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National Government Services, Inc.
Moderator: Dr. Ella Noel
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Coordinator: Welcome, and thank you for standing by. Parties will be on a listen only mode for the call today. The call is being recorded. If you have any objections, you may disconnect at this time. I'd like to turn the call over to Dr. Ella Noel. Thank you. You may begin.

Ella Noel: Hi, I'd like to welcome you all to the National Government Services' J6 and JK open meeting. Next slide. As the Operator pointed out, this call is being recorded and transcribed and will be available at a later date. If you do not wish to be recorded and/or transcribed, please drop off the call. Next slide.

As part of our welcome to today's meeting, I would like to introduce our contractor medical directors at National Government Services; we have Dr. Awodele, Dr. Duerden, Dr. Lawrence, Dr. Mullen, Dr. McKinney and myself. Let's go to the next slide.

So, we have two LCDs or local coverage determinations that we're going to talk about today. The first is DL37421, magnetic resonance image guided high intensity focused ultrasound for tremor, and DL39189, mass spectrometry testing and monoclonal gammopathy. Next slide.

We'll start with the DL37421. This LCD revision is in response to an LCD reconsideration regarding unilateral pallidotomy of patients with advanced idiopathic Parkinson's disease with medication refractory moderate to severe motor complications as an adjunct to Parkinson's disease, medication treatment and the removal of bilateral thalami limitations. Next slide.

The use of the word dominant in the coverage indications has been removed from the following: moderate to severe postural or intention tremor of the hand, defined by a score of equal to two on the clinical rating scale of tremor. Indications have also been added for bilateral thalamotomy for essential tremor. Next slide. Limitations have been added for the following: both bilateral thalamotomy for Parkinson's disease and unilateral pallidotomy for Parkinson's disease. The skull density ratio has been changed from less than 0.45 to less than 0.40. Next slide.

We will now have a presentation from (Dee Kolanek) and Dr. Gordon, and excuse me if I mispronounce your name, Baltuch. So, whoever is going to start the presentation may begin.

Dee Kolanek: Great. Thank you, Dr. Noel. This is (Dee Kolanek) with Insightec, and you can go to the next slide. I'm not -- in the interest of the time allowed for the presentation, I'm just going to briefly run through the first couple of slides and then I'll hand it over to Dr. Baltuch to actually present the remaining slides and the data.

As you can see on this slide, one of the things that we wanted to speak to you about today is the limitations added for specifically the Parkinson's disease and unilateral pallidotomy for Parkinson's disease. So, next slide, please. As you can see, the specific limitation within the draft as it relates to the added limitation for the unilateral pallidotomy for Parkinson's disease as not covered is what we would like to address today. Next slide.

So, the use of MR guided focused ultrasound in the unilateral pallidotomy of patients with advanced idiopathic Parkinson's disease with medication refractory, moderate to severe motor complication as an adjunct is stated in the LCD, the draft LCD, that it is not ready for widespread use.

After review of the article in the New England Journal of Medicine, which was our pivotal trial publication based on the FDA approval. And, additionally within the reasoning that NGS made the determination as not considered covered yet, is that the conclusion stated that longer and larger trials are required to determine the effect and safety of this technique.

So, with that said, I would like to pass it over to Dr. Gordon Baltuch, and Dr. Gordon, or Dr. Baltuch, if you could just introduce yourself and give where you come from and then present the most recent data that wasn't supplied when NGS was making the review and the determination.

Gordon Baltuch: Yes, hi, thank you very much. I'm Gordon Baltuch. I'm a functional neurosurgeon at Columbia. Full disclosures, I'm not a consultant to Insightec. I'm not being paid for what I'm doing today. However, I did participate as an investigator in the clinical trial that was published in the New England Journal, and that was an industry sponsored clinical trial.

So, Insightec did sponsor and pay for that full clinical trial at the time. In terms of the New England Journal article, I mean, it's a sort of (ray of solicitor). The evidence is there for itself. Next slide.

We ran a trial, a sham control trial, in a group of patients who had very advanced Parkinson's disease, to see if using an incisional procedure, which has been developed for central tremor, we could help these patients performing a unilateral pallidotomy, and which we, I think we demonstrated in randomized, controlled fashion that there is some -- there is effectiveness in doing a focused ultrasound pallidotomy compared to sham.

Though, interestingly enough, there is a placebo, as you see in all Parkinson's -- in all these Parkinson's trial, there is a significant placebo. Every trial that you do for Parkinson's seems to always show one. And the safety was great in a big group of patients, compared to other stuff that we do surgically, in movement disorders, we had fabulous safety. This was a group of about 39 patients who did well over a decent period of time.

Again, if you look at this type of cohort, in terms of the type of patient we're looking at here, this is a patient with advanced Parkinson's who still has some responsiveness to medication, but it's probably the kind of patient who you're not going to do an open procedure on either for comorbidities or for cognitive reasons.

And as mentioned, we had no (untoward) cognitive effects from this procedure, which is something that you don't see when you do deep brain stimulation, which

I've done thousands of, as well as -- as well as open lesions, which we do very few of anymore. Next slide.

