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

Meeting Date & Time: October 28, 2025, 3–5 p.m. ET
Facilitator: Dr. Meredith Loveless

MEREDITH LOVELESS: 0:05

Welcome everyone. Welcome to CGS's Open Draft LCD meeting. Today we will be presenting 7 policies. We have 10 presentations, so we'll have a busy meeting.

To begin with disclaimers, everything that is being presented today is accurate as of today, but as Medicare rules and regulation changes, the information may also change.

Today we have 7 policies. I'm going to present an overview of these policies. I'll do so as quickly as possible to allow as much time as we can for our presenters. Today's meeting is being transcribed and recorded.

All of the presenters have completed conflict of interest forms and each presenter will be allotted 6 minutes, which is equally dividing up the time that we have. We will switch at the six minute mark to the next presenter to ensure that every presenter has the opportunity.

To present because some of the material may be duplicative presenters, I encourage you to focus on the material that has not yet been presented. All presenters are asked to submit written comments. In addition to their presentations, which will be carefully considered in the in the process before a final policy is developed. So moving forward with the topics, the first topic is peripheral nerve block procedures. This is an LCD that reviews the evidence for peripheral nerve block procedures by conditions and establishes limited coverage or non coverage based on evidence. The evidence synthesis was conducted in accordance with the grade approach, and the summary of evidence is listed for each of the indications in the LCD, along with summary of evidence tables. A CAC meeting was held. There are differences in the final policy and the outcome of the CAC meeting, and that is summarized in the rationale for decision making and the CAC meeting sections of the LCD, and this is a multi Mac collaborative policy that includes 5 Macs. The balance of the review indicates the use of relatively minimally invasive intervention, nerve block, RFA and cryoneurolysis for the treatment of chronic non-cancer pain is not supported by high quality evidence. Utilizing the grade criteria, the threshold for coverage was moderate certainty evidence.

For many of these procedures, it remains to be determined if this is an effective option for treatment. Very low certainty ratings was found across multiple indications indicating substantial uncertainty about the true effectiveness of these modalities and if they translate into meaningful benefits for patients.

In addition, when compared to current standard of care therapies, they did not demonstrate consistent sustained improvement in pain function, patient experience measures or medication use by clinically important margins.

This will replace the existing LCD nerve blocks for peripheral neuropathy. This is the existing policy is a non coverage policy that states the use of nerve blocks or injections for the treatment of multiple neuropathies or peripheral neuropathies caused by underlying systemic diseases not considered medically.

Necessary and medical management using systemic medications as clinically indicated for the treatment of these conditions and this policy expands coverage for three conditions in which the evidence bar was met, but the the rest of the conditions did not meet that threshold.

The three conditions that met that threshold was trigeminal neuralgia for which radio frequency neurolysis is considered medically and reasonably necessary when the condition has been present for six months is non respondent responsive to medical therapy.

The patient's not a good surgical candidate or decline surgery, and they've had 75% or more improvement with diagnostic trigeminal nerve blocks, with a limitation of two radio frequency

treatments within a rolling 12 months for carpal tunnel syndrome, corticosteroid injection may be used.

Peripheral nerve blocks with local anesthetic can be used for the treatment of carpal tunnels. Peripheral nerve blocks with local anesthetics is not indicated and nor is denervation. The frequency limit is a maximum of three injections per lifetime per side and Morton's neuroma corticosteroid with or without local anesthetic injection may be useful. The treatment of Morton neuromas with A2 steroid injection um lifetime limit.

Additional limitations include that that the blocks do not include any biologics or other injections in denervation procedures. Appropriate precautions are taken with implanted electrical devices or pumps.

That these wouldn't be used in conjunction with moderate or deep sedation, anesthesia or MAC. That they are not utilized to treat complex regional pain syndrome, widespread diffuse pain or systemic polynomial neuropathies. Dry needling is not covered.

And multiple injections in the same session are not covered.

The evidence was not sufficient for the following nerve blocks, which are listed in the LCD and will be discussed in our presentation, so I won't read them off.

Exceptions would be regional anesthetic block, acute surgical pain and pain related to malignancy, refractory to medical management.

The next policy for discussion.

Is temporary non-therapeutic ambulatory cardiac monitoring devices. This LCD is to provide scope and indications that are supported as reasonable and necessary for the usage of temporary ambulatory non-therapeutic monitor devices. This is a replacement and modernization of the existing LCD.

Um to the 21st century format and addressing newer technology not addressed in the current LCD. This is in collaboration with Noridian and Palmetto and aligns and all services must align with NCD 20.15.

Therefore, cardiac monitoring is reasonably necessary when present symptoms suggest cardiac arrhythmias, occurring infrequently and monitoring is necessary to regulate medication management or in patients with non lacunar cryptogenic stroke or stroke or TIA of undetermined origin to monitor for undiagnosed atrial fibrillation or anticoagulation.

Or monitoring patients after surgical or ablative procedure for arrhythmia assessment of asymptomatic ventricular premature beats or non-sustained ventricular tachycardia in in inherited arrhythmic disorders as well as embolic appearing patterns of myocardial infarction.

Devices are required to be FDA cleared. The patient devices, patient or event activated with intermittent or continuous cardiac arrhythmic event monitoring capacity monitored by the monitoring stations to receive transmission and a system is in place to notify patients or emergency services for life threatening arrhythmia.

It is not considered medically necessary if it offers little or no potential new clinical data beyond standard testing such as an EKG or Holter monitor test. The purpose is for long term monitoring to document suspected or paroxymal dysrhythmias.

And wouldn't take and wouldn't be used if a standard EKG is all that's necessary and receiving stations should be staffed 24 hours with personnel trained to read ECGS and notify patients for emergent circumstances.

The test must be ordered by a physician or a qualified practitioner and

are not covered for inpatient hospitals, emergency room, skilled nursing facilities or outpatient or facility based cardiac monitoring. Testing for more than 30 days is rarely necessary.

In addition, this wouldn't be used for routine monitoring in the absence of treatable symptoms and is in a part of a 30 day service package and the remaining details are outlined within the LCD.

The next policy is total joint arthroplasty, which establishes limited coverage for total joint knee and hip arthroplasty and revisions. This is also non coverage for CPT codes that lack evidence to support the procedures.

Primary total knee arthroplasty is considered medically and reasonable necessary when all of the criteria within the LCD has been met. The patient demonstrates advanced joint disease with moderate to severe pain and loss of function, utilizing standardized pain and function scales and

consistent radiographic.

A trial of at least one or more conservative therapy without improvement, typically for a duration of three months, is considered, and optimization of comorbidities is also recommended to improve chances of success and outcomes.

For a revision or replacement, it is medically it is considered medically necessary when the primary failure has failed due to a variety of different circumstances and modifiable factors are addressed prior to surgical intervention.

The total hip arthroplasty coverage mirrors the total knee, except for there are some differences in the advanced joint disease that are covered. Otherwise the criteria is very similar as well as the criteria for revision or replacement.

Joint replacement should not be performed in the presence of the following conditions, which includes infection and are listed in the LCD. The non coverage portion of the policy is computer aided navigation and robotics. There's been a growing trend to utilize these services.

To improve alignment and reduce bone loss, some literature does show a trend to improvement, but this is based on very low and low quality evidence. There has not been any demonstrated difference between conventional and aided outcomes with long-term follow-up, and there are concerns about increased operative time and cost.

These are not opposed by societies, but also not supported by societies. The LCD does not prohibit utilization, but they do not qualify for separate payment.

