National Government Services, Inc.
Moderator: Ella Noel, D.O.
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11:00 am

Coordinator: Thank you for standing by. For the duration of today's conference, all participants will be in a listen-only mode. I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Ella Noel. Thank you. You may begin.

Dr. Ella Noel: Thank you. Welcome to the National Government Services J6 & JK Open Meeting. Next slide. Remember, as the operator just informed us, this call is being recorded and transcribed. Please hang up if you object to being recorded.

The NGS Contractor Medical Directors include Ola Awodele, Marc Duerden, Janet Lawrence, Gina Mullen, Greg McKinney, and myself, Ella Noel. Next slide. We will be looking at two proposed LCDs. The first is DL32733, Microinvasive Glaucoma Surgery, and DL39832, botulinum toxin injections.

Next slide. We are going to be starting with Microinvasive Glaucoma Surgery, or MIGS. This is a collaborative local coverage determination revision, which is in response to an LCD reconsideration request regarding the use of stent procedures for glaucoma classified as Microinvasive Glaucoma Surgery.

Next slide. There have been extensive changes from the first draft for the MIGS LCD in response to comments fielded by the A and B Medicare contractors. Next slide. Our first speaker is Dr. Geoffrey Emerick.

He is representing the American Academy of Ophthalmology, the American Glaucoma Society, the American Society of Cataract and Refractive Surgeons, and the Ophthalmic Outpatient Surgery Society. Dr. Emerick, if you are on the call, please go ahead and let us know what your conflicts of interest are and go ahead and start your presentation.

Dr. Geoffrey Emerick: Great, thank you. Can you hear me?

Dr. Ella Noel: Yes, I can.

Dr. Geoffrey Emerick: Perfect. Thanks so much. And thank you for the opportunity to present today representing our professional societies. Next slide. I have no financial disclosures. And I serve as the Patient Care Committee chair for the American Glaucoma Society.

Next slide. First and foremost, we'd like to express our appreciation for working with the Contractor Medical Director Workgroup over the last year on this policy. This process has resulted in a proposed LCD that reflects current practice patterns and allows the physician and patient to make treatment decisions that work best for that unique patient.

We also appreciate the addition of the section on healthcare disparities, which highlights the disproportionate disease burden of glaucoma on minorities, particularly people of African or Hispanic descent.

We wholeheartedly agree that more research is needed to understand differences in treatment, and that future research must include more diverse study populations. And we appreciate the opportunity to offer a couple of additional recommendations on the proposed policy so that all Medicare beneficiaries with glaucoma can receive the treatment that best suits their needs.

Next slide. So we agree with the proposed coverage of stents as described in the indications of coverage. Number two, we've noted that should be subconjunctival. And while take home ossification with a single NAICS procedure is indicated as covered in the limitations of coverage section, for clarity, we think it makes more sense to include it in the indications of coverage section rather than in the limitation section. We recommended using similar coverage language already found within the LCD, and creating a separate Number 3 bullet as shown on the screen.

Next slide. As a result, corresponding changes to the limitations of coverage should be made. For limitation number two, we ask for just a slight clarification. We recommend changing patient to eye because glaucoma can be bilateral.

And for consistency and clarity, we recommend that
limitation Number 3 read, phacoemulsification IOL placement performed with a

combination of mixed procedures, e.g., cataract plus stent plus canaloplasty or goniotomy at the same time of service in the same eye is not covered. So the intent remains the same non-coverage for multiple MIGS procedures with cataract surgery, but this language we think will be clearer to physicians and coders.

Next slide. Although we understand that limitation, Number 3 is in the policy now, our organizations do call your attention to growing evidence showing improved outcomes and patient experience when MIGS procedures are combined.

For example, in this 2023 study by Dickinson et al in the Journal of Glaucoma found a significantly greater reduction in glaucoma medications while maintaining similar rates of IOP reduction and low complications when cataract surgery was combined with a trabecular stent and canaloplasty compared to cataract surgery and stent alone. Other studies support the combination of a trabecular stent with goniotomy at the time of cataract surgery.

And although there is currently not enough evidence for combining MIGS as a standalone procedure, we expect this evidence to grow. Adding canaloplasty or goniotomy to a trabecular stent makes sense physiologically because it addresses outflow resistance and additional clock hours of the angle.

Not only can the reduction in glaucoma medications reduce morbidity and improve patient quality of life, it also may reduce costs to the healthcare system in the long run. And while we feel it's important for a surgeon - we feel it's important to have, for a surgeon, this option in their toolbox for patients who may benefit from reduced medication burden.

Next slide. We appreciate the list of definitions included in the LCD because it helps everyone speak the same language. And with that goal in mind we encourage you to update the definition of refractory glaucoma to align with the definition that we as societies agreed upon and established in our 2021 consensus statement shown here.

While similar to the proposed definition, the additional specificity in the consensus statement better reflects how ophthalmologists think about the disease. This definition focuses on medical treatment. And we agree with your proposed definition that the failure of surgical treatment should also be included.

Next slide. So in summary, patients with glaucoma, which disproportionately affects people of Black and Hispanic descent, need access to a range of surgical

procedures, including those currently covered. Our organizations appreciate that this is generally recognized throughout the proposed LCD.

For many patients, though, treatment with medications is inadequate, and their glaucoma is not at a stage requiring more invasive procedures such as trabeculectomy and tube shunts. And for these patients MIGS help preserve quality of life and reduce total costs to the healthcare system.

