J15 Kentucky & Ohio Ad Hoc Open Meeting: Draft or Revised LCD Public Discussion

Meeting Date & Time: May 5, 2026, 5 pm ET
Topic: Botulinum Toxin Injections

MEREDITH LOVELESS 0:06

I'm going to provide an overview of the policy, which we'll be discussing today, followed by three presentations. The speakers will be promoted at the time of their speaking time so that they have audio and we will pull the slides up and you will be able to give your presentation. And we do ask that all presentations are also followed by written comments that we can then utilize in consideration of any recommended changes and any literature to be submitted in PDF format to support any recommended changes as well. If we go to the next slide, it provides our disclosures. Everything that's being presented today is accurate as of today. But as Medicare systems change, things may also change. Today's meeting is being recorded and will be transcribed. Next slide.

The policy that we're discussing today is botulinum toxin injections. This policy became effective in February of this year, and we received a good bit of communication on recommended changes to the policy updates and therefore we reopened this policy through the LCD reconsideration process to respond to the concern. And so, I'm going to summarize the changes that we are proposing before we turn things over to our presenters. Next slide.

The policy is a collaboration with CGS administrators, Noridian healthcare, Wellpoint (formally National Government Service), Palmetto GPA, and WPS Government Health Administrators and the comment period closes June 6th, 2026. Next slide.

So, we do need to receive all comments by that date and they can be, we'll go through at the end how to submit those comments. The policy changes to the general indication and limitation of coverage section. We deleted #7, which stated: "When Botulinum was used for an approved diagnosis, the Botulinum is also being used with cosmetic intent, the entire claim is denied." Medicare does not cover cosmetics in any way, including Botox. But there's no longer a required denial for the entire claim. A change to #15, image guidance is not considered reasonable and necessary for injection of botulinum toxin except for certain conditions outlined in the policy and article. So, this this language was reworded for clarity and change in this section of diagnostic procedure throughout this whole section, "diagnostic procedure" to "botulinum toxin procedure." For added clarity. Next slide.

Additionally, it was added when the FDA makes changes in a serotype's approved indication or doses. Those changes will take precedence and be allowed for Medicare coverage. This ensures that there wouldn't be any delay in access when changes do occur, as this policy process can take quite a bit of time and additionally it was added off label use of botulinum serotypes for various indications and our dosing are intended to be evaluated and covered under the policy in only unique circumstances with the robust public's clinical evidence, such as medical societies and guidelines, and this is addressing multiple requests for off label use because we are obligated by law to follow the reasonable and necessary requirements outlined in the in the Social Security Act. We do need to have a solid rationale and evidence to support all coverage decisions and that does include off label use. Which is what this section is clarifying. Next slide.

For specifically in the blepharospasm section, it was added in the initial treatment for, I will just say, botulinum A, for blepharospasm is associated with dystonia is 50 units, 25 units per eye, and under the initial dosing guidelines deleted up to five units per site as per the literature and recommendations that were submitted. Next slide.

Additionally, for blepharospasm under subsequent botulinum toxin injection, we deleted number one which was under subsequent dosing guidelines and replaced it with the following for botulinum A in blepharospasm, subsequent doses could be increased to 100 units per treatment session, 50 units per eye administered to the affected facial or ocular muscles, and this reference was added and discussed in the analysis of evidence. Next slide.

For blepharospasm with orofacial dystonia, the number one item was changed from "submentalis"

to “mentalis” in the following sentence – “There is no standard dosing recommendations for orofacial dystonia, which is typically administered into, and it lists the muscles, and there is where the change was made. Next slide.

Under cervical dystonia, the dosing guidelines in number four, it was changed units per treatment session from 120 to 400. And under laryngeal dystonia the correction under the diagnostic section. Typographical errors were corrected. And which corrected laryngeal spelling and Botulinum toxin A. Next slide.

For upper and lower spasticity under the initial dosing guidelines, the dose units from 8-5 was changed to 8-16 in item number four, the total initial dose of botulinum A for upper limb spasticity must not exceed a dose of 8-16 per upper limb to a maximum of 1500 units per upper limb. Under upper and lower spasticity required was changed to allowed inn #4 under initial botulinum toxin injection and in subsequent. Next slide.

For chronic migraine, at least five attacks fulfilling criteria B-D was changed to at least five attacks fulfilling criteria 2-4 to add clarity and at least two attacks fulfilling B and C was changed to at least two attacks fulfilling 2 and 3 Next slide.

