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| First Coast Service Options, Inc.  JN Open Meeting |
| Thursday, October 27, 1 p.m.  Topics:  Proposed LCD DL36393– Controlled Substance Monitoring and Drugs of Abuse Testing  Proposed LCD DL39492 – Ambulatory Electrocardiograph (AECG) Monitoring |
| CORPORATE PARTICIPANTS  Juan Schaening-Perez, MD – First Coast Service Options Executive Contractor Medical Director  Alicia Campbell, MD- First Coast Service Options Contractor Medical Director  Roberta (Bobbi) Kelly, BSN, RN- First Coast Service Options Medical Policy Nurse  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  Jyme Schafer, MD, MPH - Novitas Contractor Medical Director  Jan Green, RN, MSN, CPC – Novitas Medical Policy Nurse  PRESENTERS  Harold Dalton, DO- Florida Society of Interventional Pain Physicians- Interventional Pain Management CAC member |

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PRESENTATION

Mandy McGarvey

Good afternoon. I'm Mandy McGarvey, and I'll be your WebEx host for today's open meeting. Before we get started, I want to take a moment to remind everyone that this meeting is being recorded. At this time, I'm going to 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 October open meeting. My name is Dr. Juan Schaening, I'm First Coast's executive contractor medical director. Joining me today from First Coast are my colleagues, Dr. Alicia Campbell and Bobbi Kelly. Joining us from Novitas are Dr. Leslie Stevens, Dr. Patrick Mann, Dr. Susan Doud Galli and Dr. Jyme Schafer, and Jan Green. Please be aware that the First Coast Service Options is recording this virtual open meeting to comply with CMS guidelines. By remaining logged 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 consolidations. Open meetings allow interested parties the opportunity to present information and offer comments related to new proposed LCDs and or the revised portion of a proposed LCD during the 45-day comment period. The proposed LCD topics for today's meeting are controlled substance monitoring and drugs of abuse testing and ambulatory electrocardiograph monitoring. 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 November 26, 2022. At this time, I would like to turn it over Jan Green to provide a brief overview of the proposed LCD in controlled substance monitoring and drug of abuse testing. Jan, please proceed with your review.  Jan Green  Thank you, Dr. Schaening. Good afternoon, everyone. This LCD has been revised to create a uniform LCD with other MAC jurisdictions. Once this revision to the LCD becomes effective, the current First Coast LCD, L36393, controlled substance monitoring and drugs of abuse testing, and the related billing and coding article, A57077, will be replaced with this revised policy. Urine drug testing or UDT provides objective information to clinicians by identifying the presence or absence of drugs of potential abuse in the body to assist in making treatment decisions. This LCD provides an overview of presumptive UDT and definitive UDT testing by various methodologies, outlines the covered indications and limitations for UDTs, and details the documentation required to justify a UDT for coverage purposes. With this revision, a list has been included in the drug classification section, which illustrates parent drugs and their metabolites, and defines all the various drug classes that are recognized as distinct classes by this LCD. This listing is based upon the drug classes listed in the Drug Enforcement Administration, or DEA, Drugs of Abused Resource Guide, the American Association for Clinical Chemistry, or AACC, Evidence-Based Guidelines, and the AMA CPT Codebook References. In this regard, coverage has been limited to the use of no more than 14 classes of drugs for UDT. As indicated in the billing and coding article, CPT and or HCPCS codes that describe a specific number of drugs, metabolites, or substances rather than drug-- excuse me, rather than number of drug classes - for example, 25 drug panel - will be non-covered until documentation is provided, demonstrating both, number one, to which class each of these analytes belong, and number two, all classes represented by the analytes are listed as covered by the LCD. 14 specific classes described and allowed. If documentation is provided to the MAC, demonstrating that the panel only test analytes belonging to covered drug classes, the article will be updated accordingly. Thank you. And back to you, Dr. Schaening.  Dr. Juan Schaening  Thank you, Jan. Now, let's go to our presenter. Our presenter on controlled substance monitoring and drugs of abuse testing is a [inaudible] CAC member, Dr. Harold Dalton. Dr. Dalton, please go ahead stating any conflicts of interest and go ahead with your presentation after that. Thank you.  Mandy McGarvey  Dr. Schaening, I'm still not seeing that Dr. Dalton was able to get connected. I am still trying to work with him to get him on.  