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| First Coast Service Options, Inc.  JN Open Meeting |
| Thursday, June 23, 1 p.m.  Topics:  Proposed LCD DL34522- Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder  Proposed LCD DL39367 - Genetic Testing for Oncology  Proposed Retired LCD DL36234- Special Histochemical Stains and Immunohistochemical Stains |
| CORPORATE PARTICIPANTS  Juan Schaening, MD – First Coast Service Options Executive Contractor Medical Director  Alicia Campbell, MD- First Coast Service Options Contractor Medical Director  Leslie Stevens, MD- Novitas Executive Contractor Medical Director  Patrick Mann, MD - Novitas Contractor Medical Director  Suzanne Kim Doud Galli, MD, PhD - Novitas Contractor Medical Director  Bradley Davidson, MD - Novitas Contractor Medical Director  Laura Mathewson, RN, BSN, CRRN, WCC, CPC-A- First Coast Service Options Medical Policy Nurse  PRESENTERS  Paul Rudolf, MD, JD- Arnold & Porter, LLP- Senior Counsel  Scott Blackman -BrainsWay, Director of Market Access  Thomas Nifong, MD- Pacific Edge Diagnostics USA, LTD- Laboratory Director |

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PRESENTATION

Operator

Good afternoon. My name is Mandy McGarvey, and I will be your Webex host for today's open meeting. Before we get started, I wanna take a moment to remind everyone that this meeting is being recorded. This time, I'm gonna go ahead and turn things over to Contractor Medical Director for First Coast, Dr. Juan Schaening. Dr. Schaening?

Dr. Juan Schaening

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| Thank you, Mandy. Good afternoon. I would like to welcome everyone to First Coast June Open Meeting. My name is Dr. Juan Schaening. I am the First Coast Executive Contractor Medical Director. Joining me today from First Coast are my colleagues, Dr. Alicia Campbell and Laura, Laura Mathewson. Joining us from Novitas are Dr. Leslie Steven, Dr. Patrick Mann, Dr. Suzanne K. Doud Galli, and Dr. Bradley Davidson. Please be aware that First Coast Service Options Inc is recording this virtual to our open meeting to comply with CMS guidelines. By remaining log in and connected via telephone or webinar, you acknowledge that you have been made aware that this virtual open meeting is being recorded and you are consenting to the recording. If you do not consent to being recorded, please disconnect from this virtual open meeting. We are holding today's open meeting to discuss the review of the evidence and the rationale for two proposed LCD revisions that are based on LCD reconsideration requests and consolidation and one proposed LCD that is to be retired. The proposed LCD topics for today's meeting are: genetics testing for oncology, transcranial magnetic stimulation in the treatment of adults with major depressive disorder, and special histochemical stains and immunohistochemical stains. During today's meeting, interested parties will make presentations of information related to the proposed LCDs. Please remember today's call is being recorded, and we request that all formal comments be submitted in writing before the end of the comment period on July 23rd, 2022. At this time, I would like to turn it over to Dr. Leslie Pre-- Stevens, who will provide a brief overview of the proposed LCD on transcranial magnetic stimulation in the treatment of adults with major depressive disorder. Dr. Stevens, please proceed with your review.  Dr. Leslie Stevens  Thank you, Dr. Schaening, and welcome everyone to this open meeting. We're happy to have you, and wanted to let you all know about these proposed LCDs and the scope of them. So, I wanna give a brief overview of transcranial magnetic stimulation and the treatment of adults with major depressive disorder. Scope is for transcranial magnetic stimulation with, for treatment-resistant severe major depressive disorder in the Medicare population.Transcranial magnetic stimulation is FDA approved for the treatment of major depressive disorders and obsessive-compulsive disorders. It is a non-invasive procedure that uses pulsed magnetic fields to induce an electro current in a localized region of the cerebral cortex to modulate the area thought to control depression and compulsive actions. This updated part A and part B LCD was completed to address two issues. One, create a uniform evidence-based coverage criteria for adults with treatment-resistant severe major depressive disorder between the Novitas and First Coast Service Operations' previous LCDs, including alignment of a covered indication for failure of one or more trials of pharmacological medication and/or demonstration of an intolerance to psychopharmacological medications as defined in the policy. And the other issue that we needed to address in this policy was two valid reconsideration requests. One was a request to expand TMS coverage to include the indication of OCD and the other reconsideration was a request to expand coverage to include a subtype of major depressive disorder, which was moderate as opposed to the severe subtype within major depressive disorder. Novitas and First Coast participated in a multi-jurisdictional subject matter expert CAC meeting on 9, 29, 2021, specifically to evaluate existing evidence for the use of TMS for OCD. Based on the current available literature, which has multiple limitations, for example, lack of long-term safety, small sample sizes, inconsistent results, and bias and overall lack of high-quality studies, our SME panel acknowledged there was potential for improvement for refractory OCD with TMS, but overall agreed that clarity was lacking. For treatment to be considered medically reasonable and necessary per the social security act 1862(a) (1) (A), the treatment must be appropriate, including duration and frequency furnished in accordance with acceptance standards of medical practice for a condition. Novitas and First Coast, concluded that the-- with the existing available literature and lack of acceptance standards for TMS for OCD, it does not meet the requirement for medically reasonable and necessary. Novitas and First Coast Service Options and reviewed submitted literature for expansive coverage to include the subtype of moderate depression within MDD, current clinical evaluation or rating tools can assist clinicians in their diagnosis of MDD and provide guidance to an MDD as the major depressive disorder and provide guidance to severity, but because there's no defined standard of measurement for the various subtypes of major depressive disorder, existing evidence-based literature does not address expanding moderate depression severity subtype to the existing severe co-- I'm sorry to the existing coverage for severe major depressive disorder coverage diagnosis.  