

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

Meeting Date & Time: June 9, 2026, 4 pm ET

Topics:

- DL40356 – Anterior Segment Intraocular Nonbiodegradable Drug-eluting System
- DL34356 – Erythropoiesis Stimulating Agents

MEREDITH LOVELESS 0:09

Hello everyone and welcome to CG S's J15 Open meeting.

I'm accompanied today by Curtis McFadden who is our producer, as well as the other medical directors for CGS, Doctor Earl Berman and Dr. Vidya Nagamangala and our policy analyst Jessica Olsen. And we are going to be reviewing several proposed policies after I'm going to do an overview of those policies and then we'll have time for presentations from our community on these topics. Today's meeting is being recorded and transcribed and will be available on the CGS website within three to four weeks. Our disclosures include that everything is accurate as of today. However, as Medicare changes, there could be changes reflected in the information presented today.

The topics for which we'll be discussing today include a minor change to our erythropoietin stimulating agent policy, as well as the proposed anterior segment intraocular non-biodegradable drug eluting system policy. The comment period has begun starting 5/21 and will close July 4th, 2026. The comment period will be open till midnight and will close thereafter. Review at the end how to submit any comments and a note that all presentations today will be considered, but we do need to receive written comments from all of the presenters for this to be considered in any changes between the proposed and final LCD. In addition, comments to be supported with peer review published evidence to support any recommended changes.

For the ESA policy, this is a very minor change. We're updating the upper limit of the hemoglobin cut off from 12 to 11 to align with updated guidelines, practice patterns and FDA warnings. So, this is a simple change. This is only open to comment for this one change. That is just updating this policy to reflect current practice and guidelines.

For the anterior segment, intraocular non-biodegradable drug eluting system. This is a policy that addresses a single Food and Drug administration. FDA approved anterior segment intraocular drug eluting system as being reasonable and necessary for the management of ocular hypertension or primary open angle glaucoma.

The policy permits use per eye when all of the following criteria have been met.

A history of failed medical management, defined as at least 2

Topical drops that can be given sequentially as monotherapies or together simultaneously for the treatment of open angle glaucoma or ocular hypertension, and the drops did not achieve the goal of a reduction of 20 to 30% from the patient's baseline IOP. That cut off is derived from the American Academy of Ophthalmology, preferred practice guidelines. Which make a recommendation for a target range.

IOP to be individualized, typically aiming for 25% reduction in IOP from tree treatment IOP level and recommending that first line treatments be medication or laser or incisional surgery. Which is addressed on this slide.

Continuing on, if they have adverse side effects from different ophthalmological drops severe enough to warrant discontinuation and this is documented in the record, or the patient is physically unable to place the drops due to disabilities such as loss of use of dominant hand and no caregiver who can perform this. Those all support that failed medical management. Additionally, given that the that the laser incisional laser surgery is considered initial or adjunctive therapy. A history of failed FLT.

Meaning that it did not result in clinically significant reduction. IOP is also required. This positions



this as a second line therapy with first line therapies being medical management or the laser management. And this aligns with the recommendations for the medication or the laser therapy as first line options. Of note, the preferred practice guidelines for glaucoma surgery do not mention intraocular implants for delivery of medication in the guidelines.

Limitations set forth in this policy include that the device cannot be performed at the same time as other eye surgeries or procedures, with the exception of cataract surgery. Now, cataract surgery is pro doing these. Together with category with cataract surgery is only supported by low certainty evidence. However, we did have a CAC meeting and our subject matter experts explained that that this is clinically optimal because we didn't want to subject patients to two separate procedures if the patients met the criteria for insertion of this implant and therefore to ensure access at the time of the cataract Surgery and reduce any risk from duplicated procedures.

This is allowed based on the clinical expertise of our subject matter expert.

Device implantation is not permitted when there is contraindications as aligned in the FDA Label it cannot be readministered within two years of insertion. Again, aligning with the FDA label and also aligning with the label is pre implementation. The central corneal endothelial cell density must align with the recommendations for use for the FDA label. Additionally, this implant has a conditional recommendation for MRI. Therefore, patient should be informed of the potential impact on future MRI's and precautions that may be necessary if an MRI scan is necessary in in making an informed decision of whether to proceed with this implantation and re-administration is performed because patient needs coverage criteria.

The previous implant should be removed after the new implanted is inserted to align with that updated FDA label. When that was updated to allow re-administration.

This is within the policy and within the policy is an extensive evidence review that demonstrates the evidence and how that was analyzed to make the conclusions that are reflected in the coverage criteria. I do want to point out that there's moderate certainty evidence to support that the implant is effective for lowering IOP or intraocular pressure, this would be expected because this is a medication that's known to be effective in reducing intraocular pressure, and this is a reliable delivery mechanism to provide that medication.