This has been, if we keep going with the slides, I mean, the safety was great in this procedure. We had very good changes in UPDRS considering, I mean, is it a super robust effectiveness? No, it's not. I don't think you're going to get the -- the robustness that you get from deep brain stimulation, comparatively. But these are patients who are not going to get deep brain stimulation.

In general, they're either not candidates because of comorbidities or because of cognitive reasons, et cetera, in general. So, this is a very sort of select type of patient population. Yes, you will have certain patients who don't want deep brain stimulation and they'll want an ultrasound procedure. That's a bit of a different type of cohort. But in general, these were advanced Parkinson's patients.

Let's get to the (meta) analysis, which is recent. And I didn't think you had that information. I think next slide.

Dee Kolanek: Actually, it's the previous slide. It's the previous slide that was showing. Yes, this one. You went -- you went back one too many. I'm sorry.

Gordon Baltuch: One forward.

Dee Kolanek: There you go. That's it. Number eight.

Gordon Baltuch: Yes. In a larger cohort of people, you can see it extends itself. One of the criticisms that's been made is you don't have really long term effect of this. Again, pallidotomies were never meant to have long term effect. These were procedures that were meant to be sort of palliative salvage procedures for people with end stage Parkinson's disease.

And if you've got six months, a year, maybe two years out of it, it was considered good. No one ever had this procedure with the idea we're going to get five-year data out of it. That's never what a pallidotomy was really created for. So, this is how we look at that. Next slide.

So, next slide again. And these are some of the other types of -- these are some of the other type of procedures. Again, what you're looking at here is really, I don't

think you're going to get the effectiveness that you have with DBS or with an RF procedure. However, I don't think this the safety is incomparable. The safety is much better, number one.

Number two, these are patients who are likely not going to be candidates for those procedures. And I think with that, I think I'm going to turn it back over to (Dee) so she can summarize. Unless you want to talk about some of the other things.

Dee Kolanek: If we can could go to slide -- if we could continue for the next few slides, there is a couple of things that we do want to continue.

Gordon Baltuch: okay. Yes.

Dee Kolanek: This one here, slide number 20. One of the things that we do want to make sure that NGS understands is that the risk and benefit analysis of the actual FDA approved pivotal trial for the PMA was a very rigorous study design. The safety showed good safety profiles for the thermal ablation of the GPI area of the brain that we are targeting.

And obviously, the effectiveness demonstrated a 68% responder improvement rate. Now, the overall conclusion for the FDA premarket approval that we received, the data supported that reasonable assurance of safety and effectiveness of this device when used in accordance with your indications for use based on the results of the pivotal trial, the unilateral thermal ablation of the GPI adjunctive to medication using the exablate neuro may provide benefit as an alternative to other existing treatments relative to the risk in the selected patients with severe disabling motor complications of the advanced idiopathic Parkinson's disease patients. Next slide.

You can go to the next slide. In the interest of time, we're trying to go through. So, the summary and recommendations that both Dr. Baltuch and other providers that will be commenting during the comment period, Insightec feels that the unilateral pallidotomy for the Parkinson's disease patient using the exablate neuro device, also called MR guided focus ultrasound, should be considered safe, effective, and a durable treatment for patients with those idiopathic, advanced idiopathic Parkinson's disease patients.

We believe based on the most recent meta analysis that wasn't available at the time when NGS reviewed the data for the LCD reconsideration, that Medicare wants to, and we will provide that study post meeting. But we believe that NGS Medicare should consider adding allowing coverage to Medicare beneficiaries.

As Dr. Baltuch said, this is not replacing any other procedure. It is just another tool in functional neurosurgeons on the (materium) for patients who either are not the best candidate for other options or prefer an incision list. Next slide.

And then lastly, we do applaud NGS' decision within the draft regarding to the other language. And we do recommend that you finalize the following: the use of the word dominant in the coverage indication, and then obviously, the moderate or the indication for the bilateral style (laminotomy) for essential tremor, and then the change in the skull density ratio.

One last thing I do want to make mention that is not included in this slide is it may be beneficial to change the title of the LCD because it originally is related to tremor and this technology is advancing for other movement disorders besides essential tremor.

With that said, that concludes our presentation. We do appreciate your time and if there's any questions, now would be a great time with Dr. Baltuch on the call.

Ella Noel: Great. Thank you very much.

Coordinator: Would you like to ask questions on the phone line? Are you wanting to go to questions on the audio line now? Thank you. We begin our question and answer session. If you'd like to ask a question, please press star 1. Please unmute your phone and record your name. Again, that's star 1 if you would like to ask a question. One moment please.

At this time, we have no questions on the phone line, but as a reminder, if you would like to ask a question, please press star 1. And we have no questions on the phone line.

Ella Noel: Can I have the next slide, please? So, the comment period for this draft will end on August 10 at 11:59 p.m. All formal comments must be submitted in writing to us. I

would ask that you send any new articles in their entirety to us with your comments so that we may have that literature available to review as we read your comments for the draft.

