WPS GHA

Moderator: Noel, Dr. Ella

October 28, 2019

06:00 PM ET

Operator: This is Conference # 8549908

Operator: Ladies and gentlemen, thank you for standing by and welcome to the J8 MAC Contractor Advisory Committee Meeting conference call. All lines have been placed on mute to prevent any background noise. Throughout today's call, there will be moments in which you'll be able to ask a question. You may do so by pressing star one on your telephone keypad. If you need operator assistance, please press star zero and an operator will come online. I will now turn the call over to Dr. Ella Noel. Doctor?

Dr. Ella Noel: Thank you. I'd like to welcome everybody who is attending in person and on the telephone. Dr. Pawlak was not able to attend today's meeting. She's the Michigan Co-Chair. So, I will be calling the meeting to order and running the meeting tonight. We will discuss two draft LCDs. Both were reconsiderations. We will approve the minutes first before we start reviewing those LCDs. As a reminder, this is no longer a closed meeting for this initial part of the meeting at the beginning where we go over the policies. The CAC meeting will be followed by a closed educational meeting. The educational meeting is not considered part of the open CAC. If you continue to stay on the line and if you speak, that will be an assumed allowance for us to record your voice and note your comments in the minutes of the meeting. They may also be noted in the draft LCD as it goes final.

If you do not want to be quoted, or be known to be at this meeting, then please disconnect from the call. We would also appreciate that you clearly identify yourself if you are speaking or asking a question about the draft or during the educational meeting and please remember that we would like you to follow up any verbal comments with written comments at medicarepolicycomments@wpsic.com.

The comment period lasts for a total of 45 days once the draft policy is posted, and for these drafts, it ends on November 10th of 2019.

Can I have somebody approve the minutes from the last meeting in June? Dr. Di Lorenzo has approved them. Can I have someone second them? Dr. Sengstock has given a second. If anyone has any comments or -- send me an email so that I can make corrections for them.

At this time, we'll move on to the draft LCDs. The first one is DL35490 Category III Codes. This policy is supervised by Dr. Kettler and Ann Everson. We had two separate reconsideration requests for this LCD. The first one was for 0254T, endovascular repair of iliac artery bifurcation, using bifurcated endograft from the common iliac artery into both external and internal iliac arteries and/or nonselective catheterizations required for device placement and all associated radiological supervision and interpretation unilateral.

The reconsideration request asserts that evidence supporting the use of the Gore-Tex excluder IDE with the Gore excluder AAA endoprosthesis is sufficiently robust to support that it is reasonable and necessary under the statute and the LCD. Wisconsin Physician Services Government Health Administrators does not agree. The literature submitted for review is mostly retrospective studies with limitations well outlined by the respective author. WPS GHA believes that the author’s caution is warranted. Coverage is denied at this time. Do we have any comments in the meeting on this reconsideration for 0254T?

We have no comments in the meeting. Do we have any comments on the phone about this portion of the reconsideration? Ian, you can open up the phone lines to the CAC members.

Operator: Again, that's star one if you have a comment. At this time, I'm showing that we have no comments over the phone.

Dr. Ella Noel: Okay. If you have any comments that you like to send this in writing, please send that to medicarepolicycomments@WPSIC.com. Next, we will look at the second portion of the reconsideration for this policy. This was about 0355T, Gastrointestinal Tract Imaging – Intraluminal, eg. Capsule Endoscopy-Colon, with Interpretation and Report.

The reconsideration request asserts current published evidence and FDA approval support PillCam Colon II as a safe, effective and clinically meaningful diagnostic option in patients after an incomplete colonoscopy, or for patients with evidence of a lower GI bleed with major risk for colonoscopy or moderate sedation. Wisconsin Physician Services Government Health Administrators does not agree.

The literature submitted for review is mostly preliminary studies with an unjustified sample size with limitations well outlined by the respective authors, as well as the associate editorials that were provided. WPS GHA believes that the author's caution is warranted, coverage is denied at this time.

Do we have any comments in the room on this portion of the reconsideration? We have no comments in the room. Do we have any comments on the phone line, Ian?

Operator: Again, that's star one if you have a comment. And at this time, there are no comments over the phone.