However, there is low certainty evidence for the reduction past the 12 month mark at the 36 month mark, as well as low certainty evidence regarding serious adverse events. This is why the decision for second line therapy is made. There's a lack of long-term data or understanding how the implants affect the patient's eyes for future procedures and there is high quality evidence to support the first line treatment options of glaucoma medication, or SLT.

Therefore, the LCD limits coverage to patients who fail primary management with topical medicines and Ft. This approach ensures access to a novel new technology but does not replace first line treatment in the absence of evidence or societal support that this device is indeed.

The limited coverage does not permit off label use outside the areas that have been investigated. If future evidence is developed, that changes the limited coverage that can be submitted on LCD reconsideration as well as evidence developed and knowledge about this new device continues to grow.

Comments can be submitted up until July 4th. The preferred way to submit the comments is to send them to CMD.inquiry@CGSadmin.com.

We do have a form on our website to facilitate the submission and ensure you have all components submitted. Again, comments should be supported with peer-reviewed published literature that is preferred to be in a PDF document that's attached to the comments. If it's not in a document PDF file, we may not be able to open or access that literature due to security. And if the literature is not provided, we may not have access to it. Well, attaching and providing that literature is important for the comments to be to be considered and supported, comments could also be faxed or mailed. And now I'm going to be turning the floor over to Curtis who's going to facilitate our presentations?

CURTIS MCFADDEN 10:58

Good afternoon, everyone.

First up, I will be sharing the slides for Doctor Fred Chu.

Hopefully I am pronouncing your name correctly.

Give me one second as I bring those up.

Umm, also.

Doctor Chu, give me one moment and let me give you the ability to speak.

Let me find you.

I have allowed your mic, doctor Chu.

You should be able to unmute yourself.

Fred Chu MD 11:44

OK. Can you see me?

CURTIS MCFADDEN 11:47

We can hear you angry.

Fred Chu MD 11:48

OK.

OK.

Thank you, Curtis.

CURTIS MCFADDEN 11:51

Great, no problem.

Just let me know when to advance your slides and we can go.

Fred Chu MD 11:57

Absolutely. So, thanks so much for having us.

My name is Fred Chu.

I'm one of the glaucoma specialists at the Cincinnati Eye Institute.

I'll be speaking on behalf of the American Academy of Ophthalmology, the American Glaucoma Society, the American Society of Cataract and Refractive Surgeons and the outpatient Ophthalmic surgery society.

So if you could go ahead and to the next slide.

This is my only disclosure and it's not relevant to this discussion.

Next slide.

We appreciate the Max thoughtful work evaluating new therapies and the opportunity to present our feedback on this proposed LCD.

Our goal today is to share targeted feedback to help ensure policy development that aligns with current evidence and real world clinical practice. So, we can go to the next slide.

As an overview, several of the provisions in the proposed LCD may go beyond currently available evidence and could unintentionally limit physician flexibility in patient access. So, we'll go through our specific concerns in detail. If we could go to the next slide.

We're concerned that the LCD is being produced before sufficient long-term data and clinical experience are available. This could create a risk that the policy will outpace the evolving evidence because the eye dose was only recently approved in the past few years, we lack sufficient long term data regarding glaucoma control, interactive pressure control and some of our safety endpoints. Additionally, ophthalmologists are still determining how best to incorporate this into clinical practice to help our patients. As is our understanding that additional studies are in proc in process now, we strongly recommend rescinding the proposed LCD and pauses development until more data are available.

In the meantime, our recommendation would be that claims be evaluated on a case-by-case basis. If the LCD is not rescinded, then our concern is that there may be significant revisions required in the future.

Uh, next slide please.

So the step therapy structure is also a concern. As it is overly restrictive for our patients, greater flexibility would better support individualized care for our patients.

So I can go for the next slide.

So step therapy could significantly limit our patient's access. Many patients who have not yet

reached the required failure of two medications and SLT could benefit from such a device and procedure. First, not every patient is a candidate for SLT. Some may not be able to position or keep their eyes open for the duration of the procedure, and some may have other risk factors that make SLT not the preferred recommendation. Additionally, many patients who reach the proposed level of failure of glaucoma treatment may be better candidates for other procedures at times with more risk than this device. In glaucoma, often it is better to offer better or sorry less risky options to prevent more invasive and risky procedures and reduce risk. Further, our major a major issue in glaucoma is medication adherence. There have been multiple studies that have demonstrated imperfect adherence to medication therapy. Due to this, we seek options that remove responsibility for pressure control from our patients. SLT is a great option for this in iDose could be as well. There are many patients who do not meet the proposed requirements who could benefit from such a procedure. We would recommend changing the recommendations to failure of one medication instead of two and change the criteria from AND to OR for SLT.

We can move on to the next slide.

So initially we have concerns about the limitation preventing iDose from being performed in conjunction with other procedures. There is more data to come on this, but in the meantime we would recommend removing the limitation and evaluating potential patients on a case by case basis for approval.