References were added to the bibliography with the evidence added to the LCD itself. Next slide.

For comments to be submitted, our preferred method is comments are sent to CMD.inquiry@CGSadmin.com. We do have a form that’s available on the website, but the important thing is that the comments are sent by the deadline of June 6 and that any submitting, any supporting literature is submitted in PDF format. Supporting literature must be peer reviewed published literature. We cannot accept abstracts or unpublished work. Next slide.

And alternatively, comments can be mailed, but email is the preferred route.

And I think that’s the final slide, next slide. Yes. So that’s just saying that the link for the comments is on our website.

So, I’m now going to turn things over to our first presenter and we’re going to pull up your slides. And we’re going to move over so that you have speaking privileges.

We’ve got Dr. Busby. And can you, if your mic’s unmuted and if we can just test your sound?

Eric Busby, Pharm.D. 10:03

Yep. Can you guys hear me?

MEREDITH LOVELESS 10:04

We absolutely can. So, if you just give us a moment to get your slides up, I’ll turn the floor over to you.

Eric Busby, Pharm.D. 10:07

Perfect.

Thank you.

MEREDITH LOVELESS 10:42

OK, the floor is yours and just please let our master of ceremonies here, Curtis, know when you’re ready to change the slides.

Eric Busby, Pharm.D. 10:50

Sure. Hello everyone. My name is Doctor Eric Busby. I am director, medical payer strategy and I represent AbbVie US medical affairs on behalf of AbbVie, the manufacturer of botulinum Toxin A or Botox, and the patients that we serve, we would like to thank you for the work that you guys have done to develop this well thought out botulinum toxin injection policy, and allowing us to comment on the reconsidered LCD. Additionally, all proposed language will be provided with the written comments. Next slide please.

I am a full-time employee and shareholder, so today I’ll focus specifically on areas within the reconsidered policy that impact patient access and clinical decision making for Botox across three key indications, chronic migraine, cervical dystonia and overactive bladder. So, our goal is to ensure the policy aligns with clinical evidence.

Guideline recommendations and real-world practice while preserving appropriate provider flexibility and patient access. Next slide please.

So, the first key area that we want to focus on is around chronic migraine. So, the overall key

message here is that we want to remove unnecessary step edits. So the draft policy requires 2 two-month trials across multiple oral classes prior to botulinum toxin A, so we are respectfully requesting the removal of this requirement and it is not supported by current clinical guidelines and per AHS consensus and global recommendations, CGRP's and Botox are both appropriate preventive options and not strictly step dependent.

And so this requirement introduces, delays in care, particularly for those patients who cannot tolerate oral therapies who have contraindications or have already failed prior therapies. And also, additional point at the bottom of the slide is that the statement that's here it doesn't adequately account for combination therapy, which is increasingly used in clinical practice, when monotherapy is insufficient. So ultimately aligning with guidelines supports more timely and individualized patient care. Next slide, please.

So, continuing with chronic migraines, so here we want to simplify and standardize outcomes. So, the policy currently requires tracking both reduction and headache days and reduction in headache episodes, and so we recommend consolidating to a single clinically meaningful endpoint, which would be reduction in monthly headache days. And so why is this important? Because this aligns with the clinical trial endpoint and real-world clinical practice. So, tracking multiple redundant measures creates administrative burden without clinical value and on the disability measures, so we support inclusion of functional outcomes, but recommend flexibility and tool selection rather than mandating specific thresholds. So, this approach maintains vigor while improving provider usability. Next slide please.

So, the second key area that I want to discuss is cervical dystonia. So here we would like to remove the moderate to severe restriction and allow clinical judgment. So, the draft policy requires classification of cervical dystonia as being moderate to severe. We respectfully request removal of this language, and we're asking because neither the FDA labeling nor the AAN guidelines require severity stratification. Cervical dystonia is a heterogeneous condition and patients with mild posterior may still experience significant pain and functional impairment. Also, around equity concerns. So, severity thresholds may disproportionately limit access, especially for those patients with limited specialist access and underserved populations and regarding the objective measurements. We support objective measurement here, but tools like the scales are not designed for routine clinical use and are not reliable. It doesn't reliably distinguish severity categories. So, our recommendation here is to allow diagnosis via clinical evaluation and differential diagnosis with flexibility and assessment tools. Next slide please.

