WPS GHA
J8 Contractor Advisory Committee Meeting

Moderator: Dr. Ella Noel
June 22, 2020
6:00 PM ET

OPERATOR: This is Conference #: 2967417

Operator: Ladies and gentlemen, thank you for standing by and welcome to the J8 MAC Advisory Committee Meeting.

At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a question and answer session. To ask a question or make a comment during the session, you will need to press star one on your telephone keypad. And please be advised that today's conference is being recorded. If you require any further assistance, please press star zero.

I would now like to hand the call over to your first speaker, Dr. Ella Noel. Please go ahead, Ma'am.

Dr. Ella Noel: Hi. I want to welcome everyone to the J8 Medicare Administrative Contractor Advisory Committee Meeting. This is an educational meeting. There is not an evidentiary component tonight.

I would like to introduce the WPS staff. I'm going to just list the name for you, Rich, our administrative assistant, policy coordinators: Beth, Ann, Kathy, Melissa, and Melissa. We have Mary from Provider Outreach and Education. We have four members of the insight team presents today, Matt, Matthew, Laura, and Scott. Dr. Kettler is also on the line. He is our J5 contract medical director.

And I'd like to introduce a new addition to the WPS family Dr. Barry Whites. Dr. Whites, would you like to say a few words at this time?

Dr. Barry Whites: Yes, thank you very much. As part of an introduction, that first of all, I certainly appreciate being at WPS in Jackson, Mississippi, and I've been here in Mississippi, all of my life went to that Ole' Miss place and have graduated

University of Mississippi Medical Center. And then did internship and residency in internal medicine and specialty in pulmonary. And I'm boarded in both internal medicine and pulmonary.

And did kind of practice a pulmonary medicine here in Jackson, pulmonary consultation for 38 years, 11 years of those that I was also a part time medical director for fiscal intermediary for Part A (TriSpan) for Mississippi, Louisiana, Missouri, and that was in 2000 and 2011.

At that point in time, (TriSpan) lost the contract and I was not moving to Little Rock with my wife and children told me nor to Dallas later on, and asked should a position become available to work remotely to please give me a call.

In 2015, I received a call from the MAC in that jurisdiction and accepted a job as a medical contractor. I joined here approximately almost two months ago, and I've really enjoyed. I've known Ella and Bob for some time with our meetings, conversations, conference calls, et cetera, and look forward to meeting you and dissipating and contributing as much as I can to WPS.

Dr. Ella Noel: Thank you much, very much, Dr. Whites. We'll go ahead and start the discussions on the draft policies for tonight. I just want to as a way of an introduction open up that the J5 and J8 open meeting was held on June 17th, 2020. Because of the public health emergency, it was done over the telephone there was no in person meeting.

We had eight LCDs presented during this meeting, and we will discuss those eight LCDs tonight. There were six outside presentations given. Two of them were on continuous glucose monitoring and four were on the transurethral water jet ablation for lower urinary tract symptoms and BPH.

If you did not attend the meeting and you would like to listen into the meeting, you can go to the WPS GHA web portal and click on the link to listen to that open meeting. Remember, the comment period for the draft that we're discussing is currently open until July 11th of 2020. And written comments are requested at medicarepolicycomments@WPSIC.com.

If you make oral comments today, please follow them up with written comments at our website. And we'll get started on the policy. The first one is the fluid jet system treatment for lower urinary tract symptoms and BPH. I am the lead contractor on this policy for WPS.

This was part of a National Work Group Policy. It's DL38682. We did not have an evidentiary CAC for this draft because one was held by another MAC earlier when they develop the policy initially. This LCD addresses the use of fluid jet system treatment of the low urinary tract attributable to BPH.

Treatment by this method will be allowed once for lifetime and patients with the following indication. Currently, it is age less than or equal to 80. Prostate volumes of 30 to 80 cc by transrectal ultrasound, persistent moderate to severe symptoms despite maximum medical management including all of the following, an international prostate symptom score of greater than or equal to 12, maximum urinary flow rate of less than or equal to 15 milliliters per second, failure, contraindications, or intolerance to at least three months of conventional medical therapy. They can either have known or suspected prostate cancer with a PSA greater than 10 or other pivotal study exclusion criteria.

At this time, we will take comments or questions from the CAC members about this policy. Please push star one and (Maria) will catch you into the – ask those questions.

Operator: OK. And please press star one if you would like to provide a comment or a question.