So, this concludes this portion of the open meeting regarding DL37421, magnetic resonance image guided high intensity focused ultrasound for tremor. Next slide.

We will go on to DL39189, mass spectrometry testing in monoclonal gammopathy. This was based on a reconsideration request for the use of serum and urine mass spectrometry in monoclonal gammopathies to be added as an indication of coverage.

Use of urine mass spectrometry and monoclonal gammopathies has been deleted from the limitations of coverage. References 25 and 26 have been added to the bibliography in support of coverage. Next slide.

Next, we will hear from Dr. Murray from the Mayo Clinic on this testing. Please proceed, Dr. Murray.

David Murray: Can you hear me okay?

Ella Noel: Yes, I can.

David Murray: Okay. All right. Yes, my name is David Murray. I am the co-director of the protein immunology lab. I'm a pathologist at Mayo Clinic, and I oversee the testing for monoclonal gammopathies at the Mayo Clinic.

So, we can go to the next slide, please. In terms of conflict of interest, nothing directly related to this request, but Mayo does have intellectual property rights filed on this mass spectra spectroscopy method, and it's been licensed to Binding Site, which is now part of Thermo Fisher. Next slide, please.

So, here's the topics we would like to discuss. First of all, we'd like -- we're very appreciative of your response to our reconsideration for this request for urine. We did -- we want to suggest a few article edits in the ruling, but the bulk of what we want to talk about is expanding coverage to additional ICD-10 codes, especially as it applies to symptoms of monoclonal gammopathy. So, next slide, please.

First one, we know that the specific documentation requirements have been removed from the requirements, that is specifying serum or urine. But we also noted that those fields are still there. And we'd like to suggest that this field should -- are no longer needed. And the claims can be just filed with the references without the serum and urine. Next slide, please.

Also, we looked at the utilization guidelines. We see that there are these two utilization guidelines. One is serum, in regard to immunofixation, that it will be denied with the submission of the PLA code. But both of these are already addressed in the NCCIPTP edits and the MUE. So, we feel like this is redundant. And so, for consistency's sake, for future changes, we would like to just have them in the one NCCI version of the restrictions. Next slide, please.

But this is the main part of what we want to ask today. What is the best method for us to expand coverage as this test utilization evolves? In particular, we get a lot of requests or a lot of questions from our providers as to why this test, which is also designed to screen for monoclonal gammopathies, can't be used for symptoms of monoclonal gammopathies before the diagnosis is established.

So, we've noticed that some of the additional support and references in the bibliography section do address the symptoms of monoclonal gammopathies. And we're looking for expanded coverage into things like heart failure, chronic kidney disease, nephrotic syndrome, and not listed here, also anemia. And that was because, on the next slide, please. Just reminding everyone of the major defining events of multiple myeloma, the so-called CRAB criteria.

These are the events that sort of trigger some of the testing that we get in the lab. Renal damage, we see a lot of patients that have what we call NGRS at Mayo Clinic, and so we do a lot of screening for monoclonal gammopathies for patients with renal damage. Anemia, which is one of the main symptoms of an unexplained anemia, is one of the main symptoms of myeloma.

But right now, we don't have coverage under the ICD-10 code of anemia. So, we're looking for ways to best expand the coverage and the best method. We realize that this test is actually replaces both SPEP and IFE at Mayo Clinic. And currently, there aren't any ICD-10 restrictions on those two entities.

So, now that we've changed over, we're getting questions on how do we best cover these kind of events? Next slide. All right, so that concludes my brief presentation here. We do appreciate the opportunity to present today and looking for guideline in the expanded coverage. Thank you.

Coordinator: Are you wanting to go onto questions on the phone line?

Ella Noel: Sure. Let's check for questions.

Coordinator: Thank you. As a reminder, if you would like to make a comment, please press star 1. And at this time, we have no one in queue. But again, please press star 1 if you would like to make a comment. And at this time, we have no one in the queue.

Ella Noel: Okay, thank you. Dr. Murray, if you need to request changes to the ICD-10 codes in the article for a policy, usually all that is required is sending us a notice of what codes you want added and why because we do realize that we do miss some codes as they apply for the policy. And you do not usually need to go through a formal reconsideration request.

Please, send your comments in writing to us so that we can look at those and respond to them and make any changes that we see fit. And I believe this is due by August 10 at midnight, and we will develop the response to comments document, and that will be available on the Medicare database. Next slide.

This concludes the portion of the open meeting regarding DL39189, mass spectrometry testing and monoclonal gammopathy. Next slide.

To comment on a proposed LCD during the official comment period, you may click on the public comments button on the proposed LCD in the Medicare coverage database. Or you may send them via email to ngsdraftlcdcomment@anthem.com, or you may also send them by mail to National Government Services. LCD Comments P.O. Box 7108, Indianapolis, Indiana 46207-7108. Next slide. I believe that's it. This concludes our meeting for today. Thank you all for attending.

David Murray: Thank you.

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