Dr. Juan Schaening  Thank you, Dr. Stevens, for your presentation. So our first presenter is Scott Blackman with BrainsWay. Sorry about that, Mr. Blackman. Please go ahead stating any conflicts of interest.  Scott Blackman  Thank you. If you look at slide number two. Do I have control, or do you have control right now? I believe you have control. My name's Scott Blackman. I'm the director of market access at BrainsWay. And I am a paid employee, and I'm also a member of the Clinical TMS Insurance Committee. Next slide, please. I'm going to briefly review our comments on the major depression changes in criteria, and then really focus on the evidence review on OCD as Dr. Stevens has just reviewed. Thank you. Next, next topic, please, or next slide. The reason that I'm here today is first, we appreciate you reviewing all the information, both on depression, as well as on OCD. And what we'd like to do is, again, we would like to take a look closer at the severe and moderate to severe depression. And finally, we'd like to review the evidence on deep TMS and not the combined evidence of TMS as a whole, which includes figure 8 traditional coils and the deep TMS H7 Coil. We'd like to focus really on the evidence that's been published and FDA-cleared for Deep TMS with the deep TMS FDA, FDA-cleared protocol, and not confuse that with other studies that did not use that protocol. Next slide, please. We thank-- we thank you very much for revising your depression criteria and allowing access to patients who go through a depressive episode, and so that they don't have to have four more failed medications. So, thank you for that as well as removing the ECT criteria that you have to be a candidate for that or try psychotherapy. Next slide, please. You've already mentioned about the moderate to severe depression. So, I will move past this. Next slide, please. We recommend that if the states allow nurse practitioners to practice independently based upon individual states, the nurse practitioners, particularly psychiatric nurse practitioners or advanced practice registered nurses be able to practice as well if the state allows. So that would be our recommendation. Next slide, please. Moving on to OCD, we understand that the contractor advisory committee had met as well as your summary on the OCD evidence. And as you mentioned, very nicely, it's very confusing. We understand that looking at all the 1980 up through 2018 or '19, that there's a lot of different studies that were done. They were really small in size, low quality. They had lack of standardized protocols. None of them with the exception of Deep TMS used the FDA-cleared protocol. There was also short-term follow-up. There was a lot of bias in many of those studies, low bias in the Deep TMS. They also stimulated different brain regions. So, trying to get an accurate assessment on the mixed results on efficacy from none to moderate with the exception of the outcomes of Deep TMS was very difficult. As you mentioned, some questions still remain, long-term data, what brain regions stimulate, what frequency, how many sessions, how, how long a period of time. And really at this point, even the systematic reviews that were involved, they all concluded non-response to modest effect, but they concluded that based upon looking at all TMS devices and all protocols, there's been only one protocol that's been studied that's been cleared by the FDA, and that's with Deep TMS. Next slide, please. So really what we're asking Novitas and First Coast to do is look specifically at the deep TMS evidence with the H7 Coil. Is the treat-- is the treatment safe and effective? Is it durable for OCD? Has the Deep TMS protocol approved by the FDA identified the right brain regions, the stimulation frequency, the sessions? And are the effectiveness outcomes that you've seen in the clinical trials repeatable in real-world outcomes, and is a cost effective? Next slide, please. Number one, the FDA-cleared protocol is done by Deep TMS. We have the brain regions of the medial prefrontal cortex, the anterior cingulate cortex at 20 hertz, 29 sessions for six weeks at approximately 18 minutes per session. Next slide, please. If you look in the green on the bottom, you'll see two Carmi studies. That was the pilot and the pivotal trial with 100 patients showing evidence of high frequency with the FDA-cleared protocol significantly better than sham. If you see the other yellow rows above, you can see that those network meta-analyses that were done with many trials with the figure 8 coils, traditional TMS, they didn't even include any Deep TMS. So, to combine all these other studies that are looking at dorsolateral prefrontal cortex, orbital frontal cortex, the SMA, none included the anterior singular cortex, which is deeper. So, it's really irrelevant to look at these other studies and-- that didn't use the FDA-cleared protocol and were very small and had those challenges and try to lump them with the ones done by deep TMS. We also want to thank you for including all the references that we've previously sent to you. And we have one more today that we just briefly go over. Next slide, please. Briefly, the anterior singular cortex, which is involved with OCD is located deeper in the brain, approximately three me-- three centimeters subdural. Deep TMS is really one of the only coils, TMS coils that can reach deep enough to stimulate this region. Next slide, please. We know that the current treatment continuum of psychotherapy and medications works in about 50% of the patients. The other patients that don't respond to this first line of treatment, go on to more intensely the same, but they do it inpatient or outpatient, or they do it at residential facilities. So again, more the same, just more intense, and more expensive and a lot more length of time. Next slide, please. We also know that antidepressant and cognitive