We support further studies to investigate the indications of combining cataract surgery with more than one MIGS procedure, for example, cataract plus stent plus canaloplasty or goniotomy. We ask that carriers expand coverage when more outcome data are available.

We also anticipate that future diagnostic technologies of the aqueous outflow system will allow us to target our angle procedures for improved efficacy and efficiency. We look forward to continuing this dialog, and we will be submitting formal comments with copies of published studies on multiple MIGS procedures. Thank you very much. Dr. Noel, are you on mute?

Dr. Ella Noel: Of course I am. Thank you, Dr. Emerick. Our next speaker is Rick Fiscella, who is a Director of Medicare Payer Strategy for AbbVie. Please share your conflicts of interest and start your presentation.

Rick Fiscella: Sure. Thank you for that introduction. My name is Rick Fiscella. And as Ella noted I'm a Director of Medical Payer Strategy for Ophthalmology at AbbVie. I am a full-time employee of AbbVie.

I did want to mention, too, that we agree with Dr. Emerick's statement on the, in particular, the supraconjunctival statement change to subconjunctival space, probably just a typo. And this was under the indications for coverage, step Number 2.

The other information that's there has been well covered by Dr. Emerick. We appreciate NGS's rewriting of the draft LCD. And I would like to yield my time back to NGS. Thank you very much.

Dr. Ella Noel: Well, we appreciate that. This will allow more time for others to speak. We only had two scheduled speakers for this meeting today. So now we can go to the phone lines and get any additional comments about DL37244, Microinvasive Glaucoma Surgery. Can we go to the phone lines and see if there's any anybody

who wishes to make a comment?

Coordinator: Please press Star 1 if you'd like to make a comment.

Dr. Ella Noel: Well...

Coordinator: Dr. Mark Latina, your line is open.

Dr. Mark Latina: Oh, hi, Dr. Mark Latina. I just have a quick question because, I unfortunately, I didn't get on the computer here early enough. The question is regarding endocyclophotocoagulation. And is that considered a MIGS procedure or is it – or can – are we still allowed to do phaco ECP combined with an outflow procedure such as any of the other MIGS procedures that are considered outflow procedures?

Dr. Ella Noel: Sir, can I have you send that question to us at NGS, and then I'll double-check with that and make sure before I answer it.

Dr. Mark Latina: Okay, great. Okay, good.

Dr. Ella Noel: Okay?

Dr. Mark Latina: Yeah.

Dr. Ella Noel: Thanks.

Dr. Mark Latina: Yes.

Dr. Ella Noel: And then any other comments on the phone line?

Coordinator: I'm showing no further comments at this time.

Dr. Ella Noel: All right, so the comment period ends on July 14, 2024. Please submit any of your comments in writing to us, and watch for the changes to the draft as it becomes final, and the responses to the comments document. I will now turn the meeting over to Dr. Marc Duerden, Dr. Duerden?

Dr. Marc Duerden: Thank you, Dr. Noel. So just go to the next slide. For this portion of the open meeting we'll be discussing the collaborative multi-jurisdictional draft LCD on botulinum toxin injections. And we wanted to inform you that this policy has been developed to be consistent with the FDA-approved guidelines, as well as off-label uses, and other societal guidelines regarding the use of botulinum toxins in individuals in the Medicare population.

Next slide. The Contractor Advisory Committee for this topic was held on October the 19th, 2023. And this current open meeting that we're having today is part of the

comment period. And that comment period will continue until July 14, 2024.

Next slide. In a rough overview of the draft botulinum toxin LCD, this draft LCD outlines the use of the botulinum toxins, and lists some general indications and general limitations that will be applied for the coverage of these medications depending on the serotype that is being used.

This draft also addresses and breaks out into various medical conditions that would be considered reasonable and necessary for the use of botulinum toxins. As you know Medicare coverage for any item or service must be reasonable and necessary. And the definition for that can be found in the Medicare Program Integrity Manual Chapter 13.

Next slide. This draft LCD outlines first the definitions of the specific medical conditions that will be addressed in the policy, and then how that diagnosis for that medical condition is to be followed. This draft LCD will also provide specific indications for the coverage and outline subcategories for the use of the botulinum toxins.

For example, it will discuss the initial botulinum toxin and injection indications, as well as the initial dosing guidelines. And then we'll, the policy will address the subsequent botulinum toxin injection indications and those dosing guidelines.

For this portion of the open meeting I'm going to turn the time now over to some of the presenters. When each of these presenters start their presentation, I would like for them to introduce themselves and also state any conflict of interest that they may have.

At the conclusion of their presentation, as the moderator, I may or may not have questions for them. So I'd be curious, and I would recommend that they be ready to answer questions if any are being posed to them at the end of their presentations. To start this, I'll turn the time first over to Mr. Zuzek for his presentation from AbbVie.

Alec Zuzek: Dr. Duerden, can you hear me?

Dr. Marc Duerden: Yes, now I can hear you, sir.

Alec Zuzek: Okay, good, thank you. Thank you so much. My name is Alex Zuzek. I work for AbbVie Incorporated. So my disclosures are that I'm an employee and shareholder of AbbVie. And I want to thank everyone involved with this process of

drafting this current LCD policy for botulinum toxins.