The next policy is automated detection and quantification of brain MRI's. This is a non coverage policy for artificial intelligence assisted software tool for automated detection and quantification of the brain. There are several examples of this technology. At this time there is not sufficient evidence to support clinical utility or validity, and it is considered investigational. Investigations continue to explore the potential of automated quantification technology to evaluate for multiple different brain conditions and neurological conditions.

This process has been challenged by the lack of established standards for measurements and access to approach to the data sets necessary to train the AI devices. There's also a lack of standards because the brain volumes are traditionally calculated by imaging and while AI calculates mathematically, so the standards are not interchangeable and neither are the programs which each have proprietary data. So the results from one program may be drastically different than another.

There is concerns about sufficient diversity within the data set, and that is particularly pertinent for the Medicare population where age for the Medicare population has not been accounted for, as well as the natural changes to the brain with aging that that has not been included in the standardized.

Data set The American Society of Functional Neuroradiology and American Society of Neuroradiology acknowledge these challenges and have developed a consensus on using the levels of evidence and call for critical appraisal of enabled imaging tools. This provides a useful groundwork for future research to try to provide quality for standardized tools that may be able to be more beneficial in the future.

And also to developing comprehensive and large data sets that can be utilized to train these technologies in a reproducible and reliable manner.

The next policy is from the side. It's biomarkers for risk stratification and metabolic dysfunction associated with static liver disease and metabolic dysfunction associated steato hepatitis or MASH.

And it describes coverage for molecular or proteomic biomarkers for the diagnosis and management of liver fibrosis. In this setting, it aligns with the American Association for the Study of Liver Disease in terms and NASH will be used as a replacement for non alcoholic fatty liver disease and MASH is a replacement for non alcoholic stepatohepatitis.

The biomarker test must is used in an adult with clinical suspicion or diagnosis of one of these conditions. It's a primary risk assessment based on non molecular proteomic laboratory testing as outlined by consensus guidelines and does not indicate low risk.

Liver stiffness measurement by imaging and the results will be used to directly aid in the pending management decisions. It cannot be performed more than once every 12 months or within 12 months following the liver biopsy. Future tests must meet the clinical validity criteria for the Moldx program and algorithms must be validated, all future tests must complete a technical assessment and meet the the methodology as required by MoIDX.

The next MoIDX policy is non next generation sequencing, targeted molecular panels for predictive testing and cancer. This is a policy that clarifies coverage for molecular or proteinomic panels for non next generation sequencing targeted molecular panels for predictive testing in cancer. This is also part of the MoIDX

To qualify for coverage the test must be a next generation sequencing or NGS is utilized when an NGS testing is not feasible or will li

Because the NGS testing can take quite a long time, so this would be a much faster way to

Indicative of the same genetic content and the test must be accurate in the description of the most common genes and positions and being FDA approved aligned with an FDA approved therapy. And like all MoIDX

test, it must be validated.

Demonstrate accuracy based on the MoIDX requirements. Complete the technical assessment and meet the methodology as required by MoIDX.The final policy is

MoIDX policy

on genetic testing for hereditary thrombophilia and this policy defines coverage for lab developed test and an FDA cleared and approved testing that for hereditary thrombophilia to include next generation sequencing test.

MoIDX

the patient presents with a venous thromboembolism associated with a non-surgical major a

And it must meet all the criteria of MoIDX

n the open comment period. Comments can be sent to CMD inquiry@cgsadmin.com as well as by fax or mail. The e-mail is the preferred contact. They we also have a form located on our website. Submissions literature must be provided in the form of full text PDFs in order to be considered for the policy and they must be published. We cannot consider in press or abstract literature. The comment period is open until November

8th with the exception of the MoIDX

t period is open till November 22nd.

I'm going to close the introduction of these policies to allow us to move to our presentations.

And our first presentation will be Dr. Turakhia. I hope I pronounce your name correctly. Please correct me.

This is on the cardiac detection monitoring. We're going to be making you a speaker now.

Mintu Turakhia 20:52

Can you hear me?

MEREDITH LOVELESS 20:54

Yes.

Mintu Turakhia 20:56

Great. You did get my name right. So, thank you and let me know when you're ready for me to start.

MEREDITH LOVELESS 20:57

All right and we can see your slides. So, it looks like Curtis is going to start the clock when you begin, and the floor is yours. Thank you very much.

Mintu Turakhia 21:12

OK. And Curtis, I think you'll advance. So, thank you again for the opportunity to present. In rare events, I get cut off because I'm somewhere where I have very bad Internet, Toyin on my team will take over. Go to the next slide.

MEREDITH LOVELESS 21:26

Yes

Mintu Turakhia 21:28

The four areas we applaud CMS for modernizing the coverage. We do have four areas of concern that we're going to highlight briefly, and it's just an opportunity to refine the language here. They relate to uniform device requirements where a single set of requirements is applied to all products they're not all built to do this. The 2nd is misaligned responsibilities and separating the obligation of the device that is a cleared product from the service, some contradictory safety language, which we'll get into, and some inconsistent definitions that don't align with align with FDA modernization of new product codes particularly for MCT. Next slide, please.

MEREDITH LOVELESS 21:49

OK.

Mintu Turakhia 22:08

The problem with the one-size-fit-all requirement is although this is a great step to modernize, many of these devices like holters, patches, long term continuous monitors don't have transmission during wear and so some of these issues like 24/7 receipt and monitoring don't specifically apply to those.

If we were to take these literally, in fact, none of the devices qualify based on the intended use as prescribed as as governed by the FDA for indications for use. So it it's not, I don't think by design, they're just opportunities to clean up the language. Next slide.

We would point you to this study that is a study I happened to senior author in the New England was an invited review, largely in my academic role where I'm still an EP and a professor of medicine at Stanford that really discusses these different devices and what they do. Next slide.

The the the key thing as many of you know is that these devices vary based on the prescribed wear time. So, when we think of Holter it is 24 to 48 hours. Long term continuous can be 3 to 14 days and there are two different billing codes.

Event and MCT can be up to 30 days. There are differences in the recording type, the data that's reported and whether there's transmission during where, and we believe there's an opportunity to help clarify and refine the language in in the revived guidelines. Next slide.

It's important to understand the mobile cardiac telemetry as a category has been changed. This is through modernization by the FDA. The product code description is on the right and what it is explicitly not supposed to be is live streaming, continuous real-time or any service.

Surveillance for catastrophic arrhythmias. The new guidance does say it shouldn't be hospital, which is great. But what all really does is afford transmission during wear without regard to any life saving or emergency measures, because that's not part of the intended use. Next slide.

I'm going to skip the rest of the next few slides and just let you know that all AI is there. All AI performs differently and differently across devices. So you can keep going, Curtis.

Some details are shown here. We're not going to get into it in the in the time. Next slide and and they vary by different devices and manufacturers and categories. Next slide.

This is another example. The other issue is that ILRS also have high false positive rates and so we agree with the overall requirement to improve value and reduce ILR spend when it's not required. Next slide.

The the monitoring duration does matter and some of the new language that is in there I think gets into this. But it is important to understand that generally even Holter can fall short of the full diagnostic yield. This is cumulative symptomatic or all arrhythmias through the course of 14 days of monitoring and you can see.

How much is gained after two days of monitoring and even how much is gained after three to five days of monitoring? Next slide.

Skip this one. It's important and this was cited that the this is a comparative effective Medicare analysis that shows that the diagnostic yield varies by category. In this case it does our specific device outperforms all the others, but as categories, long term continuous is stronger than MCT.