behavioral therapy lacks durability. There are no studies to demonstrate that medications with continued uses are durable. And usually, after a month of stopping any type of psychotherapy, they're not able to show durability as well. Next slide, please. Deep TMS has been shown to stimulate deeper and broader. This electric field diagram actually shows that it-- the red stimulates deeper and broader into the brain. And that's why I mentioned the anterior singular cortex is deeper. Next slide, please. Compared to the figure 8 coils to those about four times deeper into the brain subdural 3 centimeters, and even the MagVenture D-B80, which says to be deep TMS can only stimulate about 1.2 centimeters subdural. They got approval, but there's really-- they have no studies on evidence using this protocol to show effectiveness. Next slide, please. Another slide done by-- study by Dr. Tzirini looked head-to-head at the two different coils, the BrainsWay H7 Coil and the MagVenture D-B80. As you can see from the red color, the BrainsWay H7 Coil is able to go deeper and broader. Looking at the D-B80 Coil, you can see that it's not able to stimulate deeper or broader. Next slide, please. So, in summary, the clinical evidence on efficacy using the protocol has been demonstrated by the H7 Deep TMS Coil and any other TMS coils that get FDA-cleared should adequately demonstrate their effectiveness using the FDA-cleared protocol to say that you're substantially equivalent by models--you know, benchtop modeling really doesn't demonstrate that you're effective using the protocol. Next slide, please. Next slide, please. There's been over 14 published studies so far on Deep TMS in OCD. You've already seen the pilot multi-center, the real-world evidence you've seen, and the most recent one is what I'll go over today. And that's a network meta-analysis of 19 different treatments, looking at what's the best treatment or the best treatments after patients fail their first line SRIs. Next slide, please. The pilot trial really demonstrated that high frequency was more effective than low frequency using the protocol. And so based upon the pilot trial, next slide, please, the multi-center trial, which is what we gained FDA clearance from actually showed that it was much more effective than sham. This study had 100 patients of which 94 were evaluated for effectiveness. 6 of those original 100 broke the original protocol. And by protocol, intent to treat was only supposed to be looking at safety. Therefore, we did wanna ensure that if any patient changed their medication to a higher dose and it was effective, that you could say it was because they changed their dose. Next slide, please. Ultimately, the multi-center trial showed 38% of patients achieved a response. These are patients who are chronic, OCDs chronic. They have a lot of comorbidities. Patients that didn't receive a response on their antidepressant meds, usually three or more plus psychotherapy, actually almost 40% of them achieved a response, which is a 30% or greater improvement from their baseline on a Y-BOC scale. Additionally, after the six weeks of treatments, 45% of the patients a month after treatment responded actually more after the treatment than after the original six weeks. Next slide, please. In the registry trial over 200 patients from 22 medical centers were evaluated to see what their outcomes were, and they showed that 58% of those patients actually achieved a response of 30% or greater. This is actually better than the clinical trial. So, in the real world, there was better outcomes than in the clinical trial. Next slide, please. This slide depicts the registry, patients that were involved in the outcomes registry. If they had a 33% reduction after-- the arrows on the bottom depict at roughly 29 sessions, about a 33% reduction or improvement in their OCD response or drop from baseline. But if they continued for just 10 more sessions, they actually had about a 50% response or reduction. That means you can get a patient from being severe to mild with extended treatments. Next slide, please. This is the slide I wanted to really emphasize, and that's really durability. Looking at the real-world outcomes. The average durability of patients was two years, which means that once they stopped their TMS treatment - they had a full round of course of treatment - that they did not have to change any of their medications or have another round of TMS. They were able to sustain that response for two years. And in fact, 87% of those patients that had TMS, demonstrated at least a year or more of durability. Most importantly is functional disability. Patients who were really unproductive approximately 5 and a half days a week became only 1.8 days a week were they unproductive. They had a 67% improvement in their productivity or days that they're productive during the week. And when they're taking close to two days off a week, because lost days due to their illness, they got down to 0.03 days, which basically got them fully back to work. Next slide, please. The most recent study, which Novitas and First Coast have not seen is a study that was, was a network meta-analysis reviewed 55 RCTs, 19 different treatment strategies over 2,000 patients who failed to receive a response-- OCD response from their medications, their SRI antidepressants. And what they found was the top 4 treatment strategies to be used after they fail their initial course or trials of SRIs would be either 2 medications, ondansetron, or aripiprazole. Ondansetron is an anti-nausea drug for cancer patients. Aripiprazole is an antipsychotic. Both of those, which, which would be a good course, are not indicated by the S-- FDA for OCD. They're off-label indications. CBT was the third, which we know is a first-line course of treatment with SRIs for OCD. The other one was Deep TMS, not traditional rTMS, but Deep TMS was the one that was found. In fact, in sensitivity analysis, it was ranked the number one or best treatment strategy for SRI-resistant OCD. Next slide, please. All the health technology assessments do the same thing that the CAC members said and as you've reviewed. By looking at all the mixed results, mixed protocols, mixed brain regions, mis-- mixed stimulation parameters of all the studies that were done and not looking at the only