Next slide please.

We believe there may be a potential typo in the reimplantation time requirement which states that two years must elapse prior to reimplantation. The reference for this limitation is number 14. The FDA package inserts, and it states that it is not recommended to read Minister an iDose TR more than once per year. We recommend a correction to limitation #3 to clarify, the frequency limitation is one and not two years.

Next slide.

The endothelial cell density limitation also raises practical concerns. Specular microscopy is not readily available to most physicians. It's often used in research, but also specific to corneal sub specialists. So, it does limit the number of people who would have access to these physicians and patients alike. We would suggest allowing clinical judgment where testing is not available and that would be options such as slit-lamp examination and corneal pachymetry. Corneal pachymetry measures the thickness of the cornea and when the endothelial cells are overcome and the cornea decompensates, the cornea becomes thicker. So, this would allow for a measurement that would be more readily available to most ophthalmologists.

So, when we when these requirements are taken together, they create a high cumulative threshold for access and significant limitations on real world clinical application. We feel this could delay appropriate treatment, which is particularly concerning in a progressive disease like glaucoma.

And next slide.

So at this time, our organizations believe the most appropriate path forward is to rescind the proposed LCD and pause coverage policy development until more literature is available. However, if the Macs are unable to resend the proposal, then we respectfully recommend the targeted refinements that increase flexibility and step therapy coverage indications. Remove limitation #1 and consider coverage with concomitant other procedures on a case-by-case basis. Consider revising limitation #4 to allow clinically appropriate assessment methods and correct limitation #3 to reflect the one-year reimplantation limit. Your goal is a policy that supports appropriate evidence aligned patient access. We thank you for your time today.

Our organizations will submit formal comments prior to the deadline and include PDF copies of any additional literature.

Thank you.

MEREDITH LOVELESS 19:45

Thank you, Doctor Chu, for your presentation.

CURTIS MCFADDEN 19:46

Thanks.

Next up, from my understanding is.

Doctor Steven Dixon.

Give me one moment to bring your slides up.

And then I will give.

You.

Speaking abilities give me one second.

Work through.

My technology here.

Dickson.

Doctor Dixon, I do believe.

Your mic is allowed now you would have to unmute on your end.

Stephan Dixon 20:43

OK. Can you hear me?

CURTIS MCFADDEN 20:44

Yes, Sir, we hear you.

Yes, and let me share your slides.

Stephan Dixon 20:46

Great.

Sure.

CURTIS MCFADDEN 20:51

All right, here we go.

Stephan Dixon 20:54

All right.

Sorry, I missed part of it. It wasn't letting me into the meeting. So, any ground rules I need to know about? Amount of minutes that you would like me to present or anything along those lines.

MEREDITH LOVELESS 21:06

Move forward with your presentation.

We're fine on time, Doctor Dixon.

Stephan Dixon 21:10

OK.

Excellent. OK.

Thank you very much.

So my name is Stefan Dixon.

I'm at Midwest Eye Center in Cincinnati. OH.

So, you know, here, just to talk about the recent LCD kind of proposal here concerning the interior segment and intraocular non-biodegradable drug eluting system. In this case the brand name iDose TR, we go to the next slide please. So essentially when I'm as a glaucoma surgeon, when I'm dealing with my patients and doing what I can for them to try to protect sight and protect their glaucoma from getting worse. The biggest challenge for me really is compliance, and so one of the biggest sorts of excellent things that has happened in the world of glaucoma since I've been in practice has been the ability to deliver drug medication in a biodegradable form in the eye itself. And there's a few options at this point in time on how to do that, but really, it's something that is an amazing part of the tool chest that I have as a glaucoma surgeon to be able to help my patients. And so, when it comes to things like iDose and doing it in combination with other procedures. To me it's a no-brainer. So, I mean, currently the draft LCD language talks about not being able to perform this kind of commitment with other eye surgeries or procedures except when it comes to cataract surgery. But I will tell you, you know, the most common situation I'm presented with is my glaucoma patients who have cataracts or may not have cataracts and I'm needing to do some sort of a stenting or filtering procedure for glaucoma and being able to be in the eye at the same time and to deliver medication as well. So not doing a separate device, but actually doing iDose, which is not a device it's more so, a way of storing medication and releasing medication

in a pharmacologic fashion, being able to do that at the same time allows me to really target glaucoma from multiple standpoints and be able to really help target the disease that we know is so multifactorial and so when it comes to my practice, I am I'm often stenting open or helping open up or filter past the natural drainage system inside the eye with some sort of device and then again if I'm able to also then deliver medication, especially sustained release medication. That may be able to help that patient get medication 24/7 for years to come. Without having to instill drops or have family members help instill drops and without having to undergo another separate procedure down the line. If we have this inability to combine procedures, it would be very dangerous, potentially to some of our patients to have to subject them to more anesthesia to do some other procedure down the line when we can simply do them at the same time and so really my biggest issue really is that the emerging evidence and all the things that I referenced in my in my slide deck here really helps support the use of biodegradable pharmacologic in the eye to be able to deliver medication and take that burden away from the patients and allow us to help our patients preserve sight and oftentimes combining again with these different procedures targets the multifactorial nature of glaucoma.