Dr. Juan Schaening  Then no problem. What we're going to do then is let's move toward the presentation of the next LCD to give Dr. Dalton time to join us. And after that presentation, he may then do his presentation on controlled substance monitoring and drugs of abuse testing. Okay? So let's move forward.  Mandy McGarvey  Actually, Dr. Schaening, he just appeared online.  Dr. Juan Schaening  Okay.  Mandy McGarvey  Dr. Dalton, are you able to unmute your line?  Dr. Harold Dalton  Yes. I am.  Dr. Juan Schaening  So thank you, Dr. Dalton. We just went over the brief summary of our LCD. And we are at the stage to allow you time to stage your conflicts of interest and do your presentation. Are you fine with that?  Dr. Harold Dalton  Yes. I am.  Dr. Juan Schaening  Okay. Thank you so much. Then, Dr. Dalton, please go ahead and state any conflicts of interest, and after that you can proceed and do your comments.  Dr. Harold Dalton  Very good. Thank you. I'm Dr. Harold Dalton. I am representing the Florida Society of Interventional Pain Physicians. I am also a member of the CAC for First Coast Options. As far as conflicts of interests goes, I am a physician. I'm a partial owner of a practice that utilizes all aspects of urine drug testing, and that's really my conflict of interest. So I want to take the opportunity to thank the members, the staff, and the working group that put this proposed LCD together. I've had the opportunity to not only speak with the FSIPP board of directors; I have had the opportunity to speak with numerous other pain physicians throughout the state of Florida, as well as some risk managers that help guide physicians through the urine drug testing process in regards to this LCD.  Overall, quite frankly, I think the LCD is very well-written and very straightforward. However, there are some specific concerns that we have. When we look at the number of drug classes, it is reduced to only 14 classes, which means that the G codes, G0483, which is more than 21 drug classes, and G0482, which is 15 to 21 classes, could never be billed moving forward. The way that the classification is set up for 14 is these two G codes would just no longer function. It appears that they have removed a covered indication for definitive testing in the ability to perform a definitive test when there is an inconsistent positive or negative.  There is a clear statement in the LCD that really states that if you question the results from a definitive test-- oh, I'm sorry. Of a presumptive test, or that the presumptive test may be done incorrectly, if you question that, you cannot order a definitive testing on this. And quite frankly, we use definitive testing when there is inconsistent positives or inconsistent negatives. And I think if we look at other LCDs throughout the country, you'll see that this indication for definitive testing is clear and, quite frankly, is needed by the practitioners. As we talk about the definitive urine drug testing, covered indications really should specifically state that definitive UDT is allowed to identify inconsistent positive or negative presumptive results. Otherwise, we run into problems if the patient denies unexpected positive or negative results. But the way that it appears now, as written, that we would be unable to confirm that inconsistency.  The prohibition for testing to rule out a testing error for an unexpected presumptive result, quite frankly, that language we recommend removing. The membership also has significant concerns that this is a LCD or proposed LCD for drugs of abuse, and alcohol is clearly a drug of abuse. Clearly, it affects other controlled substances in its interaction. And while it is specifically eliminated in this LCD, we do not think that should be the case. Yes, we are aware that the most accurate way of measuring blood alcohol or alcohol in a patient is blood alcohol levels. However, it can also be detected in urine. And I can't tell you a pain physician in the state, at least that I've talked to, and I was at a meeting over the weekend, that isn't concerned about alcohol use. And it can be detected in urine and should be covered by this LCD.  A bit concerned about the physician rationale and documented for a screen or testing. We want to make sure that when we state documented thoroughly and clearly, that we should be able to say that documenting compliance with prescription drugs is significant to qualify for that thoroughly and clearly, which is a requirement on page five because that's really what we're doing. We are documenting compliance or noncompliance with controlled substance prescribing. Definitive urine drug testing should specifically state to identify drugs in a large class of family drugs such as benzo, opioids, or opiates, merely stating that when presumptive urine drug testing is insufficient to identify all substances of concern, the language appears to be vague and unclear. And this is from a risk management attorney who we had review this LCD. We don't want to be vague and unclear as we look at this.  