one with the protocol that showed effectiveness and got FDA clearance is really just confusing the entire matter. Those earlier studies are not relevant. They weren't done with the appropriate protocol. Next slide, please. Next slide, please. The TMS society actually gave a very clear coverage policy. This is fairly much been adopted by Palmetto GBA. And that's when a patient fails two or more medications or two, two treatments, one antidepressant medication and psychotherapy, it would be appropriate to go on and try a course of TMS with 29 sessions over six-week period. And if the patient's doing well after those six weeks, based upon their response, they should be able to be extended for two- to four-week increments. Next slide, please. There have been almost 70 million patients that are now covered Deep TMS for OCD including six-plus payers, including Centene Healthcare Services and Highmark are the two-- are two of the top four Blue Cross Blue Shield payers in the country. Tricare is covering this. And I mentioned Palmetto, which has 9 million covered lives. So, more and more payers are actually seeing that the evidence supports coverage, particularly Centene only covers Deep TMS. Next slide, please. And finally, I know cost is not an issue, but over $10 billion a year spent on OCD, and a third of those treatments are ineffective. Next slide, please. Most importantly, cost-effectiveness. We know that when patients fail their first-line treatments of antidepressants or therapy, they go on to more of the same, just more expensive going to inpatient-outpatient residential facilities. A study done at Baylor University actually showed that Deep TMS is the most- although it might be, the cost might come after antidepressants and before antidepressants and CBT, by its cost-effectiveness, it would be placed after patients fail their antidepressant meds and CBT and before they go to either adding an antipsychotic or going to those partial or inpatient hospitalization programs. Next slide, please. Summing up, you could see the treatment continuum, the appropriate patient selection is Deep TMS would be the appropriate treatment for the right patient after they fail their first-line therapies where 50% of them fail to respond and before they go on to further treatments, which are much more expensive and have to be much more timely, Deep TMS has also been able to show that it's durable. Notice that the outcomes for cost-effectiveness were based on the clinical trial of 38% response. In the real world, almost 58% of the patients had a response. And if you look-- compared to some of the partial hospitalization or residential facilities, their outcome, their real-world data is shown about a 38% response. Next slide, please. So, in summary, we would like to thank Novitas and First Coast for at least being open to looking at all the evidence for Deep TMS, not confusing the outcomes and the mixed results based upon traditional TMS studies that had all the mixed parameters, all the mixed protocols, and all the mixed outcomes. Deep TMS has shown the evidence and the research in large RCTs, real-world outcomes, long-term effectiveness, improvement in net health outcomes, and functional disability, cost-effectiveness. And by the way, the last study that I mentioned had no bias. There was no payment was given to them, and they had no associations with policies when they did that network analysis of over 2,000 patients. Next slide, please. Thank you again for your time. If there's any questions, I'm happy to answer them at this time.  Dr. Juan Schaening  Thank you, Mr. Blackman, we really appreciate your comprehensive presentation. Does any of the contractor medical directors have questions for Mr. Blackman?  Dr. Leslie Stevens  Thank you, Mr. Blackman, it's Dr. Stevens. And thank you for your assistance during the multi-jurisdictional CAC and certainly for your ability and willingness to advocate for both patients with refractory depression, as well as OCD as these are important clinical concerns in certainly the Medicare population and at large. I thank you, if you could make sure that you-- did you already give us the new literature? You said you were going to provide it after the meeting. Have you done that already?  Scott Blackman  No, I haven't. I was gonna be sending with my comments.  Dr. Leslie Stevens  Oh.  Scott Blackman  So we, we actually sent, I believe it was Dr. Whites, all the literature, which you--  Dr. Leslie Stevens  Right.  Scott Blackman  -you currently-- you're right. You currently reference everything with, except for the last study I shared, which was the large network meta-analysis.  Dr. Leslie Stevens  Right. That'd be great----if you could get that to us. Dr. Whites is now with-- he's with another contractor, but he also did our multi-jurisdictional CAC with that other contractor. So we have not been meeting regularly, and that's why I wasn't aware of another study. So that would be very helpful to us.  Scott Blackman  I will definitely send that to you. It's actually a link. It's so large.  Dr. Leslie Stevens  Okay.  Scott Blackman  In our summary table, it'll have a direct link to take you to that study.  Dr. Leslie Stevens  Okay, great. And then I know we're going to see you tomorrow, correct, over-- at the Novitas Open Meeting.  Scott Blackman  That's correct. I'll be---sharing the same information.  Dr. Leslie Stevens  Excellent. Good. It's okay.  Scott Blackman  So if another question come up, I'm happy to answer that.  Dr. Leslie Stevens  Okay. Thank you so much. Thank you, Dr. Blackman again--  Scott Blackman  Thank you again.  Dr. Juan Schaening  Are there any other questions for Mr. Blackman? Hearing none, and since there are no additional presenters for this proposed LCD, I would like to turn it over to Dr. Patrick Mann to provide a brief overview of the proposed LCD genetic testing for oncology. Dr. Mann, please proceed with your review. Thank you.  