First Coast Service Options, Inc.

JN Open Meeting

Thursday, February 29, 1 p.m.

Topics:

DL38664 – Implantable Continuous Glucose Monitors (I-CGM)

DL33930 – Facet Joint Interventions for Pain Management

DL39799 – Cervical Fusion

CORPORATE PARTICIPANTS

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PRESENTERS

Deborah H.Tracy, MD, Florida CAC Member-Florida Society of Interventional Pain Physicians

Francine Kaufmann, MD, Chief Medical Officer- Senseonics

PRESENTATION

Mandy McGarvey

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| Good afternoon. I'm Mandy McGarvey, your WebEx host for today's open meeting. Before we get started, I want to remind everyone that this meeting is being recorded. The transcript and recording will be available on our website in the next few weeks. At this time, I'm going to turn the meeting over to contractor, medical director, Dr. Benita Jackson.  Dr. Benita Jackson |
| Thank you, Mandy. Good afternoon. I'd like to welcome everyone to First Coast February open meeting. My name is Dr. Benita Jackson. Joining me today are my Novitas and First Coast colleagues, Dr. Patrick Mann, Dr. Gavin McKinnon, Dr. David Sommers, and Dr. Anitra Graves. Please be aware that First Coast Service Options Inc. is recording this virtual open meeting to comply with the 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 provide you with an opportunity to present your comments on revisions made in response to a reconsideration request. 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 DL33930, Facet Joint Interventions for Pain Management. DL38664, Implantable Continuous Glucose Monitors, I-CGM and DL39799, Cervical Fusion. 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 March 31st, 2024. We encourage you to submit full text published evidence supporting your recommendations that have not been previously submitted. At this time, I would like to provide a brief overview of the proposed LCD DL33930, Facet Joint Interventions for Pain Management. This LCD has been revised by a multi-MAC collaboration to create a uniform LCD with other MAC jurisdictions. Once this revision to the LCD becomes effective, the current JN Jurisdiction Policy, First Coast LCD, Facet Joint Interventions for Pain Management, L33930, and the related billing and coding article A57787 will be replaced with this revised policy. |
| The spine is the most common source of chronic pain. Facet joint interventions may be used in pain management for chronic cervical, thoracic, and back pain arising from the paravertebral facet joints. There are various methods that may be used in performing facet joint denervation. This revision provides clarifying language and supporting evidence on the use of anesthesia in connection with facet interjections and radiofrequency nerve ablation, RFA. The number of levels covered under the policy has also been addressed. In addition, this revision includes the response to a reconsideration request for the expansion of therapeutic joint injections as a first-line option. Our first presenter for proposed LCD DL33930 is Florida CAC member, Dr. Deborah Tracy, representing the Florida Society of Interventional Pain Physicians. Please go ahead stating any conflicts of interest. |
| Dr. Deborah Tracy  I have no conflicts of interest. Can you hear me? |
| Dr. Benita Jackson  Yes. Thank you, Dr. Tracy. Please proceed.  Dr. Deborah Tracy |
| Yes. My name is Dr. Deborah Tracy and I've been the CAC representative for Florida Society of Interventional Pain Physicians since 2007. Right now, I have the L33930 in front of me, which was last revised 04/25/2021. And I also have in front of me the letter written to you by the American Society of Interventional Pain Physicians, of which we are a sub-chapter. I am also on the board of directors of the American Society of Interventional Pain Physicians, and I'm a fellowship-trained interventional pain physician. I would just like to say that in reading the essence of the letter, we agree with the MAC anesthesia for radiofrequency only and holding that on diagnostic blocks. We also agree with the two-level procedure, although there is literature and multiple cadaver studies noting that any level or medium branch segment is innervated from the level above. So we prefer the three-level, but if you feel the two-level is supported by the evidence, we would agree to that. But the essence of this paper from the American Society of Interventional Pain Physicians is really requesting that the current language in the LCD is that we only provide medial branch blocks or intraarticular injections with an attempt to proceed to RFA. |
| And we found that some patients actually benefit from the medial branch block or intraarticular injection for a significant period of time, three months, sometimes longer, six months, sometimes a year, so that if that is effective, it's less painful and it's less costly for our beneficiary fund. So that we would like you to consider the revision to include that there doesn't have to be an intent to proceed to radiofrequency ablation if the block, either median branch or intraarticular, is successful. The other point that we would like to make as the Florida Society of Interventional Pain Physicians is a point in the letter noting that intraarticular blocks can be difficult, but also that they can be effective, especially in our younger generation of Medicare populations where they're active and they just have a little facet joint distraction causing inflammation and that leading to the intraarticular block with a little steroid being effective. So that is really all I need to say. If you have any questions, I'm right here. But I appreciate your diligence in evolving these LCDs, and I know the amount of work the CMDs put in for this. So thank you. |
| Dr. Benita Jackson  Thank you so much, Dr. Tracy. We really appreciate your participation. I also would like to clarify that the end of the period is March 30th, 2024, for the comments. And again, a reminder that these comments need to be placed in writing. All right. Since there are no additional presenters for this proposed LCD, I would now like to turn this over to Dr. Gavin McKinnon to provide an overview for the proposed LCD DL38664, Implantable Continuous Glucose Monitors I-CGM. Dr. McKinnon. |
| Dr. Gavin McKinnon  Thank you. 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 L38664, Implantable Continuous Glucose Monitors and the related billing and coding article A58136 will be replaced with this revised policy. Recent advances in technology have enabled providers to better utilize blood glucose measurements to improve patient care. Based on current evidence, recent changes to DME policies have broadened coverage of Non-Implantable Continuous Glucose Monitor for Medicare beneficiaries. The scope of this LCD is limited to implantable continuous glucose monitors, but many of the same principles and applications are the same as for the non-implantable products. The revised LCD aims to align coverage criteria with the revised DME policies to provide an implantable option when appropriate.  Dr. Benita Jackson |