I know that it takes a lot of work. It's a huge lift to get us to where we are today. And I appreciate the time to speak on behalf of, both the company that manufactures OnabotA, also known as Botox, and for all the physicians and patients for which Botox has been a key part of their lives.

Next slide, please. Just given the time I want to cover at a very high level what I'll be going over today. As Dr. Duerden had mentioned, the draft LCD policy is looking at drafting coverage based off of FDA approved information, as well as what is known on disease states on some of these indications.

AbbVie, or on behalf of AbbVie, I'd like to go through some of the key details which we've noted should require some revisions to bring the draft policy up to the level of the current OnabotA FDA approved labeled indications. So, next slide, please.

Starting with chronic migraine, we have noted some key elements from the draft policy on the left-hand side of the slide as highlighted, Items 6, 8, and 9. I'd like to refer to the purple boxes on the right-hand side.

What we are noting here, and we will provide in greater detail in our written comments on each of these pieces of information that we're discussing today on the slides, far greater detail than in the written commentary process.

So with regards to migraine, we would like to note that current AHS consensus guidelines consider that OnabotA and CGRPs are first-line for chronic migraine. Additionally, many of the products listed in the proposed policy are not indicated by the FDA for migraine, so we just want to bring that into consideration. And so, therefore, we're respectfully requesting the removal requiring a two-month trial of a pharmacologic therapy before the use of OnabotA for chronic migraine.

And lastly, for chronic migraine, Statement Number 8 as written, is somewhat unclear. We are asking that there's consideration on revising the exact verbiage to ensure that in practice it is not causing any mistakes with regard to additional prescriptions or the care pathway that needs to be undertaken.

Next slide. For spasticity the item highlighted in yellow is one that we want to call to attention. We are respectfully requesting that moderate to severe chronic spasticity is removed from the current policy.

The information that we are providing, and we'll go into further detail in our written

comments, is that the FDA-approved label for OnabotA is indicated for the treatment of spasticity in patients 2 years of age and older. It is broad and it's regardless of severity.

Furthermore, the most recent American Academy of Physical Medicine and Rehabilitation spasticity guidelines furthermore calls out that there's no level of severity for which there is a definition for which toxin or no toxin is to be used in the treatment of spasticity.

Next slide, please. For cervical dystonia, we have called out the items that are highlighted in the current draft policy. We are requesting that there's rewording of the policy given the following. The American Academy of Neurology guidelines do not state routine assessment utilizing objective measurements.

A differential diagnosis of cervical dystonia encompasses mild to severe neck and head postures and/or associated pain. And OnabotA is approved broadly for the treatment of cervical dystonia and associated neck pain. To that point, we have provided additional information which we will go into a deeper dive in our written comments.

Next slide, please. Now, on the urologic indications, first I'll cover neurogenic bladder, and then I'll cover overactive bladder. For NDO we are calling out the moderate to severe phrasing included in Item Number 3 of the current draft policy.

We are respectfully requesting that the moderate to severe language in neurogenic detrusor activity is removed for the current policy. The information we'll be going into a deeper dive on is that OnabotA is approved for NDO in that there's no language in the label itself related to severity.

Next slide, please. For overactive bladder, we are calling out these few items highlighted in yellow. The key pieces of information that we're providing here is, again, the actual language out of the FDA approval for OnabotA with regard to the lack of mentioning of any severity, et cetera.

Furthermore, the more recent AUA/SUFU guidelines published on urologic indications no longer classify step-wise fashion a first, second, or third line approach to treatment. Instead, they've eliminated that language.

And so there is language in these updated guidelines from the AUA that clinicians may offer on OnabotA as a minimally invasive therapy as a primary therapy before

any types of failures, etc. So we will go in a deeper dive on that one.

So we are respectfully requesting that moderate to severe and objective assessments are removed from the draft policy. And that we eliminate the need for conservative and pharmacologic management before OnabotA therapy in alignment with the most recent updated AUA guidelines

All right, next slide please. So importantly we would like to point out to our MAC committees that the definition for spasticity has been updated yet again. So looking at what has been published in the most recent 2024 AAPM&R consensus guidelines on spasticity assessment and management, we are going to go into a deeper conversation on this in a written commentary, that we would like to see the LCD draft policy update its definition from spasticity. That's all we're calling out here. We can move on to the next slide.

And I'm going to actually, for the sake of time, try and bundle the following slides very rapidly. Really what we're calling out on this slide, and I'll focus only on the light blue boxes at the bottom Dr. Duerden. And if we have time later we can go into questions. We're requesting the policy revised statement to expand to any of the approved muscles versus just only the few muscles that have been stated in the draft policy for cervical dystonia.

Next slide. For specificity, we had noted that the current dosing, maximum cumulative dose, stated in the draft policy is aged. It's a historical number. It's not actually the current approved number which had gone up to 400 units in 2016 for the OnabotA label. So we're requesting that the initial dose of OnabotA for lower limb spasticity be revised to 75 units to 400 units. And that subsequent dosing is up to 400 units.

Next slide. Staying on spasticity, we also noted some of the other approved toxins that do have approvals for pediatric patients, their pediatric dosing was included. However, our pediatric dosing was excluded. So we're requesting that the policy acknowledge that OnabotA is indicated for pediatric specificity and that the FDA dosing guidance is applied as necessary.