Dr. Patrick Mann  Thank you, Dr. Schaening. This is Dr. Mann and today we are going to be reviewing genetic testing for oncology, which is a new LCD. The LCD will include the services that are currently addressed in the following LCDs. Our BRCA1 and BRCA2 genetic testing LCD, the genetic testing for Lynch syndrome LCD, and the molecular pathology procedures LCD. Therefore, these LCDs and their related billing and coding articles will be retired when this new LCD becomes effective. Additionally, the LCD will include some services that are currently addressed in the following LCD, molecular pathology, and genetic testing, which is a billing and coding article A58918. Therefore, these LCDs and the related billing and coding articles will be revised when this new LCD becomes effective in order to remove any overlapping CPT codes or coding instructions. Multiple reconsideration requests have been received regarding a variety of molecular pathology services. This is a rapidly evolving field in an area of study. Therefore, First Coast decided to create a broad LCD that addresses all testing of DNA and RNA in the context of oncology through the use of multiple evidence-based third-party databases. Coverage for testing is based on whether the genetic target or targets in a test are found in these databases and whether the test meets the criteria outlined in the LCD.  Dr. Juan Schaening  Thank you, Dr. Mann, for your review. Let's then proceed with our following presenter, that is Dr. Paul Rudolf with Arnold & Porter. Dr. Rudolf, please go ahead stating in any conflicts of interest.  Dr. Paul Rudolf  Yes. Thank you very much, Dr. Schaening, and thank you for that background, Dr. Mann. I'm still not 100% sure I understand exactly what's gonna happen to the other LCDs. And I just would ask that tomorrow's meeting, the Novitas meeting, you go over that and maybe we can have a chance to, to ask some questions. So go to the next slide, please. Oh, sorry. So, my disclosure was on that previous slide. I thought there was another slide. I'm a physician, a former contractor medical director. A number of years ago worked at the Medicare central office for five years doing hospital and physician payment policy. And since I left the government, I've been practicing law, and in this case, I represent Pacific Edge, which has a lab that's located in the Novitas jurisdiction. However, we're presenting at both meetings because we know that First Coast and Novitas are, are trying to harmonize all their policies, and we'll be finalizing the policies together. So, we've just started reviewing this policy, and we have a number of process concerns that I'm going to articulate today and will continue to review it. And these will all be included in our comment letter. I think in summary, we do not believe that these policies should be finalized. They should be retired for a number of process reasons, let alone substance.  Dr. Paul Rudolf  So, the first point was sort of addressed. That was unclear how this-- the proposed LCDs will interact with existing LCDs and coverage articles. I was trying to make sense of, of how they could work, and I, I had a lot of trouble doing that. The proposed framework defers to external knowledge bases rather than a MAC review of individual tests. We believe is likely to stifle innovation and delay coverage of new advanced molecular diagnostics that could benefit Medicare beneficiaries. Our preliminary review indicates that the proposed LCDs do not appear to be compliant with statutory and program manual requirements for LCD development. First, these LCDs may not even meet the definition of an LCD. Second, they do not appear to meet the procedural standards required under the 21st Century Cures Act. They do not appear to meet the evidentiary requirements in section 13.5 of the Program Integrity Manual, nor do they appear to allow Novitas and First Coast to comply with the process and reconsideration requirements in sections 13.2 and 13.3 of the Program Integrity Manual. And I'm gonna go over each of those briefly. Next slide, please.  Dr. Paul Rudolf  So, this is, goes to what Dr. Mann was talking about. We are not quite sure how this LCD will interact with L35396 and their accompanying articles. I guess that, from what I heard, L35396 is going to be retired. It's unclear whether all the tests that are currently covered by Novitas and First Coast will continue to be covered. The proposed LCAs 59125 and 59123 identify diagnosis codes for which certain test will be considered reasonable and necessary. Yet, there's no explanation of how those codes were chosen. There was no discussion of any evidence as to why those were chosen instead of others. There was no discussion of indications for any of the tests, and there was no discussion actually of any tests at all in the proposed LCDs. We also don't know how Novitas, and First Coast determined an individual test was or was not included in the knowledge bases. And we don't know which knowledge base, was the basis for coverage for individual tests. And we think that's a fundamental problem with the LCD and that it cannot be finalized because there was essentially no proposal. In addition, the, LCD non-cover certain tests of draft LCD is non-cover certain tests without explaining how the determination was made to non-cover those tasks. There's no evidence showing why those tests should be non-covered appearing to be a process violation of chapter 13, provision the-- sec 13.2. Next slide, please. So a-- the statute defines an LCD is a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an in-- on an intermediary or carrier-wide basis under such parts in accordance with section 1862(a)(1)(A) The proposed LCDs limit coverage to tests that meet criteria established by at least one of the following knowledge bases, but it does not address whether a particular item or service is reasonable or necessary. All it talks about is whether these knowledge bases meet the good guidelines criteria of the Institute of Medicine that was published in 1990, over 30 years ago. So, the only thing discussed - I wanna repeat this - are whether these three knowledge bases meet certain guidelines of the IOM. There was nothing in, in this draft LCD that discussed any particular test or even tests that were included in those knowledge bases. So again, not allowing commenters and stakeholders to respond. Next slide, please.  