Where we can really have a sort of a belt and suspenders approach to be able to help our patients and deliver medication, while also stenting with separate procedures.

Next slide please.

And so again, I like to really just emphasize that iDose is a pharmaceutical therapy.

It is not a stent. It's not a device when it comes to how it how it works, it's anchored within to the within the trabecular meshwork which is one of the traditional outflow pathways for fluid inside the eye. But it is not actually stenting open, and so it is very different in in methodology and functionality to some of the other things that we have at our disposal, such as a laser with SLT and other minimally invasive glaucoma devices or surgeries mitigate that help stent open or bypass the trabecular mesh work and also the medication that is released from this from the eye dose in the pharmacologic fashion is not only targeting that outflow pathway that it's directly adjacent to it's also targeting the outflow pathway of the Uveoscleral pathway, which is a separate way that fluid flows out of the eye and helps lower pressure. And so, it is very multimodal in how it's helping our patients. And again, being able to do this all at one time to be able to do these adjacent sort of surgeries, our procedures or you know these devices/pharmaceutical therapies being able to do them all at once is not doing the same thing multiple times, it really is targeting glaucoma in very, very different ways. And then you know, you worry about the stage treatment approach if we are sort of restricted by the LCDS decisions here to only doing one procedure at a time or doing things separately and maybe not other things. It really does restrict our ability to help fight disease progression in our patients because a lot of these patients may not be able to be subjected to multiple bouts of anesthesia or multiple surgeries. And so, if we are, if we do have that flexibility to be able to provide for our patients, that's going to be incredibly important. And then also you know when you look at the LCD zone analysis of evidence, it acknowledges that the clinical advantages of combining treatments in a single setting to reduce just the cumulative surgical risk within one's lifetime is extremely important. And that is a certain advantage for our patients. And then when we're sort of again restricted to be able to not do multiple things and kind of target different modalities of glaucoma at the same time, it really kind of contradicts and goes against that that sort of methodology.

Next slide please.

And then again, you know this is some of the evidence that was not necessarily included in the draft LCD and not necessarily reviewed. And so again, I urge you to look at some of the burgeoning evidence that's going on in the burgeoning research that's going on in this area because this really is, in the past several years, a newer area of pharmacologic treatment for our patients. And so again this is included for your review here as well.

And so I'll go the next slide please.

And so again, you know, my big ask here is really, really kind of stayed this this decision at the very least just because you know, there certainly is a lot more evidence out there to support being able to perform con commitment procedures. And again, as you know I want to make sure that the understanding is that this is not targeting glaucoma in the same exact way. This is not putting multiple stents in or doing multiple sorts of device management at the same time. This really is a really, different sort of approach to being able to help our patients. So again, being able to deliver medication in the eye is very, very different from being able to put a stent in the eye. And again, they very much work in conjunction together as the research is showing.

And I believe that might be my last slide if you go to the next.

So again, in summary, you know, talk about some of these things, but really glaucoma is very

much a personalized multimodal treatment approach. And you know every patient really just oftentimes does need something different or needs to have that flexibility as a physician and the surgeon in my hands to be able to offer my patients the proper therapy and having my ability to sort of do what I think is best for the patient. And what has been shown to be best for the patient can be very limiting and honestly will make it a lot harder to treat this this chronic disease.

So again, I really hope that you know being able to reconsider this, the kind of the draft proposal and be able to hear us out, I think, would very much appreciate your time to be able to do so.

MEREDITH LOVELESS 29:39

Thank you very much for your presentation.

Stephan Dixon 29:42

Thank you.

CURTIS MCFADDEN 29:53

Up next, I do believe it is Dr. Christine Funke, if I am saying your name correctly.

Christine Funke MD 30:11

Funke.

CURTIS MCFADDEN 30:12

Funke, OK?

Christine Funke MD 30:13

I know everybody does it.

It's a good one.

CURTIS MCFADDEN 30:17

OK.

Give me one second, doctor Funke and I will get your slides up.

Christine Funke MD 30:25

Thank you.

It's good to get a giggle, at least.

CURTIS MCFADDEN 30:29

I was at. I'm being honest, I was a tad bit concerned.

I did not know which way it would go, but hey.

Next up we have Doctor Funke.

Christine Funke MD 30:40

Thank you.

Thank you guys so much for having me. My name is Christine.

I am cataract and glaucoma specialist out of the Phoenix area and I'm just. I'm really, really thankful for everyone's attention here as we're talking about something that's really meaningful, which is how we're able to offer our treatment and care for our glaucoma patients who can go to the next slide.