Next slide. For neurogenic bladder, for NDO, we're requesting that the policy allows for doses up to 300 units of OnabotA in patients with neurogenic bladder. This is supported by both Phase II and Phase III clinical trials in which patients not seeing improvements of 200 units were able to be escalated up to 300 units.

Next slide. For overactive bladder, again, we are requesting that the policy be revised and allows for doses up to 200 units of OnabotA in patients with OAB. And this is supported by AUA guidelines and additional clinical trials, one of which is called ROSETTA. It was an NIH-funded study. Again, these data support that patients not achieving benefit with 100 units, by dose escalation, the 200 units provided efficacy with similar safety profiles as the 100 units.

Next slide. For blepharospasm, we noted that some of the items highlighted here may have been incorrectly be transferred from the OnabotA label. So we are respectively requesting that the wording and the policy reflect the OnabotA label explicitly, so it states the 5 units per site, not per eye. So that's the first item, Number 2, that's highlighted.

Furthermore, it was noted that the overall cumulative dose for blepharospasm was missing in the blepharospasm draft policy, or sorry, the draft policy. So in a 30-day period a blepharospasm patient may receive up to 200 units. So we're noting that we just want to bring that back up to par with the label as approved.

Next slide. In the preambles to the policy we noted that image guidance is not considered reasonable and necessary for injection of botulinum toxin. That's a statement that was made, we respectfully disagree. And we'll be providing a considerable amount of evidence to support the utility, usefulness of using ultrasound whenever it's available.

So we request that the imaging guidance is considered reasonable for initial and subsequent injections of botulinum toxins for conditions, especially in cervical dystonia and spasticity. We will, again, provide deeper detail in our written commentary.

Next slide. And this is the final slide. We also noted a considerable number of ICD-10 codes that are missing in the current policy in relation to previous policies. We will, again, provide a greater level of detail in our written commentary, but the majority of those codes were missing in specificity, 156 of them to be exact, eight in overactive bladder and four in cervical dystonia. And that should be my final slide, Dr. Duerden.

Dr. Marc Duerden: Mr. Zuzek, thank you for your presentation. I do have a question for you. You referenced the AAPM&R consensus guidance on spasticity management - assessment and management. That was the 2024 article that just got published by

Verduzco and Gutierrez recently.

My question to you is, you're just requesting that the removal of the severity of spasticity be removed. But the table that they used in their article, I think it was Table 1, A4, talks about the, and I'll paraphrase, the need to mitigate for other things that cause spasticity and used medications prior to - or use medications for the management of spasticity.

How do you equate, or justify, the removal of the language of moderate to severe when the consensus guidelines address, you know, preliminary steps that need to be taken prior to the initiation of onabotulinum toxin?

Alec Zuzek: It's a good question, Dr. Duerden. I think if I'm going to answer that question I'll try my best to reflect those authors driving that consensus statement on the guidelines. It's sort of thinking through what they've been going through, and the process is that it's more of a quality of life decision.

It's a spasticity getting in the way and needs to be treated. Furthermore, there is no standardization as to which measurement needs to be used to demonstrate that the spasticity is moderate or severe. I think when we look at the approvals for botulinum toxins in the spasticity space, we note that modified Ashworth Scale or the modified Tardieu Scale is used to demonstrate a change in tonicity by the intervention, which would be the botulinum toxin.

However, I think in actual real-world clinical practice there's no standard assessment being used for which I think it would be easy to define whether everyone is defining moderate to severe spasticity or mild spasticity, etc.

I think it's a quality of life decision, is the spasticity actually impacting the ability of patient to do something, whether it is something passive like hygiene care to possibly something more functional like the ability to, let's say, manage a purse or even possibly hold a hand of a grandchild, just to use some examples we've heard anecdotally.

Dr. Marc Duerden: Okay, excellent. Thank you. One additional question I have for you. There has been in the literature some discussions about using what has been termed high-dose botulinum toxin injections for the management of various conditions. And each condition, obviously, is different.

When you're describing the upper-level dosing that you've described for the

neurogenic bladder, the overactive bladder, for spasticity, are - if you could, in your comments, address the quality of the evidence that is recommending that. I recognize you said that there's some Phase II and Phase III studies that are - have identified that.

Also, interested in answering a question about spasticity, and particularly onobotulinum toxin, that the use of high dose onabotulinum toxin has not received universal acceptance within the field. What is your position on that indication?

Alec Zuzek: Another good question. I think in spasticity the - first I think it's defining high dose. Furthermore, I think it's also defining the use case. So I think where we see the most likely use case for higher doses, so let's say above the maximum on-label cumulative dose that was studied, so above 400 units in spasticity.

It's most likely related to those patients with both upper and lower limb spasticity or possibly even both lower limbs are spastic and, therefore, the highest approved cumulative dose does not meet the needs of the patients.

There is substantive evidence on this topic. And, again, as you've asked we will address the quality of this evidence from both Phase IV real-world evidence to additional data that that has been published on this type of use case.

I think where, as you've called out Dr. Duerden, where there may be disagreement is how high is high or is good enough. I think what you'll see from our recommendations is at the very least upwards to 600 units we believe has substantial support in what is published out there. I won't be able to comment on anything above that as I think you'd be looking at more at case studies - case series from there.

Dr. Marc Duerden: That has been my research as well. Thank you very much. And thank you for addressing those issues.