The 21st Century Cures Act, requires that Medicare administrative contractors, when they develop LCDs meet four or five criteria. And the fourth one, which is highlighted says a summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence. Novitas and First Coast did not directly consider or even reference in the bibliography any clinical evidence about any particular test in the proposed LCDs and may have actually in our view - we're still looking at this - improperly delegated the consideration of evidence to third-party knowledge bases. And specifically, the proposed LCDs have 19 citations. Almost all of them were the knowledge bases and other websites. In contrast, the current LCD, 35396, I believe, has 780 sites, the majority of which are peer-reviewed journal articles. So that's what we consider to be a real bona fide LCD that complies with the 21st Century Cures Act. Next slide, please.  Again, in the Program Integrity Manual, it says that in every proposed and final LCD, the MAC must summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or non-coverage. At a minimum, the summary should include the following. And again, I'm not gonna read the whole thing, a complete description of the item or service under review and a narrative that describes the scientific evidence supporting the clinical indications for the item or service. In our view, the draft LCDs do not include a narrative that describes the scientific evidence supporting the clinical indications for the item or service. The evidence just describes knowledge bases, and knowledge bases are not items or services covered by Medicare. Does not address the clinical indication for any genetic test. And again, the only evidence presented is whether these three knowledge bases met some of the 1990 IOM guidelines. In fact, it didn't even discuss all of the attributes. I think there were seven or eight. The, the, the review in the draft LCD didn't discuss all of the attributes to some of them. Next slide, please.  This is again, a quote from the manual. In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research and peer-reviewed journals, systemic reviews, meta-analyses, evidence-based consensus statements, and clinical guidelines. It is our view that the proposed LCDs have failed to consider any evidence of acceptance by the medical community of first of these databases but let alone of-- or any other type of evidence published, original research, systemic reviews, meta-analyses, or anything like that. Guidelines are only part of the evidence MAC should be considering not the entirety, of the evidence. Next slide, please. So, we also-- I wanna talk a little about reconsideration. It's our view that the proposed LCDs, appear to make reconsideration impossible. Reconsideration requests, according to the manual, must be submitted in writing and shall identify the language that the requester wants added to or deleted from an LCD. It's not-- we don't understand how it's possible for stakeholders to submit a valid reconsideration request because there's no language that could be added or deleted because the language just referred-- defers everything to a knowledge base. So, it's unclear how stakeholders can submit reconsideration requests if this is finalized or even how Novitas would be able to respond to them. It seems like the response would just be, well, is it included in one of these knowledge bases or not? And that is not, the way reconsideration requests are designed under the Program, Integrity Manual. And again, it's not possible for us to even know what tests are covered or why they're covered in-including the diagnosis codes. Next slide, please.  So, the proposed LCDs don't support the selection of particular knowledge bases. So again, I will read through this. I only have a couple more slides left. Novitas and First Coast identify these specific knowledge bases that assert complies with requirements of IOM report. It's over 30 years old. But the draft doesn't propose these knowledge bases. It just says, "Here they are. This is what we're doing." So the draft should have solicited comment on whether it is appropriate to defer to these knowledge bases and why. And, and the draft didn't even do that. And so the-- in conjunction with that, the, the following items were not addressed: were other knowledge bases considered? Do other knowledge bases meet the IOM guidelines? How do the selected knowledge bases meet all the standards of the IOM report? Is it appropriate to use these or any other knowledge bases as a sole basis for coverage? In other words, as a replacement for MAC individual review, comments should have been solicited on that. Will Novitas and First Coast continue to review these and the other knowledge bases to make sure they continue to meet the IOM guidelines? Do we know? In two years, maybe they won't anymore. Maybe they'll change everything. And what will happen then? What will happen to the coverage of all of these things if the knowledge bases change and no longer meet requirements? How often do these knowledge bases update their findings? So, for all new tests, if the knowledge bases are being deferred to, how is Novitas and First Coast gonna cover any new tests? Either they are gonna have to wait three years for an update? I don't know how often all these knowledge bases are updated. I know NCCN is updated yearly, but it-- we'll get to that in just a second. So the, the coverage of new tests is a very important issue, that is another reason why we think this needs to be withdrawn and rethought through so that all these questions can be answered. Next slide, please.  So, the proposed LCDs implied that if a cover test is no longer listed in one of the knowledge bases, it will be immediately non-covered. So, if a test is in an NCCN guideline now, but then next year it's gone, does that mean it's non-covered? How is Novitas gonna-- and First Coast gonna handle that? It means there's no predictability to coverage. Co-- tests could be in and out, covered, and non-covered on-- literally on a yearly basis. What kind of notice requirement will be given if a test disappears from one of the knowledge bases? So, we think that this unpredictability of coverage and the fact that Novitas and First Coast aren't doing their own review is a real problem for reconsideration requests and a real problem for new innovative tests cause companies should be able to come to Novitas and ask for coverage of a new innovative test and have Novitas review it on their own without reference to any of these databases in order that it be covered. And we believe this is-- may end up being a really important access issue for Medicare beneficiaries to have, access to new, innovative life-saving tests. Next slide, please.  