

WPS GHA

**Moderator: Dr. Robert Kettler
January 21, 2019
Contractor Advisory Committee
4:00 pm CT**

OPERATOR: This is Conference # 4029066.

Operator: Good evening. My name is (Raffy), and I will be your conference operator for today. At this time, I would like to welcome everyone to the J5 MAC Advisory Committee Meeting.

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 would like to queue for a question during this time, please press "star," "one" on your telephone keypad. If you would like to withdraw your question, please press the "pound" key. Thank you. Dr. Stauffer, you may begin your conference.

Bradley Stauffer: All right. Thank you, everybody, for joining us. I appreciate you being on the line. We're going to actually move things just a little (bit here). We're going to go ahead and bring our draft LCD up to the top and we're going to go ahead and take care of that first there. And, then, we'll do the housekeeping toward the end.

So, we're going to go ahead and start with draft local coverage determination DL38018, MoIDX Melanoma. And I will turn it over to Dr. Kettler and let him give us a little information on that.

Robert Kettler: OK. Thank you, Dr. Stauffer. This is, again, a proposed draft LCD. It would be a limited-coverage LCD. And it addresses the clinical stage (set in the) lymph biopsy eligibility for various types of (continuous) melanoma tumors that do have clinically negative sentinel node biopsies.

This is to determine eligibility for adjuvant therapy. This particular test is a 31-gene expression profile that determines the patient's risk for metastatic

disease. The results are classified as low or high risk for developing metastasis within five years of diagnosis.

The results can be used as a guide to the – to the use of sentinel lymph node biopsy. And it is expected that the test will improve health outcomes by accurately identifying patients who are at risk of developing metastatic disease and would otherwise go undetected as well as patients with a low likelihood of having a positive sentinel lymph node biopsy. Low-risk patients can consider avoiding the sentinel lymph node biopsy along with any risk of anesthesia or surgery as well as avoiding the intensive follow up and radiation from the imaging procedures.

That is the draft LCD. As I said, it is a – would be a limited-coverage LCD. And do we have any comments from the participants on this LCD – on this draft LCD?

Bradley Stauffer: (Raffy), if you could see if there's any comments on the participation line.

Operator: Yes, sir. Again, if you would like to have a comment or question, you may press "star," "one" on your telephone keypad. Sir, there are – there are no comments or question. You may continue.

Bradley Stauffer: OK. With that, we will move on. And I think actually the observer line we can drop off, if that is OK, and we can just keep the participant line on.

Robert Kettler: Yes. As a courtesy to our observers, we will excuse them at this time because the open portion of this CAC meeting has been completed. I do want the CAC members to remain on the line.

Bradley Stauffer: OK. (Raffy), are we ready to go?

Operator: One second, sir. We are still trying to drop every listen-only line. One second, sir.

Bradley Stauffer: OK.

Operator: I will let you know, sir, once we are done.

Bradley Stauffer: OK.

Operator: Hello, sir. You are now ready.