An event and definitely Holter. Go to the next slide. And this is also true with odds of retesting. So, 14 days when prescribed leads to a much lower adjusted odds of retesting. And this is a full denominator of Medicare only patients and is relevant. So, it is important to consider the device again to get high value appropriate care. Next slide.

There's a few slides that Curtis will skip through on healthcare utilization and how long-term continuous is superior than the others. And we want to ensure that the new coverage guidelines

don't create sort of unintended consequences of overprescribing higher cost and lower value devices. And so, this data is here and can be reviewed offline.

If you want to go to the second to last slide, keep going to the the slide that was just presented. Actually, go back, Curtis, I'm sorry. There's clinical evidence to suggest that real-time or mobile cardiac and event monitoring does not expedite care all of the time differences to ablation, implants and hospitalization were not significant. And so again, the unintended consequence of shifting people toward MCT may actually provide low value care. Next slide.

And so, we'll close to just say we're happy to work with you. We think these are the five areas where there's opportunity to refine the language as we as we move this forward. Thank you.

MEREDITH LOVELESS 27:19

Thank you very much. We appreciate your presentation and if you can kindly send the literature including the article that that you shared that you wrote in the comments, that would be greatly appreciated. Our next.

Mintu Turakhia 27:32

Sure. We'll put those in the comments. Thank you.

MEREDITH LOVELESS 27:35

Thank you so much. Our next presenter will be Doctor Marc Malinowiski. I hope I'm saying that right as well.

And we're going to be pulling up your slide and Curtis, they're under Dr Kalia.

Dr. Mark Malinowski 28:06

Great. Thank you. Can I be heard?

MEREDITH LOVELESS 28:09

You absolutely can be. And let's wait for your slides. I'm dont want to start the clock prematurely.

Dr. Mark Malinowski 28:13

Great.

MEREDITH LOVELESS 28:20

Here we go. And the floor is yours. Thank you.

Dr. Mark Malinowski 28:24

Thank you. My name is Doctor Mark Malinowski and I first want to thank the medical directors and allowing myself on behalf of the American Society of Pain and Neuroscience to present today. I don't have any conflicts, conflicts of interest, but I do all 19 procedures in my practice.

As I'm 100% clinical and these procedures are proposed to be experimental and investigational. So, I'm speaking on behalf of all 3000 members, even more including but not limited to interventional pain anesthesiology.

PM&R, interventional radiology, neurology, neurosurgery, as well as all the Medicare patients we take care of. We vehemently opposed the proposed LCD and the flavors of our dissent will be exhibited during this presentation. I will take a little different approach. I won't be talking about the evidence today. I know my colleagues will be spending a fair amount of time.

In discussing the evidentiary benefit of these procedures, but I want to focus on the pathos and ethos of the part of the argument. Hopefully by the end of today's presentation I'll be able to strike a chord with the medical directors in hopes of changing the decision of CGS to reconsider. We know that CMS was founded on one unshakeable principle that every Medicare beneficiary deserves equal access to medically necessary procedures and medically necessary care, no matter their zip code. Yet today, the principle is being widely challenged by the proposed LCD changes.

And by the multi-jurisdictional MAC, not just by CGS, by the other four MAC questioning therapies like thoracic blocks and stellate ganglion blocks and radio frequency ablation for things like knee arthritis and other types of pathos that ultimately are being deemed and proposed to be experimental.

So if these policies are finalized and then we would divide this nation into two, tiered Medicare system where one patient with chronic pain has access to the evidence-based treatments in certain states where the policy is still under coverage determinant. And then there's the other

states in the jurisdiction of the specific.

Of MACs like CGS and others that it will not be covered, what is the impact of the policies? Please next slide, on these patients to really put a human face on the insurance company when the insurance companies come out with the term experimental behind every coverage policy. There is a patient who could be a teacher with trigeminal neuralgia or a grandmother who's immobilized by arthritis or intractable knee pain, or a Medicare beneficiary who is post knee replacement and is struggling with pain. These are the faces behind the data.

People have already tried and failed conservative measures and are desperate for relief. To call their best option experimental is not merely a bureaucratic overreach, but it's an act of cruelty disguised as caution to conserve healthcare dollars. Next slide, please.

These are listed all 11 procedures which will be deemed experimental and investigational if this proposed policy comes into effect. Next slide please.

There's significant geographic discrimination. I do want to put more things in perspective by giving an example of this controversy. That's really not a theoretical controversy. Imagine if you have a 72 year old Medicare beneficiary with debilitating knee pain one of them lives in Florida and the other one lives in Ohio. The Florida patient under First Coast service options will be able to receive treatment for debilitating knee pain that safely restores their mobility and cuts for opioid use in half or least reduce it.

Ohio patient who under the CGS services will be denied that same care for the same condition because the procedure is labeled investigational and this kind of arbitrary geography based discrimination has no place in a federal system. It really undermines the integrity.

Of Medicare as it replaces the fairness with simple randomness and essentially punishes patients based on zip code. Next slide please.

I want to briefly talk about some violations of CMS specific role. I would like to reference Chapter 13 in the Medicare Integrity Manual. I do want to bring the attention of all the medical directors to this chapter that requires that LCDS define medically reasonable and effective.

Treatment, in addition to clarifying appropriateness, which is furnished in accordance with accepted standards of medical practice, the MACs, including CGS, proposed neither. They instead ignore both professional society guidelines as well as real world outcomes that define modern interventional care and worse, most of these policies.

The proposed language was finalized before knowing that major meta analysis, which is recently published as recent as October 8th by Barreto at al, and new guidelines by leading pain societies like American Society of Regional Anesthesia and Pain Medicine were imminently to be published. So, the evidence that could have.

informed balanced policies. So, despite knowing these facts, the proposed language was rushed through. So we're here kind of debating the validity of these essentially safe and effective treatments, which have been really helpful in moving the needle in the opioid economic epidemic for Medicare beneficiaries. .

Next slide please. Although I promised not to go into details of evidentiary argument when it comes to treatments like genicular blocks and radiofrequency ablation, as well as other types of blocks for pain problems, they're supported by meta-analyses and systemic reviews beyond what's published by Doctor Barredo and colleagues.

And they are significant to improve prove pain relief as well as improve function. American Pain and Neuroscience Step Guidelines, which were published in 2021, also classify nerve blocks in ablation as grade level 1 evidence, which is safe and effective as part of a standard of care. They are supported

by real-world clinical evidence, as well as thousands of practices nationwide that have participated in contributing to this data. Next slide, please.

Some other disease states that we're talking about that are so rare and unique, it's almost.

MEREDITH LOVELESS 34:51

I'm sorry, you are at time. I just want to ensure if it has not been already the article that you're referring to has already been submitted, but we can only consider published literature in the consideration of policy. So, any new published literature should be submitted with the comment period so that it can be considered in the between the proposed and final policy. And I thank you very much for your presentation and I'm going to turn the floor over to Doctor Stout. It looks like we've already got your slides up, Doctor Stout.

And can we hear you?

Alison Stout 35:38

Can you hear me now? OK, super. All right. Thank you so much for this opportunity. I am Alison Stout. I'm a physiatrist at Cleveland Clinic. I'm the current president of International Pain and Spine Intervention Society.

MEREDITH LOVELESS 35:38

We can hear you all right.

Alison Stout 35:54

And next slide please. So, the proposed LCD on peripheral nerve procedures would actually broadly eliminate coverage for what is really considered medically necessary, reasonable diagnostics and therapeutics for almost all patients with neuropath.

pain and this are going to affect patient care across multiple specialties. Next slide please.