| All righty. Thank you, Dr. McKinnon. Continuing along in this discussion, our first presenter for the proposed LCD DL38664 is Dr. Fran Kaufmann from Senseonics. Dr. Kaufmann, please go ahead and state any conflicts of interest.  Dr. Francine Kaufmann |
| So I am the Chief Medical Officer at Senseonics. |
| Dr. Benita Jackson  Thank you. Please proceed. |
| Dr. Francine Kaufmann  Yes, thank you. And you'll be able to change the slides, or do I do that? |
| I'm not sure. Mandy?  Mandy McGarvey |
| Dr. Kaufmann, we are handling that for you. Thank you.  Dr. Francine Kaufmann |
| Okay, great. Thank you. So again, my name is Dr. Francine Kaufmann. I'm the Chief Medical Officer at Senseonics. I am also a Distinguished Professor Emerita of Pediatrics at The Keck School of Medicine at the University of Southern California and a Past President of the American Diabetes Association. And I'm very fortunate in that I continue to see patients as well in my clinic. Next slide, please. My conflict of interest again is that I'm the Chief Medical Officer at Senseonics. Next slide. So the Eversense E3 Continuous Glucose Monitoring system is the only system that has an implantable glucose sensor, as well as a duration of action of up to 180 days for the system. There are three components. There's a very small, fully implanted sensor that is placed in the upper arm. Overlying the sensor is a transmitter that actually powers the sensor and then also gathers the raw data from the sensor, calculates it, and sends the glucose value to an app on the mobile phone. The transmitter is removable and rechargeable and held in place with a gentle adhesive so that this system has low skin reaction rates. The mobile app shows a new glucose readings every five minutes. It shows arrows for directional change of glucose. It elicits alerts for both auditory as well as visual for glucose values that are out of range. |
| The methodology used to measure glucose is different than the other transcutaneous systems. Our methodology is a fluorescent optical technology, and the others use a chemical reaction. We are approved by the FDA as of February, 2022 for adults with diabetes. And the sensor is inserted by trained and certified healthcare providers. Next slide, please. So, we are very excited about the removal of the requirement that the beneficiary be insulin treated with three or more daily administrations of insulin or use of a continuous insulin infusion system, insulin pump, and that the LCD also has a history of problematic hypoglycemia. So the updated criteria for coverage of ICGM better reflects the current clinical evidence and standards for the reasonable and necessary use of CGM, since there is a robust body of evidence in the medical literature supporting this position. There are a number of important randomized controlled trials that have shown the benefit of using CGM and type 2 diabetes patients who use basal insulin only rather than take multiple daily administrations of insulin or use a Medicare covered insulin pump. There have been three systematic reviews with meta-analysis showing that CGM use in patients with type 2 diabetes compared to SMBG actually allows for a greater reduction of the hemoglobin A1C value, which reflects glycemic control. |
| There have been two prospective clinical trials showing that clinically significant episodes of hypoglycemia go undetected without CGM in type 2 patients, either using insulin or being treated with non-insulin regimens. And in addition, the major Professional Diabetes Associations in the United States have made favorable recommendations for the use of CGM, particularly in patients with type 2 diabetes on basal insulin only. Next slide. So for this LCD DL38664, for the implantable CGM category, the changes in coverage are in concert with the medical literature and the positions of the major Professional Diabetes Associations, and the updated coverage criteria provide parity to coverage criteria across all CGMs, whether it's DME now and implantable. However, we respectively request that first coast add all relevant ICD-10 diagnoses to the DA58136 so that both DME, CGM, LCD, and First Coast Part B I-CGM have parity across the ICD-10 diagnoses. Next slide, please. In our official comment submission, we will provide a list of 81 ICD-10 diagnoses codes not currently included in the DA58136, but are included in the DME CGM LCDs. And of course, this creates confusion among providers who are looking for consistency across covered diagnoses. And we do feel that it is essential that the following more commonly used ICD-10 diagnoses be added, and these are listed here. Next slide. |
| So in summary, Senseonics appreciates First Coast's timely review of the ICGM LCD to bring coverage criteria parity across all CGM systems. We support the updated coverage criteria included in the proposed LCD DL38664 for implantable CGM. And we do request that the draft coding article DA58136 include the requested ICD-10 codes to ensure parity across CGM systems. And I thank you very much for your attention and quite appreciative of being able to present today. |
| Dr. Benita Jackson  Thank you so much, Dr. Kaufmann. We also appreciate your participation as well. Since there are no additional presenters for this proposed LCD, we are now going to move to the last topic under discussion, a brief overview of the proposed LCD DL39799, Cervical Fusion. This LCD has been developed as a multi-MAC collaboration to create a uniform LCD with other MAC jurisdictions. Treatment of cervical radiculopathy can range from conservative management to surgery. This policy provides clarifying language and supporting evidence for the use of cervical fusion surgery. Highlighted are considerations of symptomatic cervical nerve root impingement, isolated chronic axial cervical pain, decompression of symptomatic cervical canal stenosis, and the required stabilization of the cervical spine. The role of conservative interventions has also been addressed. At this time, as there are no additional presenters, I would like to thank everyone for their participation in today's open meeting. And again, remind you to submit comments in writing before the end of the comment period on March 30th, 2024. We encourage you to submit full text-published evidence supporting your comments that have not been previously submitted. This meeting is now adjourned. |