Alec Zuzek: You're welcome.

Dr. Marc Duerden: Any other comments you want to make in summary since I took some of your time?

Alec Zuzek: Oh, no I'm good. I went over everything I needed to. I really appreciate you all opening up and giving us time to provide comments.

Dr. Marc Duerden: Thank you, Mr. Zuzek. Appreciate your time to be here today. Our next presenter today is Dr. Bersani. And so I'd like to turn the time over to Dr. Bersani to make his presentation. Dr. Bersani you may be on mute.

Dr. Ella Noel: Dr. Duerden, I don't think we have Dr. Bersani on the line at this time.

Dr. Marc Duerden: Okay.

Dr. Ella Noel: We're a little bit ahead of schedule, so I think we might still be waiting on him to join us.

Dr. Marc Duerden: That's fine. With that if you could shift down to Slide 62, and we'll turn the time over to Dr. Mann, if Dr. Mann is here.

Dr. Amandeep Mann: Hi there. Can you hear me?

Dr. Marc Duerden: I can.

Dr. Amandeep Mann: Well perfect. Thank you for this opportunity to speak to the forum here. I will start with my disclosures first. So, I'm Amandeep Mann. I am the Medical Director for Ipsen Biopharmaceuticals. I am a full-time employee of Ipsen, and hold shares in Ipsen stock.

I will start with a disclaimer that this presentation was in response to MAC requests for feedback on the updated MAC draft LCD policy consistent with the FDA, as well as off-label use of BoNT-A in the Medicare population.

Ipsen Pharmaceuticals does want to recognize, and thank, the NGS and CMS members for their efforts in updating the very comprehensive BoNT-A LCD policy. Today, I don't have slides to go through, but I will walk through some key sections of the draft policy that we hope can be updated to improve access for the Medicare population, and in select sections expand the coverage for Dysport abobotulinum toxin.

For the remainder of the presentation, or my verbal commentary, I will be referring to Dysport as ABO just as a short form. So, Ipsen will follow up with a detailed response letter, including all relevant supporting references to be considered for the final LCD policy.

Just to start off with the approved indication the FDA has approved ABO treatment for cervical dystonia in adults. And that first indication was approved in 2009. And the second indication is in the treatment of spasticity in patients of 2 years of age or older. So this is - these are the therapeutic indications for ABO.

I do recommend that you look at the ABO prescribing information for complete details on the box warning for different spread of toxins, contraindications,

warning precautions, and adverse reactions. This is a historical context for ABO. ABO has been marketed for over 30 years globally across multiple indications, including, but not limited to, cervical dystonia and spasticity.

Now, just going into some of the key elements that we like to request in terms of the updates for the policy, there are six in total. The first request is to update the indication of coverage to be inclusive of all CD and spasticity patients that can be treated and to avoid restricting access to only moderate or severe patients.

Our current FDA-approved label for ABO is not limited by disease severity for either indication, so for spasticity or for cervical dystonia. Secondarily, AAN guidelines for ABO it is actually - it's actually shown as one of the only BoNT-As that has a Level A recommendation for the use and treatment in cervical dystonia as well as adult spasticity for both upper and lower limb spasticity.

The AAN guidelines really do highlight, and do not restrict the use of BoNT-As or BoNTs in between disease severity for cervical dystonia or spasticity. In agreement with the previous presentation, AAPM&R consensus guidance published in 2024 also does not restrict or categorize the BoNT-A recommendations by severity of spasticity. So both of them - all these three points we are hoping that you can consider as supporting data that the indications for the coverage for CD and spasticity be broadened.

The second request from Ipsen would be to reinstate the on-label diagnosis codes that were omitted from the draft LCD policy for ABO. So this includes cerebral palsy, all paralysis, and collegiate classification, contractors, and muscle spasms.

ABO has established safety profile and proven efficacy in Phase III registrational trials for adult upper limb and lower limb spasticity that has led to a broad indication for the treatment of spasticity not associated with paralysis, (collostinations), or specific symptomology. We also have Phase IV studies and data that is supportive reflective of real-world usage of ABO in varying populations of limb paralysis.

In addition, our pediatric Phase III studies were done to show efficacy and safety of ABO in upper and lower limb spasticity evaluated in CP patients. And CP is actually one of the leading causes of spasticity in children.

Just as a note the reference - there are supporting references to all of the

statements that I am making. So I do refer you to the written response that we will be providing to look into detail into those references.

And just as an end to the second point that we did want to make is that the types of paralysis and spasticity for adults, as well as pediatric patients, can be classified as diaplegia, hemiplegia, paraplegia, as well as quadriplegia according to the area of the body that is affected. And therefore we request that the code be reinstated for the treatment with ABO.

The third request is to update the CPT code title, spasticity hemiplegia, back to spasticity in Group 14 for ABO BoNT-A. The current draft LCD title is highly limiting and may unduly restrict treatment of other types of spasticity in the Medicare population.

In alignment with the FDA approval of ABO for the treatment of spasticity, we are requesting this change because our FDA presentation is broad. Also, just talking to the same point for the second point that I have made, we have Phase IV studies and pediatric studies that include CP patients categorized with different types of paralysis, going beyond just spastic hemiplegia.

The fourth request is to include all ABO on-label muscles, as well as update the language for ABO BoNT-A dosing guidance to include all on-label ALL, so Adult Lower Limb and Pediatric Upper Limb dosing to the guidance there.