And then this is what I said before. I won't read through the whole thing. What's gonna happen to currently covered tests? If Novitas and First Coast are gonna stop covering tests that were previously reviewed where the evidence was found to be sufficient to cover the test, how can they then be non-covered by deferring to a database? So that question really needs to be thought through. And we also would like to know whether FDA approved, or clear test will be covered automatically. Next slide, please. And then this goes-- repeat some of the things I already said that the sole use of knowledge bases conflicts with the LCD content and procedural requirements that Novitas and First Coast-- but what-- one thing we think could be done here to be a little bit positive is it may be that Novitas, and First Coast could provide positive coverage based on inclusion in a knowledge base. Although even there, there are issues about what are the indications, what are the diagnosis codes, but others-- tests that are not in the knowledge bases should still be coverable based on submission of data to Novitas and First Coast. But again, there are a lot of notice and comment issues and other things that would have to be dealt with if Novitas and First Coast wanted to go in that direction.  One other thing that we think is that, that if this is finalized, that any test that's currently being covered and paid for should continue to be covered and paid for because that-- those tests have been reviewed in a positive way in the past, and in order to non-cover something, Novitas and First Coast would have to go through the LCD process for every single test that is non-- it will be non-covered. That-- that's the way the LCD in under se-- in, in section 13.2 is required that notice and comment be gone through for every LCD except for four very narrow exceptions. So, we think that if this is finalized and any test is non-covered and it was not specifically gone through the notice and comment process for those individual tests, that would be a process violation. I know I'm repeating myself. Next slide. I think this next one is the last one. Is this the last one? Yes. Thank you very much for your time. I'd be happy to answer questions.  Dr. Juan Schaening  Thank you, Dr. Rudolf, for your presentation. Do any of the contractor medical directors have question for Dr. Rudolf? Thank you. We appreciate your comments. And remember even though we have your presentation always follow up your comments in a written format before the end of the comment period. Let's proceed to our second presenter, Dr. Thomas Nifong with Pacific Edge Diagnostics. Please go ahead stating any conflict of interest.  Dr. Thomas Nifong  Thank you, very much, and good afternoon, everyone. I am employee of Pacific Edge Diagnostics. That is my only, conflict here. I'm the laboratory director for Pacific Edge Diagnostics Clinical Laboratory, located in Hershey, Pennsylvania. And I'm really here today on behalf of our company, Pacific Edge, but also on behalf of the Medicare patients that could potentially lose access to valuable services that they depend on for their care. I'd like to start by providing just a brief overview of our company and our CxBladder tests to help you understand how our non-invasive tests are utilized in the evaluation and management of patients with hematuria and in the surveillance of patients with bladder cancer. Pacific Edge is a New Zealand-based cancer diagnostics company that was founded in 2001. After 10 years of discovery and development, we launched our first CxBladder test in 2011 in New Zealand. We then established our US headquarters and CLIA CAP-accredited laboratory in Hershey, Pennsylvania in 2012 and launched CxBladder in the US in 2013. All of our testing is performed in this laboratory, which resides in the Novitas jurisdiction.  Over the last nine years, CxBladder has gained significant adoption performing over 90,000 tests in the US to date, over half of those in the Medicare population with orders coming for more than 1,800 urologists. The CxBladder tests have been adopted into the standard of care in New Zealand and are incorporated into diagnostic pathways at Kaiser Permanente and other prominent US medical institutions. The CxBladder tests detect 0012M and monitor 0013M are MAAA tests that identify five molecular biomarkers in a urine sample and apply a mathematical algorithm that takes into account the relative and absolute amounts to determine the probability of bladder cancer being present, allowing the patient and physician to determine if additional testing should be undertaken. The tests are performed on voided urine and use reverse transcriptase quantitative PCR to measure gene expression levels of the five biomarkers. These CxBladder tests are clinically validated to be useful in the diagnostic pathways of patients with hematuria with suspicion of bladder cancer and for surveillance of patients diagnosed with non-muscle-invasive bladder cancer. They have been adopted into multiple clinical pathways in the US and other countries. Furthermore, the assays have been covered by Medicare since July 1st, 2020, based on LCD 35396 and accompanying article A58529. And we are unsure how this may be affected by the currently proposed LCD.  From July 1st, 2020, the effective date of the updated LCD 35396, that was revision 30, through June 1st of this year, Novitas has processed over 10,000 claims for CxBladder tests and reimbursed us for all, but 11 of those claims, meaning that we have been reimbursed by Novitas on 99.9% of the claims. We're proud of this accomplishment and hope that we can continue to serve our patients in the future by innovating new technologies to detect and diagnose cancers. Our tests have been very important in serving bladder cancer patients for nearly a decade. And we hope that CMS continues to support innovation through continued coverage of current technologies at Pacific Edge, as well as at other laboratories. In reference to the currently proposed LCD DL39365, we find that the use of three knowledge databases to determine the coverage of tests is not an appropriate methodology to advance medical care. Relying exclusively on external knowledge databases would hamper the ability for companies to request reconsideration and review of individual new tests based on published information. Rather it can take several years for effective technologies to be adopted into knowledge databases, severely limiting access to advanced diagnostics for the Medicare population. Furthermore, two of the three databases suggested in the proposed LCD as the determinants of coverage ClinGen and OncoKB are really only relevant for DNA SNP markers and do not address any of the multigene expression markers such as CxBladder.  