Dr. Ella Noel: Thank you, Ian. I'm going to go on to the next draft. This is DL37228. This is Wound Care. Dr. Ryan Holzmacher is responsible for this draft LCD reconsideration and policy nurse, Kathy Fisher, works with Dr. Holzmacher. We had reconsideration request to expand the list of allowable conditions in the LCD to include diabetic foot ulcers, chronic non-pressure ulcers limited to break down of skin, and stage II ulcers for the service of debridement CPT codes 97597, 97598. Reconsideration also requests diabetic foot ulcers listed separately and stage II be listed under the coverage guidelines. Revision of language for clarification and coverage guidance and associated information to expand therapist acting within their scope of practice and life insurer may provide debridement services codes 97597 through 97598.

Revision of language to include therapists were previously limited to physical therapists. Documentation clarification to include physician orders for therapy/wound care services and fine plan of treatment also known as the plan of care detailing treatment modalities for therapy, wound care services must be established before treatment.

Overall conclusions: diabetic foot ulcerations; number one, no study was presented to show clear evidence the debridement improves ulcer healing once they suggested high frequency debridement improves ulcer healing. There was no data analysis to support this finding and shows statistical significance, one study evaluates the DPI and indirectly measures the affected debridement on diabetic foot ulcers. It is noted, however, that all ulcers debrided were classified as neuropathic ulcers.

Number two, studies repeatedly described pressure keratosis or callous debridement to prevent diabetic ulcer, the provider request for diabetic

and non-pressure ulcers. As far as stage II ulcers, no study was submitted that specifically addresses stage II debridement. No study discussed outcomes the debridement in any stage. Studies presented referred to class C evidence and supported debridement and debridements may decrease the time to healing. Non-pressure limited to breakdown of the skin, no studies presented addressing debridement for this. Frequent discussion of treatment of pressure keratosis to prevent ulcers.

Recommendation: no change to the current LCD coverage guidelines. At the open meeting, last Monday, October 21st, we did have a presenter at the open meeting, five guidelines from various societies that deal with diabetic wounds. Those were forwarded to the J8 CAC members. They were not sent to the J5 CAC members because by the time we received, the J5 CAC was over. I do want the minutes to reflect that this was done as requested by the presenter. At this point in time, I will ask for comments from the room, and the floor recognizes Dr. Sengstock.

Dr. Jodie Sengstock: Hi. This is Dr. Jodie Sengstock, and I represent Michigan Podiatric Medical Association as well as the American Podiatric Medical Association. We have the issues that you brought forward. WPS policies are inconsistent when we double check for the treatment of wound. This is the gold standard. Debridement is the gold standard of any wound. One thing that I'd like to say especially on the bottom of the foot where we deal with a slight bit, we don't even know what the stage is until we've done the debridement. So, I can't tell you whether or not only by looking at it with [unintelligible] or product issues it's stage II, III or IV [unintelligible] because we don't measure that until afterwards. It's universally and widely accepted best practice for any wound exhibiting balance issues, the debrided wound regardless of any wounds or cost.

So, that goes to both stage II and diabetic ulcers. We have an issue with the fact that diabetic ulcers are taken out if they are due to neuropathy or ischemic ulcers. They're also pressure ulcers. In diabetes, this has quite often especially in the bottom of the foot and ankle. So, we believe that the word diabetic needs to be put back in there because it looks right now as if it is a pressure ulcer, then we cannot treat with debridement or we can't get page driven. This causes the problem because as we all know diabetes is on rise and pressure ulcers that we deal with all the time are a major problem with our population getting older, fatter that's being realistic here and you get more and more pressure ulcers in the bottom of the feet, which increases -- if we can't debride them and we

wait until they're stage III or stage IV like I mentioned before, we don't know until we've done debridement which stage they are.

Then we're increasing our obesity in mortality rate, which knowing risk for patients such as increased cost for healthcare. One diabetic that goes on to an indication like $50,000, the cost of debriding a wound at stage II is very minimal. They also have an issue that 97579, 97578 do not have a diagnosis code for a physician to use. So, as it stands right now, there's no diagnosis code for physicians and the therapist, that was meant for physical therapy 11040 and 11041 were replaced by these codes that were used by physical therapists, and now, we don't have a diagnosis to use it.