For cervical dystonia, we request the expansion of muscles that are including levator scapulae, splenius, as well as splenius capitis, as well as longissimus. The on-label dosing for recommendation for ALL as well as PUL, which is currently missing from the draft policy, should include for ALL it is the starting dose is 1000 units or 1500 units with a maximum dose of 1500 units for Adult Lower Limb spasticity.

And for Pediatric Upper Limb spasticity the starting dose is 8 units per (TIG) to 16 units per (TIG) per limb. And the maximum dose for Pediatric Upper Limb is 16 units per (TIG) with 640 units as the maximum dose, whichever one is lower.

The fifth request is similar to the previous presentation, is to include the CPT code for ultrasound image guidance in the treatment of spasticity and cervical dystonia. When injecting ABO the use of guidance technique is recommended in the FDA approved ABO prescribing information.

In addition, there is a number of publications that actually support the use of guidance, and show that this usage of ultrasound guidance may mitigate adverse events and really help to visualize the injection sites, the target sites, that you are injecting the toxin into.

This data is actually also supported by our recent Phase IV study in Adult Lower Limb spasticity where we showed the treatment of - looking at the efficacy and safety of ABO in a Phase IV study. And we actually showed that there were improved patient role attainment in those patients that were injected with ABO using ultrasound when compared to those patients where there was no ultrasound guidance used. And this was published. And recently this data was presented at AAN as well as WCNR.

The sixth request from us is to reinstate ICD-10 codes for ABO that are currently in the policy, including other dystonia. And also consider additional codes for Abo-A usage in the policy. So one of our first indications for the use of ABO in Europe was in blepharospasm and hemifacial spasms in early - the 1990s.

I would like to bring awareness to the existing published data on ABO used in other conditions that fit under other dystonia. This includes, but is not limited to, blepharospasm and hemifacial spasms.

In addition, there are data that supports the ABO use in other conditions such as Neurogenic Detrusor Overactivity, so NDO, migraine, and hyperhidrosis. And these are also indications that are approved outside the US.

For all of these points that I've made, the six points I've made, I do refer you to review the Ipsen comprehensive written comment response that will be provided, along with the supporting references for additional details.

So, I thank you for this opportunity to speak at this forum. We look forward to submitting our written response with Ipsen's requests and feedback, along with the data that supports the statements that I just covered today and the PI for your review.

And hope you consider our suggestions in relation to ABO coverage as a final policy so that Medicare patients can have access to treatment options to manage their chronic and debilitating conditions. Thank you.

Dr. Marc Duerden: Thank you, Dr. Mann. I have a question for you, if I may. I have - when you use the

words, or the term, muscle spasm as one of the indications, well, I guess I'm a little surprised because I'm not sure I understand what a muscle spasm is and how it would be defined from a policy perspective.

Dr. Amandeep Mann: And so that is a great question. The - so that's referencing my second point around the reinstatement of the on-label diagnoses. So this is currently in the policy for abobotulinum neurotoxin usage. So typically when you do inject for overactivity in the muscles, you do see the effect of reduction in muscle spasms as well.

So they are defined as painful contractions and tightening of your muscles. It's just another definition for an effect that you can get with spasticity or overactive muscles. And given that the mechanism of action for ABO, or other BoNT-As, is to reduce the overactivity, you would actually see a reduction in spasms with the treatment of ABO.

Dr. Marc Duerden: Yes, actually, I agree. But my concern is, is that the use of the term muscle spasm is too general and doesn't describe the neurologic component of what is really the etiology of the muscle spasm. So for cervical dystonia it's a neurologic etiology, for spasticity, it's a neurologic etiology.

And that's why the pre-synaptic effect of the botulinum toxin it works because of the neurologic component. So I heard the terms that you wanted to have used where you wanted to include the cerebral palsy issue, muscle spasm, and contracture. It was early on in your presentation.

I guess I'm at a loss to understand the issue of muscle spasm and the use in contractures when that may or may not be an issue related to a neurologic condition and, therefore botulinum toxin which is working on the presynaptic clefts or the release of the acetylcholine, then it isn't going to be effective. And simply just having somebody with a contracture or muscle spasm isn't really addressing the issue. So can you address why you would want that terminology placed in a policy?

Dr. Amandeep Mann: So it's really to allow the flexibility for the treating physician to manage spasticity appropriately. Typically, we see that spasticity patients actually do not get the appropriate management until it is, like, they're further down in their patient journey.

By that time they may develop contractures in certain muscles or certain joints, but that does not mean that that patient cannot benefit from toxin. And we actually

have shown evidence across BoNT-A that injecting even in patients that have contractors can be beneficial in improving passive function, if not active function. So we still would like our prescribing physicians to have that option to be able to treat patients that may have contractors in their upper or their lower limbs.

Dr. Marc Duerden: Okay. Also, an additional question that I have, you said that the policy may be limiting the treatment for spasticity. Could you enhance upon that statement that you said that it was going to be limiting?

And I didn't know if you meant it was because we didn't articulate in the policy that it was spasticity as a result of a traumatic brain injury, spinal cord injury, cerebral palsy or some other neurologic condition, or were you making it as a general statement that it's - that the dosing is limiting?