So, the third area that I want to discuss is overactive bladder. So here, with overactive bladder, we want to avoid restrictive dosing caps. So, the draft policy specifies 100 units for initial dosing, and it also 100 units for subsequent dosing. So, we request a policy that allows up to 200 units, which is consistent with clinical evidence and guidelines. And so, the evidence that we will be providing to you support these 200 units will include the AUA guidelines, they support dose escalation to 200 units in patients with inadequate response to 100 units and the NIH funded Rosetta trial and other studies demonstrate safety and efficacy at higher doses. And so why does this matter? So, restricting these patients to 100 units may result in suboptimal symptom control. Limits physician ability to individualize treatment. And so, as you know, the Max dose of Botox is 400 units every 12 weeks per label? And so, this is not about extending total guidelines, it's about ensuring the policy does not unintentionally function as a hard cap, limiting clinically appropriate care. Next slide please.

So, in summary, we respectfully request three key considerations. One removing step therapy requirements and chronic migraine that are not aligned guidelines. Number two simplify outcome measures to reduce burden while maintaining clinical validity, and the third is to preserve provider flexibility in both cervical dystonia severity assessment and overactive bladder dosing, and so these refinements will help ensure the policy reflects current evidence and guidelines supports individualized patient care, and it also avoids unintended barriers to access. So, thank you guys again for your time and consideration. I'll take any questions at this time.

MEREDITH LOVELESS 18:17

Thank you very much for your presentation. We appreciate that and look forward to receiving your comments. We're now going to promote our next speaker.

And if we can pull up the slides. We have … OK, And I believe our speaker is Julian Perry. If you can confirm we had two potential speakers for this topic, this presentation.

Julian 19:01

Hi there, this is Julian.

MEREDITH LOVELESS 19:03

Wonderful. Well, welcome and we look forward to hearing your presentation.

The floor is yours.

Julian 19:09

Oh great. Thank you so much for having me. I'm a surgeon here at the Cleveland Clinic, and I can just tell you from boots on the ground, in the trenches here, our patients who are suffering with blepharospasm are just going out of their minds in terms of this new policy. They really can't function. The Botox for them is designed to help them perform daily activities like driving and working. So, I'm really happy to have this opportunity to share with you some ideas that we have. So, can you go to the next slide, please? I have no disclosures and the next slide.

Great. So, we just have about 5 recommendations here. The first one is pretty straightforward, and it really just involves the wording. So, the wording right now in the LCD is that Medicare will allow payment for one injection site, regardless of the number of injections. So, this is really just a matter of wording, because we're just talking about injections. So, we were hoping to change that to an applicable CBT code as reported once per eye or side of the face without regard for how many injections are performed. So, this one is really just more wording because this is what most practitioners are more accustomed to dealing with when they're doing the CPT codes. And the next slide.

We've also noticed some dosing inconsistencies, that the current LCD is requiring only 1.25 to 2.5 units at a maximum of three injection sites per muscle. And this is just, you know, with the boots on the ground, this is woefully inadequate. And these doses were recommended 40 years ago when botulinum toxin was first developed. And as you know, it was first developed for spasms around the eyes. So even before it was used for cosmetic uses etc., it was used for heavy facial spasm and for buffer spasm. Those initial studies are really old and in the last 40 years, we've learned that many patients require higher doses the those initial doses there are just inadequate for I would say 95% of patients. That's just not enough. So, the typical treatment for most practitioners requires 5 to 9 injections and sometimes more, totaling around 25 units to effectively manage the symptoms, and this dose of 25 units is also consistent with the initial dose and guidelines for Xeomin, which has a similar efficacy and safety profile as Botox. So, we're recommending that the initial dosing regimen for Botox should be revised so that both Botox and Xeomin would be allowed, that both of them would be allowed for as many injection sites as necessary. And for the initial starting dose up to 25 units per eye. And the next slide.

And as noted in the LCD, about half of patients who suffer with blepharospasm also have orofacial dystonia that involves the lower face as well. These patients will obviously require more medication because it's treating a greater muscle area. So, we were hoping in these cases for me syndrome that the LCD would be revised to allow Botox up to 50 units per eye. Again, this is aligning already with the Xeomin guidelines, and we're also hoping again that both Botox and Xeomin would be allowed for treatment of both blepharospasm and orofacial dystonia. We really don't see a rationale to exclude the Xeomin now. Of course, Xeomin is not FDA approved for hemifacial spasm or orofacial dystonia or benign essential blepharospasm. But it never will be. There's just no way you know the previous speaker was talking about some great NIH studies. Those are conditions that are affecting a lot of people that this is an orphan condition and there's just no way that Xeomin would ever want to be FDA approved for this. Yet we know that the botulinum toxin is almost identical in safety and efficacy. See, so we're hoping that both Botox and Xeomin can be used interchangeably for this condition just like they are right now. And interestingly, just to point out, Xeomin is generally much lower in cost, so it would make a lot of sense to allow for Xeomin usage for this as well, just on a cost basis, it's cheaper than Botox. And the next slide.