So the ask here is that we strongly urge the MACs to rescind this LCD or postpone and collaborate. We really like the opportunity to make sure that the LCD really reflects the most current research adequately and specifically.

Clinical considerations and appropriate use as is needed. However, this LCD as proposed will limit too many patients all at once as written. Next slide please.

To kind of go over my points in a real-world scenario, I'd like to present a case that I treated this patient several months ago this year, a 66 year old woman with intractable shoulder blade pain, thoracodorsal pain and arm pain.

For six months after a fall, outside recommendation from an outside hospital recommended A3 level cervical spine fusion for proposed cervical radiculopathy. She came to Cleveland Clinic for a second opinion and she actually was thought to have rib pain from several fractures she sustained.

She underwent intercostal blocks under ultrasound guidance on 2 occasions, both of which provided 80% relief and restored activity. She had been having very severe pain with inability to care for her grandkids, in which she was the primary caregiver for.

And both blocks resulted in the temporary resolution of that pain. She then went on to subsequently have intercostal nerve ablation therapy, which reduced her pain scores by 75% and also restored all her ADL's and caring for her grandkids, as well as no further t,reatment requirements. So this case is really important because without the blocks, she would have had an unnecessary unnecessary cervical spine fusion, which would have not given her any pain relief and possibly incurred more morbidity and significantly more cost to her care.

And then without the ablation therapy, she would have been without any long-term treatment and only would have been able to have opioids or possibly neuromodulation such as a spinal cord stimulator, both of which would have most likely resulted in higher cost care than that which she did receive.

Next slide please. So, this is 1 case, but there's a whole population of these individuals. Next slide please. So, you know the the the real, the reality is that there are millions of people with neuropathic pain.

Accounting for their high impact pain that is substantially restricting their activities of daily living. Next slide please. And this, you know, is supported by federal guidelines. You know that we're allowed to use nerve blocks and ablation.

Next slide DHSS actually recommends neuroblockade and radiofrequency ablation. Next slide and multiple systematic reviews actually also suggest nerve blocks and radiofrequency ablation provide target specific diagnostic and therapeutic effects. Next slide please.

So this use is supported by peer-reviewed literature and decades of clinical use with real-world value when used appropriately. Next slide please. The the issue is like this patient I just presented there. These are multiple patients with neuropathies or neuropathic.

Injuries of small nerves and there's not big populations to study. So you can't realistically do well powered RCT's for each condition. It's not reasonable and it's just not possible from from from a real world world's perspective from patient recruitment.

And financially, we can't do this number of randomized controlled trials for each individual nerve condition. Next slide, please.

And so, and the risk of eliminating all these peripheral nerve blocks and ablation is worsening disability and quality of life for individuals and millions of individuals, not just one or two, increasing the need for costly surgical interventions and actually contradicting Medicare's initiative to reduce opioid reliance. Next slide please.

So the nerve block, occipital nerve blocks was looked at. However, it fails to mention there was a significant decrease in migraine episodes in the studies that were reviewed by the LCD.

Next slide please.

Stellate ganglion blocks were reviewed. It went into the systematic reviews, but didn't address a really high quality RCT that did show a significant improvement in treatment versus control at 12 months. Next slide please.

Missing from the review on the LCD is the multi society guidelines published in 25 by Benson and colleagues. It's a multi society guideline that endorses peripheral nerve blocks and it had a rigorous consensus process and reflects best practices.

Is grounded in current evidence and clinical experience. Next slide, please.

MEREDITH LOVELESS 42:23

I think you've hit time, so I want to thank you for your presentation and encourage you to submit the supporting literature as well as the guidelines, which will be very helpful for further review.

Of the topic. And now I'm going to turn things over to our next presenter, Dr. Soin. Hello, and we should be getting your slides pulled up here in just a moment.

Amol Soin, MD 42:46

Awesome.

MEREDITH LOVELESS 43:00

All right, and the floor is yours.

Amol Soin, MD 43:08

Thanks. Yeah, those aren't my slides. Those are Bautista's, but I'm fine to after.

MEREDITH LOVELESS 43:21

Doctor Batista, do you want to go ahead and go now? So Curtis, Doctor Batista is going to go and then we'll switch back to Doctor Soin so that way we continue to move along. And I do notice that you have to reset that clock. We don't want limit anyone's time.

Alex Bautista 43:23

Yes, I can do that.

Amol Soin, MD 43:24

Sure.

MEREDITH LOVELESS 43:39

There we go. All right. The floor is yours. Thank you so much.

Alex Bautista 43:45

All right. I am Doctor Alex Bautista and thank you for the opportunity to speak today. And I identify myself as a physician clinician, physician leader and an educator. And I'm here on behalf of the American Society of Anesthesiology, American Society of Interventional Pain Physicians, American Society of Regional Anesthesia, Kentucky Society of Interventional Pain Physician, Association of Pain Program Director and the Kentucky Society of Anesthelogist. These are 75,000 physicians united in one message to protect access to essential evidence-based pain interventions. Next slide.

So let us begin with my patient, Linda. She's 72 year old, complaining of headache and migraine. Before her occipital nerve block, she could not lift her head off the pillow, trapped by daily pain that robbed her of independence. After her treatment, she could hold her head high again, literally and emotionally. These procedures aren't about numbers on the chart. They're about restoring human dignity. Next slide.

Peripheral nerve interventions don't just reduce pain, they restore function, allowing patients to get out of bed, go back to work and reconnect with life. When pain is controlled, life resumes. Not in theory, but in daily lived reality. Next slide.

Let's talk about Amanda, who is 34 year old. She lives with complex regional pain syndrome. She tells us every time the pain returns, I remind my relief is possible. I just need access to my stelate ganglion block. Next slide.

For her access, it isn't a convenience, it's a lifeline. Next slide.

Our purpose today is simple to present an evidence-based ethical case for restoring coverage of peripheral nerve interventions. Because these are not experimental, they are medically necessary, function restoring and opioid sparing. Next slide.

The proposed LCD revisions impose narrow indications, frequency limits and added documentation barriers, significantly restricting patients access to vital pain intervention. These changes directly block timely guideline supported care for many patients who would otherwise benefit. Next slide.

Chronic pain effects 52 million Americans. At the same time, our country continues to battle the opiate epidemic, fueled by lack of access to safer alternatives. The LCD restrictions threaten to rollback years of progress in opiate stewardship. Next slide.

If these restrictions continue, we will see increased opiate prescriptions, worsening disability, greater health disparities in rural and elderly population. This isn't a speculation, it's what happened the last time interventional access was cut. Next slide we have access. We have an ethical obligation to our most.

Vulnerable patients, those too debilitated to advocate for themselves. Same as role is not only administrative, it's moral to ensure that evidence based compassion guides policy. Next slide.

For refractory headache, occiptal nerve block provides immediate relief when medications fail. For those who respond, radiofrequency ablation offers months of sustained relief. Denying coverage means condemning patients to needless suffering. Next slide.

For CRPS, the stellate gangloin blocks is the only intervention that can interrupt agonizing upper extremity pain. It's diagnostic, therapeutic, and essential for identifying candidates for spinal cord stimulation. It's low-risk, it's outpatient, and it's reversible. The LCD's restriction turn treatable pain into permanent.

Go to the next slide.

The evidence base is for elderly or fragile patients with knee pain, genicular neuro procedures are often their last chance before immobility. They're effective 50 to 58% achieve meaningful pain relief lasting for up to two years. Restricting this option drives patients toward riskier surgeries or opioids. Next slide.