Thanks Curtis.

So I think it's really important and a lot of what my colleagues have already mentioned about, you know, the challenges around treating glaucoma. I think one of the big things that we have to just kind of step back and remembering what this disease really is like and kind of the nature of what it can bring to a patient's life and the big one being it's a chronic, progressive, potentially blinding disease. And we know that 16% of eyes will eventually lose their vision to this disease, which is a pretty high rate, so you know about one in six patients that we're seeing will eventually lose the battle in one eye, which is too high in my opinion and a lot of it has to do with the fact that for a very long time historically we've been using drop therapy and while we know drops work, they only work when people use them. And unfortunately, the human nature that we have, people just don't like to use their medication even when they know that they have a disease that

is going to be there for the rest of their life. And what iDose brings to the table and, minimally, invasives bring to the table is something that we didn't have 10 years ago, which is the ability to get around this huge problem of noncompliance. Noncompliance is something that really leads most patients down a road towards quality of vision loss and potentially blindness. So, when we're starting to talk about these things, I think it's so important to first remember why minimally invasive glaucoma procedures and interventional glaucoma generally is really important to all of us, as ophthalmologist, which is, we are trying to get around the big elephant in the room that's been there as long as we've been taking care of patients with glaucoma, which is compliance. The other big issue which we haven't talked about yet is the diurnal fluctuation that we know happens with pressure. So, when we talk about IOP, one of the things mentioned in this LCD discussion was the idea that you know, we have to have these gold pressures of 20% reduction, 30% reduction. The issue is that we're not great at checking pressures. When we look at someone's pressure, it's once every three to six months. It's kind of like trying to understand how a diabetic is doing by checking their blood sugar once every three to six months. It's really not helpful. So, the issue is we know pressures go up and down all day long and into the night and our ability to actually have good visualization into what's going on throughout that 24-hour period is poor. Generally, very honestly, a lot of our ability to watch glaucoma is. Still poor. We're still rudimentary. And how we're able to actually look at the progression of this disease compared to how we treat it. So, I actually think we're more ahead on the treatment aspect than we are on the observation. But one of the big issues when we're talking about treating people topically with pharmaceuticals instead of in the eye is that again, that fluctuation continues to happen. So, meaning that up and down pressure that we see, which ultimately can damage the optic nervous system ongoing. Where when we do something physically inside the eye that fluctuation is less intense, which is really, really important. The other thing that's really hard is that testing generally is very hard to come by and we know that this is another issue that we have that we don't follow the fields as often as we'd like to so we don't see progression as well as we'd like to.

Next slide.

Can we hit the next slide, Curtis?

CURTIS MCFADDEN 34:29

Sorry about that.

It's moving a little slow.

Christine Funke MD 34:30

Oh, that's no worries.

So you know when we're talking about these options, I think we also just need to remember that this is potentially a huge quality of life issue for patients. And very honestly, this is a disease that is very frightening for patients. Obviously, they don't want to go blind. They don't want to lose their vision and that also it can be frightening as a physician to be treating these patients because we don't want them to go blind. We want to do everything we can to keep around their quality of vision and quality of life.

Next slide.

So here's the big glaring problem which we need to remember when we're talking about wanting to use iDose, which is that the majority of patients within a year are not taking their medication. We have a lot of different documented evidence to show that and within even six months. The majority of patients, about half, aren't taking their eye drops. So, when I'm talking to somebody and I'm handing them a drop, I know that it is going to work. But for a limited time, because most patients will only take it for a limited time. But this disease isn't limited. We have this for the rest of someone's life, so we have to figure out a better way to treat them. Aside from just topical remedy. The other issue, which is really fascinating, was that there was a study done looking at patients who were given topical medication versus procedurally managed. So, these patients not only do we want them to get the care that they need to lower the eye pressure to keep the diurnal curve from going up and down and up and down. But on top of all of that, we need them to come back in and see us right. We can't watch chronic progressive diseases if patients aren't coming back to our care. And we also found that topically managed patients did not come back the majority of time after they were given a topical medication. Almost 70% of the time, they did not return to care within a year, which is a big problem. And this is compared to procedurally man. Patients which had a really good rate of return comparatively 36%. So still, we are having almost 40% of patients not returning to us, but at least I know that there is procedure ongoing to keep them under better control.