For the third database, NCCN guidelines, Novitas proposes to only include genes with level 1 or 2A evidence. A 2B recommendation has a consensus with a panel vote of greater than 50%, a simple majority. A 2A recommendation has the same level of underlying evidence, but it requires a uniform consensus as defined as a panel vote of greater than 85%. We think this is too stringent. We're not aware of any actual requirement for level 2A evidence, and some tests have been covered with only a 2B recommendation. We don't believe that Medicare patients should be denied access to a test based on this subjective criteria. Furthermore, the NCCN guidelines are primarily focused on treatment decisions for patients who have already been diagnosed with cancer and are less comprehensive regarding the initial evaluation. It is in-inappropriate for this to be used as the sole source for determining coverage for a diagnostic test. Additionally, it appears that the condition of medical necessity in the proposed LCD requires abnormal results from a histologic and/or cytologic examination prior to ordering genetic testing. This requirement would make many non-invasive diagnostic tests moot as they have been developed to help clinicians and patients decide if additional invasive procedures such as biopsies are necessary to further evaluate the patient for cancer.  For example, approximately seven million patients are seen annually in the US for hematuria. And although hematuria is the most common symptom of bladder cancer, the vast majority of patients with hematuria don't actually have bladder cancer as an underlying cause. Invasive procedures such as cystoscopy and radiologic procedures, such as CT scans are central to evaluating patients with hematuria for bladder cancer. Previously, the main laboratory support for evaluating patients for bladder cancer either initially or for recurrence has been lab tests on urine known as cytology and FISH, both which have significant shortfalls, in particular, very poor sensitivity and variable results. Neither of these tests can be used to safely rule out disease because of the low sensitivities. Cytology actually has a diagnostic accuracy as low as 10% for low-grade urologic cancers. In fact, even the gold standard cystoscopy produces both false-negative and false-positive results. And performance is quite variable. The American Neurological Association has a stated goal of stratifying patients with hematuria by risk to reduce the unnecessary invasive evaluations of low-risk patients. This goal will never be achieved without the use of molecular biomarkers early in the evaluation workflow. The extensive use of invasive procedures is poorly tolerated and causes harm to patients, with patients experiencing pain, discomfort, and anxiety. As such, we feel strongly that it's inappropriate to remove coverage for any test that has been covered over the past two years under the same Medicare rules and regulations.  We would also like to specifically address the following points in the proposed LCD, which we feel are important from a scientific perspective to be addressed. The title of the LCD refers to genetic tests, which really only covers the inherited malformations in the patient's genes and does not cover the somatic genomic or molecular changes in the actual cancers that are addressed by tests such as CxBladder. We ask the contractors to clarify whether the goal is to cover all genetic and genomic assays. Second, our company and our lab have worked tirelessly over several years with representatives from Novitas to provide the appropriate clinical and analytical validations requested and required for coverage of the assay established in July of 2020. Any changes in coverage should be based on an individual review of the product. Based on the information I provided, we believe that if the intent is to address all genomic markers as well, then inclusion of the CxBladder test and the proposed LCD as well as all other currently covered tests is not only warranted but essential to ensure that Medicare patients continue to receive high-quality services from our assays and allow us to continue to innovate to benefit more patients. Thank you for the opportunity to present our views on this proposed LCD, and I'm happy to entertain any questions.  Dr. Juan Schaening  Thank you, Dr. Nifong. We really appreciate your presentation. Does any of the contractor medical director have any question for the presenter? Hearing none, and since there are no additional presenters for this proposed LCD, at this time, I would like to turn it over to Laura Mathewson to provide a brief overview of the proposed LCD for a special histochemical stains. Could you proceed with your review, Laura? Thank you.  Laura Mathewson  Thanks, Dr. Schaening. This LCD and related billing and coding article, which addresses the medically necessary criteria for the use of special stains and/or immunohistochemistry stains is being retired. Recent review of the LCD identified that the LCD is not reflective of the current standard of practice.  Dr. Juan Schaening  Thank you, Laura, for your presentation. Since there are no presenters for this LCD, I would like to thank everyone for their participation in today's open meeting and remind you to submit comments in writing before the end of the comment period on the two LCD revisions and the proposed LCD for retirement on histochemical-- special histochemical stains and immunohistochemical stains. The comment period will be open until July 23rd, 2022. If there is no further questions from Laura or any of the CMDs, then this meeting is adjourned. Thank you and have a beautiful day. |