The evidence base is overwhelming, spanning peer-reviewed data from Pain Medicine, Cephalgia, Pain Physician, International Journal of Surgery, among other top journals. These studies consistently confirmed safety, durability and functional improvement. This not emerging science, it's established medicine. Next slide.

We must also acknowledge the systemic consequences. When CMS limits coverage, private insurers follow Aetna, United, Anthem, Humana. The ripples across the healthcare system denied care to millions of working-age Americans who depend on those plans. This isn't just a local LCD issue, it's a national public health emergency. Next slide.

These procedures are not performed indiscriminately. They follow standardized protocol. A diagnostic block before ablation, imagery guidance with ultrasound or fluoroscopy. Repeat procedures only when clinically justified. Next slide.

From program directors to academic departments to private practices, organizations stand united. Together, we represent a community of deeply committed physicians to evidence, education and patient well-being. Next slide.

We urge CMS and the MACs to reinstate full coverage preferable nerve interventions, continue outcome tracking to refine best practices, expand coverage to include modern RFA modalities supported by new data.

MEREDITH LOVELESS 49:55

Thank you very much for your presentation. And once again, if I can encourage you to submit any literature, especially any that wasn't included in the in the proposed policy, that would be most helpful. And we are going to pull up your slides now, Doctor Soin.

Amol Soin, MD 50:12

All right.

MEREDITH LOVELESS 50:13

All right, we got the right ones now, so I'm turning the floor over to you.

Amol Soin, MD 50:17

Oh, thanks. Thank you so much. Hi, everybody. I I'm sure you can hear me and I turn my camera on so you can see me. I combed my hair. You're welcome, everybody. I am here representing ACIP and obviously we are going to provide our rebuttal here for the next couple of minutes to the proposed LCD. Next slide. Like all a lot of the other speakers, I am opposed to this new LCD, the way it's written and what it does and how it impacts care. And I spent a little bit of time trying to understand why this was happening and I didn't quite understand.

Exactly what was happening until I heard Doctor Loveless Hi, Doctor Loveless and Doctor Berman. Of course, I I heard you speak in the beginning when you were introducing the LCD and you said, look, this is replacing a peripheral nerve block policy for peripheral neuropathy, which is probably a good thing because I I never really liked that policy anyway.

And you said it's actually expanding care and you listed rationale and reasons why. Ultimately, I believe that that premise that's an expansion of care or that it's replacing a neuropathy policy and it's somehow a good thing for beneficiaries to be false at its face, partly because as you read this new LCD it listed a bunch of nerve blocks. There's like 11 or 12 of them and the number line item 12 or 13 says all other peripheral nerve blocks are considered medically unnecessary and that results in a very drastic cut to service and as Doctor Bautista mentioned once that's.

And the CMS guidelines, it kind of percolates through all private pay. The problem is the LCD you are replacing specifically talks about peripheral neuropathy. And I think that might be why there's so much confusion here. And that could be why if you're only looking through that lens, you know, perhaps you can come to some conclusions.

These aren't effective. The problem is there's a lot of reasons why we do peripheral nerve blocks unrelated to peripheral neuropathy. But if you pass this LCD and all of those are listed carte blanche as non-covered, you are now shutting the door on a lot of modalities that are absolutely essential and necessary for our patients. And I'll explain why here.

Shortly, next slide, a couple of arguments that we want to talk about, just a little bit background of ACIP. We'll go to the next slide here about the opioid crisis that I really want to get across here is the health equity piece. Malinowski mentioned it, but you know what, we all pay taxes to Medicare and we want to get care for ourselves and our elderly and our sick patients. But it's just odd that my $1.00, my hard earned dollar that I spend and I give to you guys as my taxes to cover CMS is worth less here in Ohio than it would be say in New York who's not adopting this policy or Florida who has their own policy.

If you look at Florida's LCD for peripheral nerve blocks, it's not terrible. It allows for diagnostic and therapeutic injections, which could be quite helpful. That HealthEquity piece seems inconsistent with the Medicare Health Manual, and that's something that I think we'd have to reconcile and talk about.

More importantly, I want to talk about peripheral nerve blocks as a diagnostic modality. This is something that I am extremely concerned will not be allowed in this particular LCD, and that's problematic for a number of reasons, first of all.

It is an absolute essential diagnostic tool. In fact, if you go into ChatGPT, Google or whatever and type in what is the first line diagnostic tool to treat, let's name a nerve, let's say to treat pudendal neuralgia, you know what pops up as a first line diagnostic tool or treatment? A diagnostic nerve block.

According to this policy, you won't be able to do that. That's terrible. You know what it's like? It's like saying if someone has anemia, Medicare is not going to cover the first line diagnostic tool, which is a CBC. You know what it's like? It's like if you fracture your arm and you go to a hospital, what's the first line diagnostic tool?

X-ray, it's like saying, well, we're not going to cover that. I don't see a scenario where CMS can reasonably and realistically not cover a standard of care first line diagnostic tool. That's very odd. And I got to tell you something else. I'm on the State Medical Board of Ohio and I have been for three terms appointed by three different administrations and we have something in Ohio called the Medical Practice Act and you have to follow standard of care. And in fact, if you breach standard of care or do not use, say, a first line diagnostic modality, you are breaking the law in the state of Ohio. But that's problematic because this LCD essentially forces physicians not to be allowed access to first line diagnostic tools.

I just don't understand how that can even be a thing. And there's a lot of neuropathies out there that will not be covered because of the one line item that says all peripheral nerve blocks other than the ones listed are considered experimental where you can't even do that. That's odd, right. And I think that's something that we're going to have to reconcile and you'll see in the comments as it comes to data for each of these. I think it's more appropriate for us to list that in the comments. You'll see our comment letters quite long and we'll post that with the data that supports what we want. Outside of peripheral neuropathy, we use diagnostic and RF ablation for things that aren't peripheral neuropathy. So for example, arthropathy, the genicular stuff that you see for the post-surgical adhesions, ilioinguinal blocks, shoulder pains, suprascapular blocks, intercostal blocks if someone falls and breaks ribs. And that's really problematic because what happens if you fall and break a rib and you're an elderly?

Patient you get atelectasis, pneumonia and you can die. Converse to that is you could have intercostal blocks and cryoneurolysis. It could save the patient. Same thing with hip fractures. You will be not allowing things like obturator femoral blocks and RFA. The sequelae of immobilization leads to DVT death. We all know that.

But you guys aren't going to allow it with this policy. Now, that has nothing to do with a peripheral nerve block, but you're lumping it as it is part of the peripheral nerve block, and that's problematic. Thank you, Dr. Loveless, Dr. Berman, I respect you both. I appreciate the time.

MEREDITH LOVELESS 56:32

Thank you very much for your presentation. We appreciate it. And our next presentation is Doctor Abshier. I hope I pronounced that correctly and we're going to pull up your presentation. Can we hear you?

Sarah Abshier, DPM 56:43

Yes, can you hear me OK?

MEREDITH LOVELESS 56:48

A little quiet.

Sarah Abshier, DPM 56:49

Is that better? All right, so thank you. I'm a full-time podiatrist and I'm speaking on behalf of Ohio's Foot and Ankle Medical Association. I will keep my camera off because unlike Doctor Soin, I did not brush my hair today.

MEREDITH LOVELESS 56:50

That is better!

Sarah Abshier, DPM 57:04

We have two concerns just with our area we practice. We do appreciate that Morton's neuroma were included, but we are concerned about that lifetime limit. It does not seem to practice or coincide with the way I practice and most of the other podiatrists in the area would practice. Second concern is exclusion of the posterior tibial nerve injection at the tarsal tunnel. I'm not going to go through all the slides because I do not want to be redundant with those who have spoken before, but I do echo all of their general concerns. I do want to state that the 21st Century Cures Act states policy must be rooted in science, and these principles should also apply when.