Dr. Amandeep Mann: Right. If I understand the question correctly, this might be referencing my third point around the CPT code title, which has changed from spasticity to spastic hemiplegia. That would be restricting for ABO BoNT-A usage in spasticity population.

Dr. Marc Duerden: Okay, so you're - I think that the codes in particular, correct?

Dr. Amandeep Mann: Yes, yes.

Dr. Marc Duerden: Okay.

Dr. Amandeep Mann: It was the titling for the CPT code which actually became more restrictive for ABO versus being more general and aligned with our FDA approved indication.

Dr. Marc Duerden: Excellent, okay, now I understand. Thank you. And Dr. Mann, anything further you would like to add?

Dr. Amandeep Mann: No, I just wanted to thank you for this opportunity to speak on behalf of this and highlight some of the key points that hopefully you will consider once you're creating the final policy. And once again, the written response we'll have all those details laid out. And I do apologize for not having slides ready in time for this presentation, but yes open for any other questions.

Dr. Marc Duerden: Oh, thank you, Dr. Mann. I don't have any further questions, but I appreciate you taking the time to be with us today and giving us your comments. And we will take them under consideration. So I appreciate it.

Dr. Amandeep Mann: Thank you.

Dr. Marc Duerden: Before I turn the time over to Dr. (Bersani), and make sure that he's here, I would like to turn open the meeting to anyone that would have any additional comments that they would like to add. And so operator if you could open the lines to anyone that would like to make additional comments.

Coordinator: As a reminder, if you'd like to make a comment, please press Star 1. Our first comment comes from Dr. Zachary Bohart.

Dr. Zach Bohart: Yes, hello. How are you? Thank you for having me. Can you hear me?

Dr. Marc Duerden: Yes.

Dr. Zach Bohart: Good. Thank you very much. My name is Dr. Zach Bohart. I run the Adult Spasticity Clinic at Tufts Medical Center in Boston, Massachusetts. And I also work at University Orthopedics, which is the orthopedic department for Brown University Medical School.

I'm also on the Corporate Relations Committee for the American Academy of Physical Medicine and Rehabilitation. And we are working on a response to this misguided venture. I apologize if I speak out of turn as I have never done this before.

I am in a clinic, and I am not in Washington, D.C. That being said, those of us treating adult and pediatric spasticity take care of the most heavily neurologically disabled population in our country with diagnoses ranging from strokes to multiple sclerosis, cerebral palsy, traumatic brain injury, and spinal cord injury.

Our goal of treatment, I just want to let you know that, what we are trying to do as physiatrists and neurologists, is to improve upon care and comfort and level of active or passive functioning and human dignity, which is specifically impaired by spasticity.

And please note there is no agreed upon definition of severe spasticity. If you have it or you don't. And if there's impairing level of functioning then we - those of us in the field agree that it is severe enough to be treated first line.

The proposal to curtail the dosing of toxins, and limit the use of toxins to strictly on-label use, is severely beneath the standard of care for those of us who have been in this field for years and decades. We frequently use up to 400 units to 600 units of Botox, and similar dosing, for other brands of botulinum toxins regularly, as this is what patients frequently need to sit in a wheelchair.

This is what they need to have hygiene performed to clean their groin in a wheelchair, to wear a hand or an ankle splint after a stroke, or to walk and transfer and progress with post-stroke physical and occupational therapy.

Decreasing the dose we can use will literally tie our hands behind our backs in treating this very difficult patient population that is voiceless, that is living in nursing homes, that is living in group homes, and that is overlooked. This is strictly an issue, in my mind and those who I work with, of equity for our neurologically disabled condition, and it must be reconsidered for it is clinically misguided and wrong. Thank you for having me.

Dr. Marc Duerden: Thank you very much. If you could, as well submit those comments in writing, that will formalize those comments.

Dr. Zach Bohart: I would love to. To whom do I submit it, sir?

Dr. Marc Duerden: At the end of this presentation we'll actually give you that Web site, and the contact information for that.

Dr. Zach Bohart: Okay. I appreciate it. Thank you very much.

Dr. Marc Duerden: Thank you.

Coordinator: Our next comment comes from Dr. Bridget Walker.

Dr. Marc Duerden: Dr. Walker?

Dr. Bridget Walker: Am I off mute?

Dr. Marc Duerden: No, you're off.

Dr. Bridget Walker: Okay, I'd like to echo similar - exact sentiment. I am a physician at Hartford Hospital in Physical Medicine and Rehabilitation. And I completed one of the spasticity fellowships at the Medical College of Wisconsin.

There's two non-accredited fellowships in the country. And so, like, I missed the name of the physician at Tufts, but it's a very unique population. It's a very vulnerable population. And I feel like with the limitations on the dosing sometimes we already come into feelings of like, okay, well, it's 400, but no, it's 400 per each limb.

And sometimes these stroke patients have the upper limb, the lower limb, the neck, the trunk, and you hit ceilings on how much we can provide. I think from the comments from, I think the questions was on AbbVie in terms of like the moderate

and severe echoing again from the consensus statement from AAPM&R, is its a matter of what's a problematic spasticity.

Sometimes it's mild, and sometimes you really don't catch anything doing the modified Ashworth. But functionally while they're doing walking, or transferring, or sleeping, then they have these really bad spasms.

And so we use these toxins to do a focal treatment in order to minimize the side effects of any oral medications, especially if they weren't able to tolerate them. And it can provide a significant amount of relief and ability for them to function. So I think that's where the sentiment comes in terms of liberalizing it so that it's not just moderate and severe, because sometimes it's just certain muscle groups.