And we don't have any questions at this time.

Dr. Ella Noel: All right, thank you. I'm going to go on to the next policy. This is the – one of the five MolDX policies. It's Breast Cancer IndexTM Gene Expression Test. I am the lead on the MolDX policy. This is DL37913. The comment document will be done through Palmetto. We gather our comments and send them forward. And they answer them.

This LCD is being presented for comments due to a receipt of a reconsider request. Coverage over patients with N1 status as opposed to N0 status has been added. There was an update in the bibliography and analysis of evidence as well as coverage indications, limitations, and for medical necessity.

Do we have any comments or questions on this draft?

Operator: OK. And again, if you have any comments or questions, press star one on your telephone keypad. OK.

Your first comment or question comes from the line of Pieter Wiersema. Your line is open.

Dr. Pieter Wiersema: Yes. Before this meeting, I checked with one of our oncologists, and he's not really familiar with this test, but he is familiar with the Oncotype DX test that they use for patients with this type of breast cancer.

Ella, could you comment what the advantages of this test is, or if there's any indications other than what you've stated in your – in this thing over here?

Dr. Ella Noel: Sure. I'd be glad too.

So this LCD provides limited coverage for this test, which is a gene expression test for the management of postmenopausal women diagnosed with early stage node negative ER positive non-relapse plus or minus PR positive HER2-negative breast cancer. That's a mouthful, who are being or will be treated with primary adjunct endocrine therapy.

This test is used to provide a genomic base estimate of distant recurrence risk when considering the addition of chemo and or late distance – distant recurrence risk and endocrine responsiveness when considering extension of endocrine therapy depending where in care testing is completed.

Evidence shows that the BCI tests both predicts disease recurrence and for some patients also predicts response to adjunct therapy. NCCN guidelines explicitly recommend the use of not only clinical characteristics, tumor staging

topology, but also consideration of the inclusion of a gene expression classifier.

Does that information help?

Dr. Pieter Wiersema: Yes. I just don't understand the utility of this if there's other tests available, you know, and particularly in terms of endocrine testing or endocrine forecasting because I think most women, if they had breast cancer with either ER or just progesterone positive markers would be, you know, would be foolish not to undergo some kind of – not to undergo some type of endocrine modification of their, you know, like Tamoxifen or other drugs, you know.

Dr. Ella Noel: It's my understanding that they use this to help decide whether they're going to do five years or 10 years.

Dr. Pieter Wiersema: OK. Endocrine therapy?

Dr. Ella Noel: Yes. Of endocrine therapy.

Dr. Pieter Wiersema: Well, knowing that …

Dr. Ella Noel: You know, because there is some attendant risks to taking the, you know, the estrogen or excuse me, the aromatase therapies and stuff for a longer period of time.

Dr. Pieter Wiersema: Yes, but I think that probably is outweighed by the risk of anesthetic cancer, you know, so I'm just kind of confused. I mean, we get more and more of these tests, and I checked with my oncologist and he's not even familiar with this test. So I'm just confused about it. That's all.

Dr. Ella Noel: Yes, I understand. And, and one of the things that we're going to try to do moving forward in the MolDX program is try to develop platform LCDs for similar types of tests rather than individual LCDs each time.

Dr. Pieter Wiersema: Yes. I mean, to me, you know, there's, you know, with limited funds I, you know, I'm just wondering, you know, because there's now a new treatment for

HER2-negative estrogen negative progesterone negative therapy, which I mean, breast cancer, which seems to be very do very well.

And I'm just wondering, you know, like in this situation, but why, why tell a woman that she only has to take, you know, Tamoxifen or the other newer one for five years, you know, and, you know, if that's the indication for this test, and I don't understand it.

Dr. Ella Noel: Yes. (Peter), I will look into it a little bit more and get some more details and reach out to you after the conference later this week.

Dr. Pieter Wiersema: OK. All right.

Dr. Ella Noel: All right. Anybody else have any questions or comments?

Operator: Yes, Ma'am. And we have a question or comment from the line of Joseph LaRosa. Your line is open.

Dr. Joseph LaRosa: Hi, Ella. This is Joe. Quick question for you along the same other callers' question. Do you guys ever kind of dovetail up with the Milliman guideline criteria? So the note a lot of the commercial insurance covers that as some of the MA plans.

I'm just kind of curious just – it's very, very dicey some time for the doctors to decide is this one covered, is this not covered. I just didn't know is there anything kind of decisions to maybe dovetail some decision making with both entities?