Acts make determinations about coverage, frequency and medical necessity. Next slide, please.

The proposed LCD acknowledges that corticosteroid injections are an acceptable evidence-based non-surgical treatment for Morton's neuroma. Next slide, please.

The literature, which CGFS actually references in the proposed LCD, reflects real-world variability in how injections are administered, including number of injections, timing and combination with local anesthetics. But it consistently supports injections as a reasonable conservative therapy when clinically indicated.

Can you forward to slide 8 please?

Maybe it was 7, but Howe et al underscores that infiltrative treatments are safe, well tolerated, and clinically effective, making them a key part of evidence based conservative care. Crucially, the paper again provides no evidence to support a lifetime limit on corticosteroid injections. Instead, it reinforces that treatment should be guided by patient responses.

Safety considerations and clinical judgment. Please move to slide 13.

None of the cited literature identifies or recommends a limit on the number of corticosteroid injections that should be performed over a patient's lifetime. It recognizes that protocols vary in real-world practice. The evidence supports the clinical use of corticosteroid injections, but provides no scientific justification for rigid utilization, such as the 2 injection

per lifetime limit, which seems arbitrary. Furthermore, there is no evidence correlating that more than two injections cause harm or have lack of efficacy. There is no data from registries, observational studies, claims, or patient-centered outcome research activities to support this proposed 2 injection limit.

Next slide please.

The second concern we have is the exclusion of therapeutic peripheral nerve block at the tarsal tunnel. The proposed LCD explicitly lists posterior tibial nerve block at the tarsal tunnel among procedures considered not reasonable and necessary for chronic pain.

Please move forward two slides.

While large randomized control trials are limited, multiple peer review studies, including case studies, small cohorts, and interventional report document clinical benefit. Taken together, the studies provide low to moderate quality but consistent evidence of safety and efficacy in selected patients. Please skip forward to slide 18.

This study found that following injection, 77.5% of patients did not require surgery, indicating that therapeutic injections at the tarsal tunnel can provide sustained lasting symptom relief for many individuals. Next slide.

In this 2023 cohort study at seven week follow-ups, 53% of patients experienced meaningful pain relief and nearly half maintained that benefit at 18 months, demonstrating the potential for long term symptom improvement. Next slide.

This review found that 75% of cases achieved good or excellent outcomes overall. Please forward two slides.

I'd just like to summarize we would like to reiterate that the 21st Century Cures Act states that the policy must be rooted in science, and there's really no science that supports lifetime limits on Morton's neuroma injections. We respectfully request that the proposed lifetime limit of two injections per side be reconsidered.

A rigid lifetime limit would contradict the evidence and restrict clinical judgment without improving patient safety or patient outcomes. Furthermore, we request reconsideration of the proposed exclusion of therapeutic posterior tibial nerve block at the tarsal tunnel. We believe it should be covered by indication.

Studies demonstrate meaningful, durable pain relief with excellent safety profiles. Coverage should be criteria-based and not excluded outright, allowing use when conservative therapy fails and diagnostic evaluation supports the indication. These changes would help align that LCD with 21st Century Cures Act framework.

Ensuring that your policy decisions remain grounded in science and real world clinical practice. That's all I've got.

MEREDITH LOVELESS 1:02:09

Thank you very much for your presentation and I also encourage you to submit the supporting literature in PDF format to the CMD inquiry e-mail is in the chat and then I'm also going to add to the chat an article that's on our website about how we look at literature just to help everyone understand.

When we are evaluating this literature, what lens we're using for that evaluation, I'm going to now turn the floor to our next presenter, Dr. Chen.

Can we hear you? And we're pulling up your slides and we'll turn the floor over to you.

yian Chen 1:02:42

Hello, can you hear me?

OK. Thank you.

OK, so I just have to say next slide to navigate?

Is that right?

OK.

OK. Thank you very much. My name is Ian Chen, actually on faculty at the University of Washington, speaking on behalf of Azra Pain Medicine. Thank you very much for having me here today to discuss this very important issue.

So the topic we're going go over is chronic pain coverage, gaps and pain needs. Chronic pain affects over 50 million adults in the United States, many of whom are Medicare beneficiaries.

When conservative therapies fail, peripheral nerve interventions are very important in the role of reducing pain, restoring function, and decreasing opioid use. The proposed LCDs currently exclude established evidence-based procedures, and these exclusions risk limiting access to safe, minimally invasive and often effective care. Next slide.

So quick overview, the scope of procedures and indications covered. Occipital nerve blocks are commonly performed for occipital neuralgia and migraines. They have diagnostic, prognostic and therapeutic applications. As we'll discuss, trigeminal neuralgia nerve blocks are performed for a crippling condition trigeminal neuralgia. They can sometimes prevent the need for surgery. Sympathetic blocks play roles in disorders such as ranging to PTSD in cardiovascular and vascular conditions. Genicular nerve blocks and suprascapular blocks can play the role in the management of shoulder and knee pain, providing non opioid alternatives to therapy and with ongoing NIH funded trials, pudendal nerve blocks play roles in pelvic and postsurgical pain, whereas posterior tibial nerve interventions are emerging intervention for neuropathic foot pain. Next slide.

Yes.

So in terms of evidence and rationale, I'm going by condition, occipital neuralgia, 50% of migraine patients, many of whom require hospitalization, improve after

Occipital nerve blocks, which help to break the pain cycle. Occipital nerve block responses recognized by the International Headache Society as a diagnostic for occipital neuralgia. A federally funded multicenter, double-blind, double-blinded randomized controlled trial demonstrated that patients.

With short term responses, actually had sustained improvement after pulsed radiofrequency, demonstrating their prognostic importance. Occipital nerve flux also showed benefit in cluster headaches, often the most disabling of the headache disorders.

And in refractory cases, occiplanner blocks can also guide progression to decompression surgeries or peripheral nerve stimulation. Next slide.

Nerve blocks also play a role in more complex pain syndromes. Trigeminal nerve blocks, for example, are useful in trigeminal neuralgia for both diagnostic and surgery sparing roles. Early intervention can prevent more invasive procedures.

Down the line and reduce long term disability from uncontrolled pain. Sympathetic blocks are crucial in the management of complex regional pain syndrome for the purposes of diagnosing sympathetically maintained pain for facilitating physical therapy participation.

And pushing people through functional restoration and then predicting response to more advanced therapies such as spinal cord stimulation and ketamine infusions. There have been two randomized controlled trials showing predictive and therapeutic benefits, and it's important to note that there are no FDA approved medications for CRPS.

Thus, without coverage, patients face escalating opioid use up to and even including extreme measures such as limb amputation. Next slide.

Stellate ganglion blocks, a special type of sympathetic block, has been used for cerebral vasospasm, ventricular tachyarrhythmias, and most very importantly, PTSD. So there are two RCTs with mixed outcomes, but strong anecdotal and observational evidence.

There's a congressionally mandated ongoing randomized control trial sponsored by the National Defense Authorization Acts of 2021 through 2024 is a multi-site trial involving both military and academic sites and the Ukraine double-blinded multi-center trial evaluating stellate ganglion blocks for PTSD.

Federal investment and pending results denying access now is premature. Next slide.