We recommend that the LCD should specifically state that the provider can order definitive testing without a presumptive test. Go directly to definitive, in other words, when a screening test cannot be done for the drug issue. And this is particular when we look at fentanyl or other substances that really cannot be tested at point of care. Numerous members were very concerned about the requirement for presumptive testing, particularly at the point of [care cups?] using the reagent strips that are known to have very high rates of false positive and false negative errors. And we'd like to be able to move directly to definitive testing in those individuals. It also comes as for-- some physicians may not be able to do presumptive testing in their office. They may not have a restroom in their office, or they may not have the facilities to be able to do presumptive testing. And those individuals should be allowed to go directly to definitive when possible. These are the suggestions that we've come up with. Are there any particular questions that I can answer for you regarding the physician statements?  Dr. Juan Schaening  So thank you for your presentation, Dr. Dalton. We appreciate your comments. Even though this meeting is being recorded, we will appreciate if you could submit the comments to our LCD in writing before the end of the comment period on November 26, 2022. So we greatly appreciate your comments regarding the LCD. That would be draft LCD L36393 on controlled substance monitoring and drugs of abuse testing. Please provide any related change to verbiage that you're proposing with related evidence, if possible, before the end of the comment period, and we will greatly appreciate that.  Dr. Harold Dalton  I planned on doing that. And we'll get that out to you as quickly as possible.  Dr. Juan Schaening  Thank you so much.  Dr. Harold Dalton  My pleasure.  Dr. Juan Schaening  So do any of the CMDs have any questions for the presenter?  [silence]  Okay. Hearing none, I want to thank, again, Dr. Dalton for his service as one of our tech members and for his comments and interest on this LCD and on our beneficiaries. So let's move on to the next one. Since there's no additional presenter for this LCD, I will turn it over to Bobbi Kelly to provide a brief overview of the proposed LCD, ambulatory electrocardiograph monitoring. Bobbi--  Dr. Harold Dalton  Hey, doc. How are you doing?  Dr. Juan Schaening  present your review. Thank you.  Bobbi Kelly  Thank you, Dr. Schaening, and good afternoon. This is a new part A, part B, LCD developed to create a uniform LCD article for Novitas and First Coast Service Options. The scope of this LCD is ambulatory electrocardiograph monitoring that will provide a record of the heart rhythm during daily activities. AECG is ordered by healthcare professionals, but the ECG can only be read by a physician. This LCD article will consolidate one LCD article from First Coast, which is the long-term wearable electrocardiographic monitoring, and two LCDs and articles from Novitas. First being cardiac event detection monitoring, and the second, real-time outpatient cardiac telemetry. These LCDs and related articles will be retired when this new LCD becomes effective. The LCD addresses monitors that can be worn as external machines with leads, a small mechanical patch that adheres to the chest wall, or a device inserted under the skin to monitor for irregular heartbeats such as arrhythmias, atrial fib, atrial flutter, and life-threatening arrhythmias. The monitors are prescribed for people with symptoms such as dizziness and palpitations that are not diagnosed with the conventional 12-lead ECG monitor and cardiac history or workup.  These monitors are also helpful in assisting the healthcare professionals to regulate heart medications such as anti-arrhythmic drugs, determining the patient's cardiac health after an acute coronary syndrome, congenital heart disease, and certain cardiac syndromes. They also are used in assessing if the patient is having a silent MI or heart disease. These devices must be FDA-approved. The consolidation provides guidance related to these monitors that are based on capability, duration, reports, indications for use, and limitations of these certain types of monitors. Limited coverage is based on diagnoses which are related to arrhythmias, medication adjustments, and disease process. The list of covered diagnosis codes have been revised to ensure the diagnoses are consistent with the LCD indications and limitations, resulting in fewer covered diagnosis codes. The consolidation of these LCDs also provides guidance to the present NCD. Thank you, Dr. Schaening.  Dr. Juan Schaening  Thank you, Bobbi, for your presentation. Since there are no presenters for this LCD, I just 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 November 26, 2022. With this, this meeting is adjourned. Have a beautiful day. Thank you. |