Dr. Ella Noel: I will bring that up at our MolDX meeting that we have with Palmetto.

Dr. Joseph LaRosa: Thank you.

Operator: And your next comment or question comes from the line of David Macari. Your line is open.

Dr. David Macari: Sorry, I'm an oncologist. So I can speak to the first question about the BCI. It's so the utility is some – not all women need to (ensure) AI with early stage, ER PR positive HER2-negative breast cancer.

So there's a trend towards the node positive patients leaning towards 10 years of AI. And the question is always, who do we not need to give 10 years? So it's really a question at year five, do we continue or not? So the BCI can help. And the patient that's really interested in continuing to say whether or to have one more piece of information about whether or not they may derive any extra benefit for five years of therapy.

So this is a test that is often discussed. I'm in Southeast Michigan. It is something that is used by some oncologists. So I imagine regionally there may be different practice patterns, but this is definitely a test that is being used and discussed in Southeast Michigan.

Dr. Ella Noel: Thanks very much for that clarification.

Operator: And Dr. Noel, we don't have any additional comments or questions.

Dr. Ella Noel: OK, great. Great. We had some good discussion there. Let's move on to the next MolDX Policy. It's prognostic and predictive molecular classifiers for bladder cancer. I am the CMD on this policy. It is DL38684. This contractor will cover molecular diagnostic tests for the use in bladder cancer with the following conditions.

The beneficiary is being actively managed for bladder cancer. The beneficiary is within the population and has indications for which the test was developed and discovered. The beneficiary has not had a cystectomy. And BNI he has at least one of these two criteria, candidate for multiple potential treatments, which could be considered to have an ordered intensity based on a consensus guideline. And the physician and patient must decide among these treatments or candidate for multiple therapies and the test has shown that it predicts response to a specific therapy among acceptor therapy options based on a consensus guideline, testing demonstrates an analytical validity.

If it uses an algorithm that must be validated, clinical validity has been demonstrated, and the test completes with technical assessments. For patients with bladder cancer, an array of treatment possibilities exist at all stages of disease. Clinicians must consider not only the potential treatment

options but must also make an individualized risk benefit assessment to determine how to treat specific patients.

Diagnostic tests to aid in this assessment are expected to change physician management in a way that it improves patient outcome. Maria, I'm ready for any comments or questions from the CAC members.

Operator: OK. And again, if you have any comments or any questions, press star one on your telephone keypad.

And we don't have any comments or questions. You may continue.

Dr. Ella Noel: OK. Moving on to the next molecular diagnostic LCD, phenotypic biomarker detection and circulating tumor cells. I am the lead CMD on this policy. Its number is DL38678. This is a limited coverage policy for assays to detect circulating HER2-positive cells. The essays are covered when the patient has been diagnosed with breast cancer.

The cancer has not previously been tested for HER2 or there's a newly metastatic cancer that has not been tested for HER2. Clinical validation includes a comparison to tissue HER2 testing and tissue based HER2 testing is not currently feasible. Do we have any comments or questions on this draft?

Operator: And again, if you have any comments or questions, press star one on your telephone keypad.

And we don't have any comments or questions. You may continue.

Dr. Ella Noel: All right. Next is MolDX liquid biopsies for solid organ transplantations. I am the lead CMD on DL38680. This policy provides limited coverage for liquid biopsies to assess transplanted allograft with rejection status when the following criteria are met.

It demonstrates analytic validity, demonstrates clinical validity by providing information about at least one of the two following clinical status determination that is rejection status and T cell mediated versus B cell

mediated. It's used in a patient population in which the test was analytically validated and has demonstrated clinical validity. It is being used in place of tissue biopsy to make a management decision in a patient. It should not be used in place of a protocol biopsy and transplant centers that do not have a management algorithm for using that kind of testing.

The benefit to risk profile the liquid biopsy is more favorable than the benefit to risk profile of a tissue biopsy or it is not possible to get a tissue biopsy. And the test must complete a technical assessment.

Do we have any commenters or questions from the CAC members?

Operator: And again, if you have any comments or questions, press star one on your telephone keypad.

And we don't have any comments or questions. You may continue.