Genicular nerve procedures. Genicular nerve blocks have provided consistent benefit for chronic knee pain in non-randomized and prospective studies. There is a large multicenter NIH funded trial, the SCOPE trial costing upwards of $20 million with over 1000 patients underway evaluating genicular nerve blocks and radiofrequency ablation. Results are expected in December of 2025. We had an anticipated publication in New England Journal of Medicine. Next slide.

Pudendal and posterior nerve interventions also are emergent procedures for the reduction of opioid use and reduction of pain. Next slide.

So it's important that we align coverage with evidence and national priorities, minimally invasive, low-risk interventions with which provide diagnostic clarity and guide therapy to improve function. They support national goals to reduce opioid dependence and expand access to non-pharmacological care.

MEREDITH LOVELESS 1:09:17

Thank you so much for your presentation, Doctor Chen, and we appreciate your input and look forward to receiving the comments and literature as well. I'm going to be turning the floor over to our next presenter, Doctor Kaplan.

And we'll be pulling up your slides, Doctor Kaplan.

Yes, we can hear you.

Kaplan, Hilton 1:09:36

Great. Thank you.

MEREDITH LOVELESS 1:09:39

And we'll get these slides up in just a moment.

Kaplan, Hilton 1:09:40

Thanks. I'm Doctor Hilton Kaplan. I'm the Chief Medical Officer at Avanos. Thanks, Doctor Loveless and the medical directors and the KL's have already spoken, obviously. I'm speaking today on behalf of the Coalition for Interventional Pain Treatment which is a industry partner group that have come together around this and includes Abbott, Avanas, Boston Scientific, Medtronic, Becerra, Stratus and Stryker and we urge the committee to retire the proposed LCD as evidence has changed significantly since it was drafted and they're pending regulations. Next slide please.

So the proposed LCD was drafted in February, but since then Cajana Penang and Madrid published a systematic review in pain medicine and this synthesized 28 studies with over 2200 patients and included 11 RCTS.

And it found that large lesion RFA achieves 50% or more pain reduction in 61% of patients at six months and 54% at 12 months with moderate certainty evidence. That's a solid majority of sustained responders, not as sort of minimal effect that the LCD speaks to.

And next slide please.

When we look at the spectrum of available treatments, eliminating coverage drives patients either back towards oral medication, opioids and NSAIDs or onwards towards surgery. And this really, you know, as other speakers have said, contradicts.

The federal initiatives that promote non opioid pain cares that includes HHS's Pain Management Best Practice No Pain Act that specifically calls out RFA and chronic neurolysis as non opioid alternatives.

And then, you know, non-coverage will also disproportionately impact older adults who cannot tolerate opioids or major surgery or have already had the surgery. And next slide, please.

Looking at utilization data from CMS, we see in 2024 genicular RFA and cryo together represented just 6.6% of all peripheral nerve procedures. And you know, it should also be noted that therapeutic blocks and diagnostic blocks.

Are two different things. Therapeutic block is a treatment on its own and a diagnostic block is part of the process towards an RFA treatment and so lumping them together or double counting them and as the LCD does, you know it doesn't get either justice.

Next slide please.

The pain societies have already put out clinical guidelines and I know Doctor Chen just mentioned the scope trial that is still coming out, but so far Aspen's guidelines give RFA level one grade A support for Neo A and post TKA.

With strong consensus, NICE in the UK, the India Pain Society peer reviewed the literature carefully and support RFA and the AOS guidelines also supported in terms of improved function and that they state patient preference should be a substantial.

So other than scope, there are two pending guidelines. There's the big nine society group who

are putting out their guidelines and that includes ASRA and ASIP and EPSIS and all the others you see on the screen. And also there's a CRNA set of guidelines coming out. So this is not fringe medicine and it's mainstream evidence grade practice. Next slide please.

So if we look at the data and I'm just showing sort of one study that came out after the proposed LCD was written, but the LCD largely relied on the Almeida meta-analysis and you know, you know this concluded that RFA had a very low certainty.

Evidence and no sustained benefit beyond 12 weeks. But first of all, that analysis, excuse me, predominantly included data from outside the US. It excluded 17 observational studies and many large lesion protocols, and importantly, it pulled all RFA together so as you know, as if they're equivalents, like taking full surgeries and judging them by the worst one. So, you know, in August, Kanjana Panang and Madrid from the University of Utah and New Mexico School of Medicine published their systematic review in pain medicine and Doctor McCormick is on this, it's just a great set of ? and this corrected the limitations that I mentioned earlier. So just as a reminder, this is 28 studies, 11 RCTS over 2200 patients and they found that OAE pain treated with large lesions using fluoroscopic guidance showed pooled responder rates of 61% at six months and 54% at 12 months. If you can jump to the next slide, please.

So the proposed LCD also sets a higher bar than other recent coverage decisions. SIJ joint fusion and MRGFUS used low to moderate evidence, whereas now we have moderate evidence for RFA.

And that's also inconsistent because of regional inequities in Medicare access. Final slide, please.

So these are the conclusions and you can see the three reasons we believe this should be retired. Thank you.

MEREDITH LOVELESS 1:16:08

Thank you so much Doctor Kaplan for your presentation and I look, we look forward to receiving the literature that you mentioned as well as if you can provide links or sites for the guidelines that that have already been produced, just reminding everybody that we do.

We have to look at only published peer review published evidence for 21st century cures. Our next presenter is Doctor Gunn.

Kaplan, Hilton 1:16:40

Hello.

MEREDITH LOVELESS 1:16:40

Hi, we can hear you, Doctor Gunn, and we'll just have your slides up in a moment.

Clay Guynn 1:16:42

OK.

MEREDITH LOVELESS 1:16:50

And the floor is yours.

Clay Guynn 1:16:52

All right. Thank you. Hello, everyone. I'm here as a representative for Pasira Biosciences. I'm a PMR Sports Medicine physician in Atlanta, GA, but I trained at the University of Kentucky. You can go next slide.

So we're here today to talk about cryoneurolysis and Ivera. What is Inova? It's a handheld device that's FDA cleared, which delivers cryoneurolysis or an ice ball providing a drug-free nerve block was really for up to 9 days and even more in some scenarios. It's important to mention that the Ivera was specifically called out by the CMS with the 2023 Congress ruling of the No Pain Act and qualifying for extra HCSPCS codes with the CC code of 9809. So this is one reason why it's really important to maintain this coverage along with the other things that we'll obviously discuss here shortly. So if you can go ahead and move on to the next.

So very quickly here, the Ivar system, it's a handheld device. It provides an ice ball reliably at -88 degrees Celsius, which affects the Axon and myelin, which causes a reversible nerve block. Next slide.

The nerve block then the ice then causes ? degeneration and it's really important that it's done at -88 degrees Celsius and with the Ivera device it very precisely gets this which other cryo devices internationally do not reliably do this.

You can move on to the next.

So clinical support, most importantly with this slide, cryoneurolysis provides an opioid free option and in many cases, especially in the options of our pre total knee patients and post total knee patients that still have pain, it can be opioid sparing which is also very crucial.

You know, so these are, these are treatments that we're treating the patients that don't have a lot of options. Cryoneurolysis, RFA, as a physiatrist, I see patients all the time that I'm treating patients that have been told they have no options and things like Inova cryoneurolysis and radiofrequency ablation provide real meaningful treatments that can really change lives.

Can move on to the next.

Cryoneurolyisis has been mentioned in by many organizations. The AOS specifically mentioned the Radnovich study, which we'll talk about in a minute, was very high quality and that denervation therapy may improve symptomatic OA patients. HHS and ASA also had similar comments kind of expanding that as you'll see here, which we won't discuss in detail.

