via telephone or webinar, you acknowledge that you have been made aware that this virtual open meeting is being recorded, and you are consenting to the recording. If you do not consent to being recorded, please disconnect from this virtual open meeting.

We are holding today's open meeting to provide you with an opportunity to present your comments on revisions made in response to an LCD reconsideration request. Open meetings allow interested parties the opportunity to present information and offer comments related to the new proposed LCDs and/or the revised portion of a proposed LCD during the 45-day comment period. The proposed LCD topic for today's meeting is DL33274 botulinum toxins.

During today's meeting, interested parties will make presentations of information related to the proposed LCD. Please remember, today's call is being recorded, and we request that all formal comments be submitted in writing before the end of the comment period on November 23rd. We encourage you to submit full-text, published evidence supporting your recommendations that have not been previously submitted. This is a critical component in effecting any change. At this time, I'd like to turn the meeting over to our medical policy supervisor, Deneen Schroyer, who will provide a brief overview of the proposed LCD DL33274 for botulinum toxins.

Deneen Schroyer

Thank you, Dr. Mann. This local coverage determination is a result of a reconsideration request. Additionally, the indications for off-label uses have been expanded upon [in offering?] clarification. The proposed policy is available for review on our website as well as in the CMS Medicare Coverage Database. 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. A reconsideration request was submitted, requesting coverage for the treatment of benign essential blepharospasm with Myobloc in patients who are refractory to Botox.

After review of the submitted literature, it was determined that there was a low certainty of evidence supporting Myobloc for the treatment of blepharospasm. Therefore, coverage was not expanded for this use. A request was made to remove the language in the billing and coding article regarding the specific muscles that should be injected. The billing and coding article has been revised to remove language regarding specific muscles that are approved for injections. Providers are encouraged to follow the FDA guidelines. Additionally, the paraplegia, quadriplegia, monoplegia, and hemiplegia ICD-10-CM codes have been removed from the article. These codes do not fit the definition of specificity. The article contains ICD-10-M codes that better describe the indications for use. Dr. Mann, back to you.

Dr. Patrick Mann

[Pharmaceuticals?]. Thank you, Deneen. Our first presenter for proposed LCD DL33274 is Jonathan Bouchard from Ipsen Biopharmaceuticals. Please go ahead stating any conflicts of interests.

Jonathan Bouchard

Good afternoon. I'm Jonathan Bouchard. I am the director of health economics and outcomes research for Ipsen. I am a full-time employee of Ipsen, and I also hold shares in Ipsen stock. So this presentation is in response to a MAC request for feedback on the updated MAC draft LCD policy consistent with the FDA-approved and off-label uses of botulinum toxin A or BoNT /A for the Medicare population. I am here to fill in for Dr. Amandeep Mann, who is our medical director, who is supposed to give this presentation. Unfortunately, she's stuck on an aircraft right now, so I'm filling in. She will be presenting tomorrow, I believe, to the same group. So if there are any questions after this presentation, she would be more than happy to address them tomorrow at the end of this presentation that we're doing again tomorrow.

Ipsen Biopharmaceuticals would like to recognize and thank First Coast members for efforts in updating this very comprehensive BoNT LCD policy, and what I'll do is I'll walk through some of the key sections of the draft policy that we hope can be updated to improve access for the Medicare population to treatment options like Dysport or abobotulinumtoxin. I'll also provide comments on Dysport or abobotulinumtoxinA to be considered for sections of the draft LCD policy that we feel significantly limit access to the appropriate treatment options for Medicare patients. Ipsen will follow up with a detailed response letter, including all supporting references to be considered for the final LCD policy.

So, first of all, ABO, or abobotulinumtoxin, for therapeutics is FDA-approved for the treatment of cervical dystonia in adults and for the treatment of spasticity in patients of two years of age or older. You can refer to the approved abobotulinumtoxin prescribing information for complete details, also on the box warning for distance spread of toxin effect, contraindications, warnings, precautions, and adverse reactions. ABO has been available in Europe since 1990 and was first approved in the US in 2009. It's been marketed for over 30 years, with more than 5 million treatment years of patient experience and over 1,300 peer-reviewed publications globally across multiple indications, including but not limited to cervical dystonia and spasticity.

So there are a couple of comments I'll go over now. The first one is a request to update the indications of coverage to be inclusive of all cervical dystonia and spasticity patients that can be treated and avoid restricting access. First of all, the LCD policy should cover all cervical dystonia and spasticity patients to avoid restricting treatment. The FDA approval label for ABO is broad and is not limited for either indication such as by etiology. Furthermore, in the American Academy of Neurology guidelines, ABO is the only abobotulinumtoxinA with level A recommendations for use in cervical dystonia and in adult spasticity patients in both upper and lower limb.

Secondly, we would ask for restatement of the 116 on-label diagnosis codes omitted from the draft LCD, including cerebral palsy, the paralysis, pelagia classifications, contractions, and muscle spasms. For our approved indication spasticity, ABO has an established safety profile and proven efficacy in phase three registrational trials. There are also phase four studies reflective of real-world use of abobotulinumtoxin. For pediatric spasticity, the efficacy and safety of ABO in upper and lower limb was evaluated in CP patients with spasticity, which is the most common cause of spasticity in children. And of note, the types of paralysis and spasticity in both adults and pediatric patients can be classified as diplegia, hemiplegia, paraplegia, or quadriplegia according to the area of the body that is affected. And therefore, we request these codes to be reinstated for treatment with ABO.

Thirdly, additional codes that should be considered for ABO that will ultimately impact patient care. I would like to bring awareness of existing published data of ABO and other conditions that fit under the category of other dystonias. And these include but are not limited to blephalospasm and hemifacial spasms. One of the first indications for use of ABO in Europe was for blepharospasm and hemifacial spasm in the early 1990s. We have a number of studies showing the improvement of symptoms and outcomes with ABO in these populations. In addition, there is data that supports ABO use in other conditions, such as NDO. Please refer to the written comments for response for more details. That's really the end of my comments this morning, and I want to thank you for the opportunity to be on the agenda and speak. As mentioned, you'll receive a written detailed response from Ipsen with feedback on the codes, supportive data, and the PI for you to review and consider the ABO coverage in the policy update. And thank you.

Dr. Patrick Mann

Thank you very much for the presentation and stepping in to present that for the meeting. Since there are no additional presenters, I'd like to thank everyone for their participation in today's open meeting and remind you to submit comments in writing before the end of the comment period on November 23rd. This meeting is adjourned.