And again, for hemifacial spasm and strabismus. There in hemifacial spasm, the LCD is asking us to wait a full year before we can change or escalate the dose. These are patients just to remind you, they can't drive. They can't work. They physically can't get out of the house because they're effectively blind. And so, we feel that waiting a year is just not appropriate. And we're hoping that we can escalate the dose based on clinical symptoms and if a patient hasn't responded to a dose, why subject them to the exact same underdosage, three more times for an entire year. So, we really don't see a clinical justification for waiting an entire year, and we're hoping that we can increase the dose based on clinical response at the discretion.

Of the treating physician at the very next treatment session, if one treatment hasn't worked just again from the boots on the ground point of view, if one dose doesn't work it's not going to work the next time. It's just not enough. It's not like it takes several doses for the medicine to work. If it isn't working the first time, it's not going to work the next time. And then for strabismus we already talked about the inadequate dosing here and again, this was all the way back from the initial approvals 4 decades ago, and we're asking that paralytic and large -angle strabismus often

require doses up to 10 units. So, we're hoping that we can enact that change as well and another really important point here is right now that the medicine is wasted after it's not used. So right now, Botox is individual patient vials. And so, whether a patient receives 10 units, 20 units, or 50 units, the remainder of that vial is thrown away in the trash instead of being used to help these patients that are really suffering. And the next slide please.

This is for established patients that we already have that for example, I've been treating for 10 or 20 years. I've been practicing for 27 years, and I have the privilege to be able to help a lot of patients who suffer with this condition for that entire amount of time, and many of those patients have already gone through dose escalation over the last decades. And there's no provision in the current LCD for how I can help those patients other than drastically reducing the dose that took years to find out what works for them. So right now, there's no provision for patients who are already receiving doses higher than what would now be authorized by the LCD. And I can tell you I have at least 125, maybe 150 patients who suffer with this condition. Patients that are not going to do well with a much lower dose. So that's going to provide care disruption despite having positive outcomes and safety. And my guess, and we've already had this where patients are denied medically necessary treatment because their previous treatment doses were higher than what's currently allowed for the LCD.

Also, the mandatory clinical scales that are being asked for we feel are unnecessary and burdensome. The Jankovic scale is used for research, so that's something that is used in a research arena. We're hoping that we can simply use a narrative element, basically that if the patient says that they're suffering and it's not working. And it's lasting only six weeks or seven weeks and that they still can't drive and that they're still having a lot of spasm. That says a lot more than a Jankovic score of four. A Jankovic score of four really doesn't express that what the patient is suffering with.

So we're hoping that we can report quality of life forms just like we do in the chart, and we would hope that that would be sufficient. And next slide.

So, in summary, the American Academy of Ophthalmology, our ASOPRS group of oculoplastic surgeons In the NANOS Group are encouraging these policy revisions to basically support for physician discretion in patients access to this medically necessary care. I can tell you that serving at the Cleveland Clinic. No private practitioners are even doing this anymore because of the burdens that they're facing so they are not giving it. And so, all of these patients have come to me over the last year or two because private practitioners don't want to do this anymore. And these patients, I really want to advocate for my patients because they're suffering. I saw two patients yesterday who were denied care, and they begged me to come to you with everything that I could to let you know how much they're suffering without their care.

So we're hoping to align this with real world practice and this can reduce the administrative barriers still providing safe, effective care. And if we can use Xeomin as well, it will be a lower cost burden. As well, so our organizations will follow up with more detailed recommendations, and our submissions have written comments, and we have plenty of supporting literature as well. Thank you.

MEREDITH LOVELESS 30:52

Thank you, Doctor Perry, for your very clear presentation and clear recommendations. We greatly appreciate it as well as your clinical insights into the impact we will look forward to the comments received and our final presentation will be Doctor Amandeep Mann. I hope I pronounced that correctly.

And we'll be pulling…

Amandeep Mann 31:20

Hi there. Just confirming, everyone can hear me.

MEREDITH LOVELESS 31:25

We can thank you so much.