Today you can move on to the next.

So this is talking about the Radnovich study. The Radnovich study also mentioned by AOS was a high quality, perspective, double-blind, randomized, sham-controlled, multi-center study with 180 patients, 121 that were treated with cryoneurolysis. Patients had KL grades of Neo A2 and 3 with primary endpoints looking at the WOMAC at day 30 and then the VAS pain scale as a secondary along with the total WOMAC, you can move on to the next.

And as this shows here, there were statistically significant results, also notably clinically significant pain reduction at 30, 60 and 90 days. This is something I regularly see in my clinic as someone who's been treating with this treatment for years. More details can be provided in writing, but these kind of results that the Radnovich study is what we want to see in our patients.

Next slide.

Also, it's important to mention the 2019 Interagency report, including the DoD, VA and the others as it's listed here. The task force found the interventional pain procedures, which do include things like cryoneurolysis and very frequency ablation, deliver durable pain relief and reduce opioid use for acute and chronic pain.

On to the next.

Also really important to mention, Pasir has this revolutionary ? data. There's one study that's made from this already, but it's a big one coming out 12 months pain and function assessment. And if you move on to the next slide, we'll actually show you a little bit about what that.

That's showing here. So this 2025 publication that's coming shows the effectiveness of various treatments in patients with the OA results in the study of the current one that's been published four months out, but 480 patients. Essentially what we're looking at is cryo showed higher minimally clinically important differences.

Being compared to common and regularly used treatments such as intra-articular hyaluronic acid, NSAIDs and corticosteroid injections. So this is other more real world world data to provide verification of what was originally shown in that Radnovich trial. You can move on to the next.

Not going into detail with all these, but again, other studies showing durable pain relief out to 12 weeks in the TK context, which is a very painful surgery. And again, opioid reduction, that's so key in this opioid crisis. We don't want to do things that could reverse us back into this opioid situation that we were in before.

You can move on to the next.

And a real concern is that the evidence standard used to deny coverage for all of these pain treatments is higher than the Max previously applied, as noted on the slide here. Treatments like cryo, they're simply well proven standard of care. Patients who don't obtain relief with other therapy, we're literally going to be taking away options from patients.

That don't have any other options or may go on to more costly surgeries that still may or may not work. You can move on to the next slide.

The effects of these, these changes will be devastating for our patients in chronic pain and even in in the acute pain scenario could increase opioid use. So just as we're turning to opioid crisis, let's not, let's not go back there and moving on to the last slide there. So for these reasons.

We're asking that that you continue to allow Medicare patients access to these treatments for chronic pain therapies like Inovo and cryoneurolysis. They are supported by high quality evidence and treatment recommendations to fully consider. We ask that you fully consider the evidence and

adopt an appropriate coverage framework working with.

Look with societies, clinical societies to really figure out the best option. So thank you for your time.

MEREDITH LOVELESS 1:23:13

Thank you very much for your presentation. And our final speaker will be Doctor Emmerich. Dr. Emmerich will also be talking on this topic without a presentation. So I'm going to turn the floor over to Doctor Emmerich.

Trent Emerick 1:23:28

OK. Thank you. I don't have any slides today because what I really want to do instead of going over logistics and evidence and specific pieces of technology, I really want to focus on the human impact of these changes and the human toll of these policies.

And I really want to focus on how patient care will be affected. I'm a board certified pain physician, anesthesiologist, addiction medicine specialist. I practice at University of Pittsburgh Medical Center. And today I'm here representing the American Academy of Pain Medicine, which is 2500 members. It's a multidisciplinary Society of physicians, pain psychologists, pharmacists, researchers, and physical therapists. I'm also a member of the American Society of Regional Anesthesia and Pain Medicine, the Association of Pain Program Directors, and the American Society of Anesthesiologists. So the peripheral nerve blocks that we're discussing today are a big component of my practice.

I treat a lot of cancer pain and there would certainly be a lot of cancer patients that are affected here too. So what I want to do is walk you through a few patient scenarios, the patients that I've seen over the last several months and years and I've anonymized their names, but their stories are real.

So first I'd like to talk about Morgan. That's a 66 year old patient. She's a retiree. And Morgan has a history of coronary vasospasm so we're not talking pain here. This patient has a four year history of chest pain.

Maybe not the typical type of pain we see, but it is pain. Her coronary arteries of her heart don't have plaque buildup, but instead the vessels tend to spasm, otherwise known as Prinzmetal's angina, and they've led to a debilitating condition for her. And our local academic Medical Center cardiology team has me to perform a stellate ganglion block to try to reduce the chest pain and this is a common scenario that I see. This block was performed several months ago and the patient, like I said, had a four year history of chest pain and was just seen recently and has not had chest pain since and now she's in talks with thoracic surgery for a possible permanent surgical sympathectomy if the pain does happen to return. So there is no RCT for this, right? Who's going to, you know, spend the millions of dollars to study this specific scenario? But it is a common scenario. It's just as others have mentioned, there's not an RCT for every single patient.

Condition in every single nerve block. Let's talk about another patient. This is Jamie. It's a 74 year old patient with metastatic colon cancer. But Jamie actually sees me for rotator cuff pain that limits her ability to do activities of daily living.

You know, the interesting thing is it's her rotator cuff pain and not her cancer. That's the main complaint. And I've been doing suprascapular blocks for the persistent pain that she has, and each block gives at least several months of relief. She's not a candidate for shoulder surgery. She doesn't really want surgery anyhow. Her options are very limited without this injection.

If she can't get her pain under control, she's going to have a harder time getting to her chemotherapy visits.

Another case I want to talk about, let's talk about Jordan. This is a semi-retired part-time retail employee working in retail and this patient has significant and severe occipital neuralgia. We've mentioned this before in other talks as well.

Interestingly enough, Jordan was offered morphine for her pain. That was covered. Morphine was covered, but was able to avoid this because of the occipital nerve blocks. She actually drives 2 hours to see me for occasional occipital nerve blocks. She's tried numerous over the counter medicine. She's tried physical therapy, various nerve pain pills, but occipital nerve blocks are the only thing that helps. She receives months relief from a single injection and she stated to me multiple times without these occasional nerve blocks she's unsure if she could continue working in retail and would probably need to fully retire. And as I mentioned, she hasn't had to go down the morphine route, which is covered.

So obviously we recognize that robust trials are lacking for some of these conditions and certainly

like other speakers have mentioned, we're happy to send along plenty of high quality evidence to support what we're talking about. But what I really wanted today is focus on, you know, this human impact of.

Of what this policy will have. Obviously we can talk all day about, you know, flow charts and spreadsheets and who deserves these blocks, but it's really the human impact that's going to lead to more surgeries as patients aren't able to get these conservative options, more reliance on the opioids, more emergency room visits, more urgent care visits.

More hospitalizations for pain and increased Office visits, which may not actually decrease expenditures at all. So I appreciate your time and I appreciate this. This is maybe a nice way to end this section to talk about some of the human toll and the human influence on this policy. So thank you.

MEREDITH LOVELESS 1:28:18

Thank you very much, Doctor Emerick, and I want to thank all of our presenters for taking time out of your busy schedules to educate and inform us today. We'll look forward to receiving your comments as well as the supporting literature in PDF form.

And that we do need to receive that by November 8th for all of the peripheral nerve block and the 22nd for the MoIDX policies. And thank you everyone for for being concise. I know we we didn't have a lot of time for your presentations and we finished. We got to everyone got to speak and I greatly appreciate your cooperation with that effort and have a wonderful evening. Thank you very much.