And using the expertise from our physiatry colleagues, our neurology colleagues on treating it, you know, I think also the comment in terms of what's a high dose versus a low, you know, a low dose. I think it's also - it's sort of - it's hard to say because 400 to me is not necessarily a high dose, but certainly talking about like 600 and 800 units that would definitely be a higher dose in terms of onobotulinum toxin and incubotulinum toxin versus the equivalent for abobotulinum toxin.

So I think, similarly, just echoing the sentiments of the physiatrists at Tufts that this is a really vulnerable population. And putting the limitations on the dosing, and the ICD-10 or CPT codes, or not - ICD-10 codes for the diagnosis will really inhibit our ability to treat this already vulnerable population.

Dr. Marc Duerden: Thank you very much. I would also like to request that you submit those comments in writing...

Dr. Bridget Walker: Okay.

Dr. Marc Duerden: ...so we can formalize them. So thank you, Dr. Walker. Operator, are there any additional comments or has Dr. Bersani joined us?

Coordinator: I'm showing no further comments and Dr. Bersani is on.

Dr. Marc Duerden: Dr. Bersani, this is Dr. Duerden. I'm going to turn the time over to you for your presentation.

Dr. Bersani: Can they hear me? I can't tell. I'm trying to tell whoever...

Dr. Marc Duerden: Now I can hear you.

Dr. Bersani: Oh, you can hear me?

Dr. Marc Duerden: Yes, I can.

Dr. Bersani: Okay, good.

Dr. Thomas Bersani: Okay, I'm just getting into the website here, but okay, I'm Thomas Bersani. I'm an oculoplastic surgeon in Syracuse, New York. I'm a professor at the State University of New York State Medical Center for 37 years. I trained at the University of Michigan with Dr. Bart Free, I think the first human to use Botox on a human for any disease, and that was for a benign essential blepharospasm.

I've done a number of research papers on this disease and these treatments over the years because of my early exposure, and I was one of the first physicians in New York State to use it when it was approved by the FDA in '89. And back then, there were very crude recommendations as to how much should be given and where, but over the years, we have developed a much more elaborate, detailed protocol that is very individualized to the patient's needs, because blepharospasm is really a wide spectrum of severity from patient to patient.

And we start with a low dose of maybe 2.5 to 5 units of toxin in three or four locations around the eyes, in the eyelid area. And then depending on how they respond, we gradually up the dose until we get to a therapeutic level where they can function. These patients are absolutely unable to function. They can't ride. They can't drive. They can't read. They can't work.

I am proud to say that in 37 years, I have not had one patient go on disability due to this disease, even though many have asked me to put them on disability. And the reason is, if we stick with it and work with them and try different dosages and patterns, we can get them functioning. We can get them seeing and doing what they need to do.

And it's really an incredibly useful drug. But the typical dose might be 20 to 40 units per eyelid in six or eight locations per eyelid. So that's way higher than what is being proposed as a dose for treating this. And I think it goes back to the early FDA, you know, recommended - the earliest descriptions of it when it first was FDA-approved. And those descriptions have not kept up with many decades of clinical practice.

So, we are hoping that the decision of the committee will be to give us flexibility with the amount we use and the frequency with which we use it In the two-to-four-month range, between anywhere from 40 to 80, even 100 units per patient is sometimes needed to control this very, very challenging disease. I'm happy to answer any questions about this disease or its treatment, but that is my primary recommendation and request, is that we let the doctors make the determination on an individual basis, because that is the best way to regain control of this disease.

Dr. Marc Duerden: Okay. Thank you, Dr. Bersani. I don't have any further questions. I appreciate your comments, and I think I understand your position.

Dr. Thomas Bersani: Great. I'm glad I could help, and thank you for asking me to speak.

Dr. Marc Duerden: And I appreciate that, and thank you for especially coming out of surgery today to help us with this very important topic.

Dr. Thomas Bersani: I agree, it's very important, and I'm happy that I was able to help.

Dr. Marc Duerden: Thank you, sir.

Dr. Thomas Bersani: Okay.

Dr. Marc Duerden: Operator, I'd like to now look and see if there's any additional comments in the queue, and if you could check that first.

Coordinator: As a reminder, please press Star 1 if you'd like to make a comment. I'm showing no comments at this time.

Dr. Marc Duerden: Thank you, operator. At this time, what I'd like to do is close my portion of the open meeting but inform all participants that the comment period is still open and will remain open until July 14th, 2024, just before midnight. And all comments that have been presented here today must be submitted in writing to National Government Services. And this concludes my portion of the open meeting for the draft LCD for botulinum toxin injections. And I'll turn the time now over to Dr. Noel for the concluding remarks.

Dr. Ella Noel: So, as promised, you can send your comments to us at NGS. You can click on the public comments button on the proposed LCD in the Medicare coverage database. You can send that information to PartBLCDcomments@anthem.com. Part B LCD comments are all run together and at Anthem.com, or you can send them snail mail to National Government Services, LCD Comments, PO Box 7108, Indianapolis,

Indiana, and the zip code is 462077108.

Next slide, or is that the last slide? I believe that's the last slide. We will adjourn this meeting, and I want to thank everyone for attending and participating today. Thank you very much.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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