WPS GHA

Moderator: Dr. Ella Noel
February 18, 2019
Contractor Advisory Committee
6:00 pm ET

OPERATOR: This is Conference #8361719

Operator: Good evening. My name is (Donna) and I will be your conference operator today. At this time, I would like to welcome everyone to the J8 MAC Advisory Committee Meeting conference call.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session.

If you want to ask a question during that time, simply press star then the number 1 on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you. I would like to hand the call to your speaker for today, Dr. Ella Noel. Ma'am, you may begin.

Ella Noel: Hi, this is Dr. Ella Noel for the J8 Medicare Administrative Contractor Advisory Committee meeting. The (policy) agenda is subject to change as far as the order that is listed. We'll call it to order – this meeting to order at this point in time and will introduce the WPS staff that is present.

Mary Muchow: Good evening, everyone. My name is Mary Muchow. I represent the Provider Outreach and Education department at WPS GHA.

(Melissa Jacobs): Hi, my name is (Melissa Jacobs). I am the Policy Coordinator at WPS J8.

Ella Noel: And also joining us is (Ann Giberson), one of the other Policy Coordinators. She's tied up right now. Normally, we would approve the minutes and then have a section from Provider Outreach.

We're going to go directly to the draft LCD today. The draft LCD that we're looking at is a MolDX LCD decision diagnosis melanoma. It's DL number 38018.

With the changes in the LCD process, we are going to have kind of a hybrid meeting today. The draft has already been posted to the Internet. They may not be posted in the future, that we just assess evidence and ask a few questions.

This is a catch up MolDX document. These have already been taken by the other members of the MolDX joint operating agreement which includes Palmetto, Noridian and CGS. Since the last joint J8, we've been trying to catch up with all of the policies and this will be the last one that we have to catch up.

So, this LCD or this policy is going to provide limited coverage, clinical stage sentinel lymph node biopsy, eligible patients with T1b and T2 cutaneous melanoma tumors with clinically negative sentinel lymph node biopsy to be considered for SLNB for determining – to determine the eligibility for adjunct therapy. The policy had definitions for a T1a and a T1b as well as T2 tumors.

Why is this LCD important? Melanoma is increasing in incidence in the United States. To give you some information on this test, it is a 31-gene expression profile that determines the patient's risk for metastatic disease.

Results are classified as low Class 1 or high Class 2 risk for developing the disease within five years to diagnosis. The results of this test can be used as a guide for the use of sentinel lymph node biopsy.

This will improve net health outcomes by accurately identifying patients who are at risk for developing metastatic disease and otherwise go undetected as well as patients with a low likelihood of having a positive sentinel lymph node.

Low-risk patients can consider avoiding surgery along with the risk of anesthesia and as well as avoiding the intensive follow-up and radiation from imaging procedures.

Points about sentinel lymph node biopsy, positive results demonstrate increased risk for distant metastatic disease and death, provide prognostic information only, provide prognostic information only, provide low survival benefit.

The procedure can result in complications such as pain, (inaudible) nerve damage and edema. The prognostic value is limited in elderly patients.

National guidelines recommend it be done in all patients with stage T1b and above and in those with stage T1a where there is significant uncertainty about the adequacy of microstaging.

Clinically – the clinical validity of this test accurately predicts the risk for local and regional recommendation occurrence, distal metastasis and melanoma-related mortality.

So, what we are going to do in the future is discuss the evidence before we write the LCDs so that we can get your input on that process. So, we will formulate questions to ask the CAC members about the evidence and the policy itself.

So, since this is just a new process, I know we may not get a whole lot of response, but this draft LCD limited coverage makes sense to you based on the evidence that was provided in the policy.

Any responders from the phone line? You can have them also answered, (Donna). (Donna), would you open up the lines for those CAC members that wish to make comments?

Operator: Ladies and gentlemen, if you would like to ask a question, please press star then the number 1 on your telephone keypad.

Again, please press star then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. We have a comment from the line of Joseph LaRosa. Your line is now open.

Joseph LaRosa: Thank you. This is Dr. LaRosa with Indiana ACOG. And Dr. Noel, I would definitely support this – your proposal.

Ella Noel: Thank you. (Donna), if there are (inaudible) to make a comment, I'm going to go to my second question. Does the draft LCD need additional evidence to limit coverage or are you satisfied with the evidence that is available?

Operator: We have another comment from Mr. (Edward Foti). Your line is now open.

Ella Noel: OK.

(Edward Foti): I can't find the copy of this LCD. I don't know what happened to it. Could you resend it please?

Ella Noel: Sure.

(Edward Foti): I would like to see it.

Ella Noel: And it's always available on our Web site.

(Edward Foti): OK, thank you.

Ella Noel: You're welcome. The third question is, are the coverage options clearly stated in the draft LCD? Any comments, (Donna)?

Operator: We have a comment from the line of Mr. John Salter. Your line is now open.

John Salter: This is John Salter with General Surgery in Indiana. We're supportive of the LCD and answer both questions in the affirmative that were supportive of its current statement.

Ella Noel: Great. Now, any general comments that anybody else wishes to make from the CAC line?

Operator: Again, for your comments, please press star-1 on your telephone keypad. There are no comments on queue. I'm sorry, we have a comment from Ms. (Anne Pollock). Your line is now open.

Ella Noel: OK. Hi, (Anne).

(Anne Pollock): Hey, how are you doing? I'm very sorry, I just got finished with work and I'm on my way, but I don't think I'll be there till about 6:45, so I don't know how

long the meeting will be, but I'm more than happy to still keep going. I can stay online. But I just wanted to say I support on this particular issue as well, so.

Ella Noel: I appreciate that, (Anne). (Donna), do we have anybody else who wished to make comments during this part of the meeting?

Operator: We have – we have another comment from Gary Dillon. Your line is now open.

Gary Dillon: Oh, hi. I just now was able to get this thing to work so that I could speak. I'm a dermatologist in Indiana. And I was speaking with one of my colleagues who's (involved) in melanoma.

And he had some reservations about this and he asked if there was – if you reviewed these things after two or three years, and I said I don't know. Can you – do we ...

Ella Noel: That is a question in general about MolDX. Some of these tests do have additional information that becomes available later.

So, some things that we have no coverage or limited coverage may have expansion of coverage as more information becomes available. And if something else in the negative were to show up then we could remove coverage.

Gary Dillon: Yes. My colleague that is an expert in melanoma, which I don't claim to be, was concerned that he didn't feel that there was enough evidence to really tell which was better, lymph node – the sentinel lymph node or the molecular, and throughout the more (proactive) studies needed to be done.

And they also had some concerns that it might be used correctly and could lead to more lymph node biopsies and more (experience). So, I think if we can review – if we can – we probably should review this at some point along the line and see actually how it is working if we do indeed go ahead put this through.

Ella Noel: Sir, could you have him send us a written comment to our Medicare Policy Comments Web address so that we can make note of that in our Respond to Comments document?

Gary Dillon: Yes. And I don't want to take up everybody's time here but I'm not sure how – where to have this sent?

Ella Noel: I will send out a usual post-CAC email blast and I will include that address then and then you can forward that to your person who is the expert in melanoma so we can incorporate his comments.

Gary Dillon: Yes, OK, that would be very good. Thank you very much.

Ella Noel: You're very welcome.

Operator: There are no questions or comments at this time. Please continue.

Ella Noel: All right, (Donna). That concludes the portion of the meeting that needs to be open for the non-CAC members. (Donna), you can disconnect the lines of the observers. Do not disconnect CAC members, however.

Operator: OK, thank you.

Female: Thank you for attending.

Ella Noel: Thank you, everyone.