Our other issue is the NCD compared to the LCD. There are five MACs right now that don't have this issue. WPS seems to be the only one that has this issue with stage II ulcers as well as diabetic, nonischemic, non-neuropathic ulcers. The reason why they are not allowed to study, and our association agrees that there needs to be research done to back up what we're doing, however, the code standard has been through multiple, multiple decades. So, there is no IRB that would allow a study to happen that someone isn't debrided and then someone else is debrided because we know that that's correct gold standard of care. So, our major concern is that if we leave these two sections out that it's going to increase the risk for morbidity and mortality as well as increase healthcare costs and don't think that this is doing anything to decrease healthcare cost.

Dr. Ella Noel: Dr. Evans, do you have any comments that you want to make?

Dr. Evans: I apologize for being late.

Dr. Ella Noel: And no is fine. We've received a lot of comments.

Yeah or if waiting, we'll see what's on the phone and give you a little time to gather your thoughts. Okay, and do we have any comments on the phone?

Operator: Once again that's star one if you have any comments. Indeed, we have a comment from the line of Wendy Winckelbach. Doctor?

Dr. Ella Noel: Okay.

Dr. Wendy Winckelbach: Hi. This is Dr. Wendy Winckelbach. I represent Indiana Podiatric Medical Association, and I would just like to second everything that Dr. Sengstock has just said, but I would also like to add that I have read all of the articles that were sent this week and every single one of them list debridement as an accepted or the gold standard techniques and management of diabetic ulceration. So, your own data also lists debridement as important in the care of ulceration. So, I would just like the record to reflect that even information that you guys are looking at talked extensively about debridement, and I'll leave it at that. Thanks.

Dr. Ella Noel: Thank you. Ian, would you see if there are any other commenters on the LCD draft?

Operator: Indeed, we do have one more. The next commenter is from the participant line of Dr. Don Selzer. Your line is open.

Dr. Ella Noel: Dr. Selzer, can you tell us who you represent?

Operator: Dr. Selzer, your line is very faint. Could you please pick up the handset?

Dr. Ella Noel: Dr. Selzer, I can't hear you, if you're speaking right now.

Dr. Don Selzer: Sorry about that. I'm a general surgeon that represents Indiana and I would like to concur with the comments provided by -- regarding the debridement of diabetic foot ulcers.

Dr. Ella Noel: Okay. Thank you. Dr. Evans, are you ready to make any comments right now?

Dr. Evans: I believe Dr. Sengstock probably presented --.

Dr. Ella Noel: Okay. I just want to give you an opportunity. Ian, do we have anyone else who wishes to speak?

Operator: Again, that's star one. No other comments on the phone at this time.

Dr. Ella Noel: Okay. I quickly want to go through the other LCDs that were draft for the open meeting last week that do not need to come to the CAC because they're not controversial. Most of them are MolDx, and they were new policies. There is one “Combinatorial Pharmacogenomics” that was a limited coverage policy. We had an “Oncotype Dx AR-V7 Nucleus Detect

for Men with Metastatic Castrate-resistant Prostate Cancer”. That is a limited coverage policy.

We had a MolDX policy on this called “DecisionDx Melanoma” and this is also a limited policy. We had a “Pharmacogenomic Testing” policy, again MolDX, with limited coverage. Then we had several drafts on “Tests on Allograft Kidney Biopsy Tissue to Assess for Graft Rejection.” We had another policy on “Select MDx for Prostate Cancer,” again a limited coverage policy. We had another MolDX for “Decipher Biopsy Prostate Cancer Classifier Assay for Men with Favorable Intermediate Risk Disease,” again a limited coverage policy. We had another MolDX policy, “Erythrocyte Molecular Antigen Testing,” which was limited coverage.

Another limited coverage MolDX for “Razor 14 Gene Lung Cancer Assay” and another one for “Repeat Germline Testing.” Finally, the last one MolDX with “Signatera and Minimal Residual Disease Testing for Colorectal Cancer,” again a limited coverage policy. There was one other additional reconsideration for “Erythropoiesis Stimulating Agents.” We had a request to add a new group for coverage under myelofibrosis and that will be added. Unless there are other comments that make us change the draft, then we will allow primary myelofibrosis to receive ease to coverage as part of the LCD both for Aranesp and Procrit. All right. That will conclude the CAC portion of the meeting that is open. The people who are on the public line should be disconnected. The people on the CAC line should continue to stay so that we can continue with our comments for tonight's meeting.