You can go to the next slide and because we know that this issue around topical medication

use is poor, we just have to figure out a way around it because it's never going to go away. It's unfortunately just part of the nature of taking care of human beings. How does that then relate to blindness, right? Because we have to understand if patients aren't taking their medication, they're not coming back to clinic. What does that ultimately need mean to the amount of actual vision loss that we're seeing? And patients who did not come back to our care within three years had doubled the rate of blindness. That's a big problem. So again, we're starting to just get more and more patterns of evidence to state that I really don't know if topical therapy is the same in terms of actually slowing down progression of disease compared to other interventional procedures. And we know medications work well, which is why iDose is so great, which Doctor Lovelace said very nicely, which is we know it works well. It's medication. But it works better because we know we can place it in the eye and we don't have the compliance factor. The other big thing to remember is that rates of patients having noncompliance much higher in people of color including black patients and Hispanic patients, so we also don't want to limit, especially to certain ethnicity groups when we're talking about being able to control disease.

Next slide. You can hit a couple of buttons this is all in the same slide. One more.

So, we've known for a very long time with Aegis study, which is one of our landmark trials looking at glaucoma that there's two modifiable risk factors when we are talking about taking care of patients, one lowering IOP which we've talked about and that we can see even with topical therapy. But the second one is again, this reduction in the amount of fluctuation and pressure because we're not good at watching that. We really don't have a good way of understanding how well these pressures are going up and down, but we know that this fluctuation just doesn't get tamp down with topical therapy. So, my fear is if we are not more aggressive in terms of trying to make sure that people are under control with non-topical options, we're going to continue to see more and more visual field loss next.

Next slide please.

Some things to also remember when we start to talk about combining, right.

So we're discussing the idea of iDose and in combination with minimally invasive glaucoma surgery. We have to always remember how complex this whole system is in the eye and that there's actually multiple modalities of fluid being able to escape the eye, one being the conventional pathway and the second being the unconventional pathway and we know that the conventional pathway is how we work with Migs. So, working on the trabecular mesh work. Working on the Schlemm's Canal, getting the dilation of all these canals. We're really trying to maneuver fluid through the majority of the conventional out pathway with Migs, but the unconventional pathway is another great way of tapping into better control, and that's the uveal scleral outflow and that we've been talking about is also seen in people who are getting pro Analogs, which is what is in the eye dose. So when we talk about doing stenting or canaloplasty in conjunction with these drug eluting stents, the beauty is that we're mirroring these different mechanisms of action and what's hard about glaucoma too is that we don't have a lot of good diagnostics telling us where the problem is in the eye as to why we're not getting good fluid outflow and why we're getting elevation and pressure and ultimately loss to the optic nerve. So you've got to remember that we're hedging our bets a lot and I hate to say that, but it's just kind of how it is at this point in glaucoma, which is we really want to hit multiple mechanisms when we're in the eye because we really don't know exactly where out flow insufficiencies are and so if we can hit multiple modes, we're hoping to get as much control as we can in one fell swoop. And why that's important is because the eye is a small, very fragile piece of tissue that we don't want to be operating on every Two months, Four months. We really want to try and do as much as we can in one fell swoop so that we can get people under control.

Next slide please.

So when we're talking about all of these different mechanisms of action, we really have to consider why things are symbiotic. So, we're not doing stenting and then also putting an eye dose, but it's all the same mechanism. It's completely separate and so I kind of have put this into different mechanisms of action as to how we use these different minimally invasive techniques along with the drug eluting stents to get us the best pressure control we can. And again, remembering also good diurnal control, which is really important for a long-term outcome of trying to save vision. Next slide.

So again, all of this sounds great, but I think we have to look at ourselves and understand are these combinations really doing what we are hoping for? So, for me, I like to look at my own data. I think it's the best way to understand if what I'm doing is actually effective for my patient, and that's what this is, which is a recently published study looking at some of my data retrospectively. So, this is an all comers. This is truly what my practice looks like. And we are looking at iDose in combination with MIGS with or without laser or emulsification at the time. And this is just kind of a

broad overview of the patients.

Next slide.

And I think what was most important is just understanding my own surgical results and then translating it to you guys just to basically say this is a really good outcome better than I would expect with my single Mig patient or my single eye dose patients and that's what important too is that we have to understand what we're trying to do here, which is we're really trying to slow down the progression of a very devastating disease. And whatever I can do to do that for my patients. You know, it means a lot to me. And that's why this combination means a lot to me, because I've seen my own results, which is we are seeing the rate of IOP go down and also the rate of medication use go down, which again we know is important because we know a lot of people don't take their medications.

Next slide please.

And then here's some more of the data and again looking at these combinations and understanding that these rate of mean IOP drop was significant. As well as the mean amount of medication needed was significant and across all different modalities of Migs in conjunction with iDose, with or without FACO. So, we always saw success in each pairing, some a little bit higher than others and some of these patients again are going to be skewed because it was retrospective data, but. I'm now part of clinical trial where we're looking at this prospectively. So, when we're talking about changing an LCD, I think what's most important is understanding what evidence we have now, which this is where we're at currently, but that we're actively looking at more evidence to understand the significance of these symbiotic relationships between different surgeries. And the reason that we, as glaucoma specialists and ophthalmologists are becoming much more heavy-handed in our glaucoma patients is because all of these techniques are very low risk compared to traditional glaucoma surgery. And we also know that, unfortunately, again, the issues around patients using their medication as well as diurnal is just not going to be solved with topical therapy. So, when we're discussing changes to the LCD, please keep it in mind that what we're trying to do is deal with a very challenging disease that can be again very frightening for patients and really have a high rate.