Amandeep Mann 31:26

Perfect. Thank you. I'm doctor Amandeep Mann and I'm representing IPSEN biopharmaceuticals, the manufacturer and distributor of abobotulinumtoxin, also known as Dysport. Next slide, please.

Disclosures. I am a full-time employee of IPSEN and hold shares in IPSEN stock. Next slide, please.

Just some disclaimers before we start the presentation. This presentation is in response to

MAC request for feedback on updated MAC proposed LCD policy for bond a coverage for the Medicare population. IPSEN does not recommend the use of this product or any other products in any manner other than that described in the FDA approved prescribing information. IPSEN biopharmaceuticals wants to recognize and thank the Members for their efforts in updating this very comprehensive bond LCD policy.

I will walk through some key sections of the draft of the LCD policy that we feel need clarification or updates in accordance to the FDA approved label and published evidence for abobotulinumtoxin. IPSEN will follow up with a detailed response letter, including all relevant supporting references to be considered for the final LCD policy.

Before we start off, I did want to highlight the approved indications for Dysport or abobotulinumtoxin for therapeutics approved indications by the FDA include treatment of cervical dystonia in adults and treatment of spasticity in patients two years of age and older. Please refer to the approved prescribing information for Dysport for complete details on the box warning. Next slide please.

Abobotulinumtoxin has been available in Europe since 1990 and was first approved in the US in 2009 for cervical dystonia. It has been marketed globally for over 40 years with greater than 5 million treatment years of patient experience in over 1300 peer reviewed publications globally across multiple indications including but not limited to cervical dystonia and spasticity. Next slide please.

Our first request is to correct the language for abobotulinumtoxin initial dosing guidance for adult lower limb spasticity to align with the FDA approved label dosing in the table on the bottom right corner indicates the dosing as per the approved label. And request the update for lower limb spasticity to include dosing up to 1500 units. This is in accordance with the registrational study that looked at two doses of abobotulinumtoxin versus placebo, where statistically significant improvements were only shown with the 1500 units versus placebo. Next slide please.

The second request is to correct the language for abobotulinumtoxin dosing limits in the subsequent dosing guidelines, and this includes the approved FDA abobotulinumtoxin dosing recommendations for adult upper limb spasticity is 1000 units. So, this is the Max dosing that's indicated on the table in the bottom right corner, lower limb spasticity is 1500 units and that the total body dose should not exceed 1500 units for abobotulinumtoxin. The dosing in the FDA approved label is as per the registrational trials for both adult upper and lower limb spasticity as the effective dose versus placebo. Next slide please.

The third request is around clarification for the dosing limits described in the subsequent dosing guidelines in ensuring that these guidelines are applied to pediatric beneficiary, we do appreciate that the typos have been corrected for the subsequent dosing, but did want to highlight that the maximum dosing for pediatric upper limb spasticity is 1600 units per kid or 650 units and also that the maximum total body dose for pediatrics is 30 units per kid, or 1000 units. Next slide please.

The last request from IPSEN is to clarify the use of EMG, or EMG and ultrasound guidance usage in relation to cervical dystonia when injecting abobotulinumtoxin A, the use of guidance techniques is recommended as per the FDA approved prescribing information. In addition, there are multiple pieces of literature that actually indicate the use of guidance techniques can assist in medicine. Adverse events can be reduced by helping to visualize target injection sites in recent data that IPSEN has published, although it is in spasticity, does support that the use of guidance can improve patient goal attainment and adult lower limb spasticity patients when compared to those patients that were treated with abobotulinumtoxin that did not have the use of ultrasound guidance. Next slide please.

We want to thank you for the opportunity to be on the agenda and speak. As mentioned, you will receive a written detailed response from IPSEN with the feedback on the corrections requested for abobotulinumtoxin A and the PI for your review for the final policy. Thank you.

MEREDITH LOVELESS 37:18

Thank you very much. We appreciate your presentation and again look forward to the written comments. I want to thank all of our presenters today as well as everyone in attendance. This is a collaborative process, we take your feedback and input seriously and work towards trying to create the best quality policy and without your expertise and input that wouldn't be possible; So, we appreciate your time today and your work in helping us with this process. Again, the comments are due by June 6 to the CMD.inquiry@cgsadmin.com mailbox. This meeting has been transcribed, and the recording and transcription will be posted within the next month. And if there's any specific questions in the interim that we can assist you with that CMD.inquiry@cgsadmin.com is the best mailbox to reach us at. Since that concludes our presentation, we will conclude this meeting and I thank everyone for their attention.