Of quality of life changing for a lot of these patients. And I think that if we can become again very thoughtful in how we're combining procedures, ultimately as we continue to assess our evidence, we are going to see better and better salvation of people's vision and their quality of life and ability to be independent. I think that's my last slide and thank you guys so much for having us. It means a lot.

MEREDITH LOVELESS 45:12

Thank you for your presentation and please submit your research in the PDF form of the peer reviewed published paper.

Please with your comments.

Christine Funke MD 45:22

So happy too, yes.

MEREDITH LOVELESS 45:26

Our next speaker will be Doctor Proctor. I put him into presenter for you. Curtis, if you can pull up the slides.

CURTIS MCFADDEN 45:38

Awesome. Give me one second.

OK.

Doctor Proctor, are you there?

You would need to unmute your mic.

Benjamin Proctor, MD 46:05

Can you hear me?

CURTIS MCFADDEN 46:06

Yes.

All right.

Thanks for allowing me to speak.

So. Specifically. I'm First off, I'm a comprehensive ophthalmologist.

From Elizabethtown, KY. I've been in practice for over 20 years and take care of quite a few Glaucoma patients And Just wanted to speak on the concerns about kind of the barriers to iDose as an option for the glaucoma patients, you can go to the next slide.

So I guess First off, there's a maybe a tendency to think about this as a device, but really it's an FDA approved drug. Not a device. And so, we need to think about it in that sense in terms of where it falls into the. Process of choosing. A good therapy for our patients. And you know, the current proposal is that patients should fail two topical medications and a laser before. Before this would be an option. And that's really in my view, excessive Because for a few reasons. One is It takes a lot of time for patients to figure out if they've failed one drop, much less 2 drops, and then another procedure and all that time that you're trying to figure out. If those have worked, that's time that the patients are potentially being exposed to vision. Loss before that can be determined and as some of the other speakers have discussed, you know, the advantage of having something like iDose in the eye is that we're not waiting on something to happen once it's in there it's affecting the eye pressure. And regardless of what the patient is doing. And so, you know What's More what I think would be more in line is something similar to what we see with the MIGS procedures is that they fail 11 drop as opposed to two drops and a laser and this would be more consistent with the AA OS preferred practice patterns. Along this, and just to elaborate on the concerns about Having to fail all the two drops in the laser, this kind of disproportionately harms Certain populations you know, in terms of their ability to get to the appointments, their abilities to afford the co-pays And In addition Those people also were at a disadvantage with actually finding success with drop therapy.

Elderly patients have more difficulty administering the drops. They have significant costs associated with them that can and a lot of times be higher than the cost of them if it was Something like iDose that was a 1 time thing.

Next slide.

So and just to kind of give the big picture here and if some of these things are already covered, I wasn't on the whole time. So, I apologize, but you know the reason that treating these patients is so complex is there's lots of drop therapy options.

Administering drops is very difficult for the patients. There are many unwanted side effects that these patients get with the drops, which certainly effects Clients As does the drop installation And as I said before, you know, evaluating these therapies takes time And even if the patient. Is compliant with their follow-ups you're talking about.

Months before we can figure out if certain therapies aren't working and that and that's enough time for nerve damage to occur from glaucoma, while we're trying to see if they fail these other therapies before we can Use something like iDose To work immediately effectively. And again, you know there's financial Burdens on the patient and family with travel costs and visit costs trying to determine these whether or not these therapies have failed, and that affects whether or not the patients even returned for follow up. And then once they're lost for follow up is I think one of. Other speakers have discussed. You know, that's when they really get exposed to a higher risk of permanent vision loss or blindness.

Next slide.

So, you know, I think the overreaching point is that at least if we can just pause this process so we can see, you know, pause the restrictive language while we see More evidence Becomes available And That, you know, we definitely agree that it should be considered reasonable and necessary for the management of ocular hypertension or glaucoma in each eye. But you know, the step therapy requirements, just they interfere with the practice. You know what we think is best for our patients. You know, we want to get therapy started for the patient as soon as possible without delay and having an opportunity to have an implantable drug, you know, gives us that opportunity without exposing the patients to risk and it does tend to single out.

You know, certain vulnerable populations. When all of these barriers are created before you know, we can provide what we feel like is the proper therapy.

Next slide.

So. Again. You know, we feel like these current restrictions, you know, overlook the reality of how

we manage glaucoma patients and It's just unreasonable to have to wait for that much failure before we have this as an option.

Next slide.

And yeah, as you know more or less have already kind of alluded to this, but you know some patients just are not good candidates for drops either. They can't physically, you know, many of our patients are elderly. They can't squeeze the bottle. They can't, You know they have tremors. They can't get the bottle, you know, over their eye, in a place where they can administer the drops effectively.

Sometimes they interact with others. Other medications And There's just many studies that support, you know, poor compliance with drops and how that results in vision loss and you know, setting real specific parameters with pressure reduction. In addition, you know doesn't. Doesn't really. Is not an accurate, you know, measurement of treatment failure There are many other things that contribute to that in real life. And again, one of the other speakers discussed this. I mean our long-term management goal is to prevent blindness and you know, Having restrictions On. Therapies like this kind of get in the, you know what may be considered a first line treatment. You know, trying to follow those recommendations may actually.

Prevent us from achieving our long-term goal of preventing blindness. Next slide.

So as I alluded to earlier, you know, I would propose that we follow something more consistent with the LCD for Migs. You know that the patients tried at least one topical medication before eye dose would be an appropriate next step.

Next slide.

CURTIS MCFADDEN 56:54

That's your last slide that brought.

Benjamin Proctor, MD 56:55

OK Yeah. So yeah. I mean, so, so, you know in conclusion, you know, we just I think the current language is just very restrictive and I think. Prevents us from being able to provide an effective therapy that takes Access to care and Compliance out of the equation. And. You know we want to our goal is to prevent blindness in these patients and you know as much as we can Remove the barriers to achieving those goals, the better for the patient and so we just at a minimum like to see. To see this at least be paused so that we can, you know, get some more information before the language becomes so restrictive, and hopefully. It isn't as restrictive as we get more evidence and that's all I have.

MEREDITH LOVELESS 58:17

Thank you for your presentation, Doctor Proctor.

Benjamin Proctor, MD 58:20

You're welcome.

MEREDITH LOVELESS 58:20

What is our final presentation? I do remind all of our presenters to Please remember to submit your comments in writing. I do want to take this opportunity just for an educational standpoint to provide. Just a couple of comments, just for everybody's educational purposes, when we do policy for local coverage determination And for all Medicare policy needs to meet the requirements of the of the Social Security Act, medically reasonable and necessary, and that definition does include that there's evidence to demonstrate, you know, the not only the effectiveness and the safety that that's really addressed by FDA but. The improvement in clinical outcomes over time for the Medicare beneficiary and we Are and part of the requirement and this is by law, so this isn't us. As medical directors, you know, saying this is how we want things done. This is the law in which we work under requires that the service is not investigation or experimental. So, there was some comments on that, you know that that what this is still developing and we don't have clear definition of the you know while this evidence is. Developing that a policy should be paused. And I just want to clarify that that you know typically in a situation where evidence is developing and there's not clear guidance that would be equate with non-coverage because it doesn't meet the definition of reasonable and necessary. So, I just want to I just to understand where we're coming from as medical directors. In this case, we're looking for the evidence that we have.

To be able to support coverage and provide access to an emergent technology.

While making sure that we're addressing the concerns that are still around a new technology

and we do have a process within policy that as new evidence emerges and the questions are answered, to be able to make changes to the policy in the future to liberalize a policy.

Benjamin Proctor, MD 1:00:34

Yes.

MEREDITH LOVELESS 1:00:38

If, if it's proven to meet, meet those standards, I just want to for everyone to understand that. And I also just want to make. Make sure that there's an understanding that in the Migs policy, there's not a single drug requirement.

It is. It is maximally tolerated medical therapy which I think there may be some in that in, in the, in the mix policy it says meet Greater IOP greater than 20.

So, so I do advise looking at that policy just to review that if, if that's being if that's going to be a recommendation. To align that that criteria with these policies.

I also want to take a moment to thank everyone for attending.

Doctor Nagamangala is one of our other CMD's here with CGS and she is going to be taking over this policy on. For J15 and for CGS, working along with Doctor Berman and our policy analyst, Jessica Olson. I will be moving to a position at CMS and so I'll be continuing to work in with, with policy and in this space, but for CMS, I just want to share that with everyone that I've worked with and trust that You are in excellent hands with the J15 team. Who will be listening to, who have listened to everything you have to say and working diligently to ensure that we're providing the best possible care and access for the for the patients that we that we both serve. Curtis, do you have any other additional remarks that you wanted that before we close the meeting?

CURTIS MCFADDEN 1:02:38

No, ma'am.

So we will not have another presentation, this is it.

MEREDITH LOVELESS 1:02:43

That is correct.

Doctor Gaddy is going to submit his presentation in written form.

CURTIS MCFADDEN 1:02:49

OK, then I have no further comment.

MEREDITH LOVELESS 1:02:54

OK. And thank you for all of our presenters for your clear presentations, your passion for patient care and we really appreciate your time to be with us today. Thank you.