Dr. Ella Noel: All right, this will be the last MolDX policy for tonight, EndoPredict breast cancer gene expression tests. Again, I am the lead CMD on this policy. And its number is DL37663. This policy is being presented due to a reconsideration request. The LCD was updated to reflect additional published data in the management of breast cancer patients who have received the EndoPredict test and for whom extended endocrine therapy is being considered.

This resulted in changes to the bibliography and coverage indication, limitations, and or medical necessity. This policy allows limited coverage for the EndoPredict breast cancer gene expression tests for the management of postmenopausal women diagnosed with early stage ER positive HER2 negative breast cancer who are either lymph node negative or who have one to three positive notes and for whom treatment with adjunct endocrine therapy is being considered.

Molecular testing has been shown to improve prognostic accuracy compared to standard clinical features. And it's become increasingly important for patients with ER positive HER2 negative breast cancers. This test should not be ordered if the physician is not going to act on the result.

Again, do we have any questions or comments from the CAC members?

Operator: And again, if you have and if you would like to provide a comment or question, press star one on your telephone keypad.

And we have a comment or question coming from the line of Dr. Joseph LaRosa. Your line is open.

Dr. Joseph LaRosa: Hi, Ella. Hi, Ella, again.

So the difference between this fifth one and the first one or just two different companies, I mean, they seem pretty similar? Is that or is there a difference?

Dr. Ella Noel: No. I think you're spot on there. I think they're pretty similar. And that's why I mentioned that we're looking at in the future doing more draft LCDs that will cover more than one potential test. And, you know, avoid having all these new LCDs for each company as they come out.

Dr. Joseph LaRosa: So does Medicare – I mean, if one has ordered versus the other one, do they do the ever choose the least expensive model or we either (inaudible) both approved?

Dr. Ella Noel: Unfortunately, we – yes, unfortunately, we have to leave that to you clinicians to do because we are not allowed to, at this point in time, to (forward you) the cheaper test, the cheaper drug, the cheaper procedure. You get to make the decision.

Dr. Joseph LaRosa: OK. Thank you.

Operator: And your next comment or question comes from the line of David Macari. Your line is open.

Dr. David Macari: Hi. This is Dr. Macari again. So just compare and contrast the two. I'm not actually familiar with the EndoPredict. But a lot of this breast cancer or a lot of these prognostic molecular diagnostics are designed for prognostic value but not necessarily predictive value. So they can tell you who is going to – if a

patient is likely to do better or worse, overall, than, you know, a million other women with two centimeter one lymph node ER positive breast cancer.

But the value in decision making comes in if the test is predictive. So meaning the breast cancer index will predict whether that same woman not only has a better prognosis, but also is likely to benefit from the endocrine therapy or not. So a prognostic tool only tells you how likely a person is to do overall but they don't tell you whether or not a certain intervention will actually additionally improve their outcome.

So an EndoPredict might be able to say, this person with one lymph node is going to do better than the other person with one lymph node. Whereas the breast cancer index might be able to say, it's not only is this person with one positive lymph node is going to do better than that one. But they are also likely to do better than if better with 10 years than five years of endocrine therapy.

So kind of splitting hairs but actually when it comes down to making a clinical decision making impact, a predictive, a validated molecular marker with predictive value actually allows us to change management.

Dr. Ella Noel: Thank you. Do we have any other comments or questions in the line?

Operator: And again, if you would like to have a question or comment, press one on your telephone keypad.

And your next comment or question comes from the line of Edward Fody. Your line is open.

Dr. Edward Fody: Hi, this is Ned Fody. I'm a pathologist in Southwestern Michigan. I found a fellowship in breast pathology and I deal with this stuff all the time. I see hundreds of cases a year.

We're currently using the Oncotype DX, which is molecular test to try and mostly to decide whether or not to give chemotherapy women with low risk. This test aims to be targeted more towards the endocrine therapies such as aromatase inhibitors and Tamoxifen, stuff like that. And I guess it's used to

decide maybe at five years if you're going to have – but at least around here, every breast cancer that strongly positive or even moderately positive for estrogen receptor gets treated with anti estrogen drugs, end of comment.

Dr. Ella Noel: Thank you. Appreciate it. Once again, do we have any further comments or questions?

Operator: Yes, Ma'am. We have a comment or question coming from the line of Dr. Pieter Wiersema. Your line is open.

Dr. Pieter Wiersema: Yes, I think, you know, like the other pathologist said I I'm kind of confused again why, you know, I really would like you to look into this. I mean, let's put it this way. If I was a woman, I had breast cancer, and it was ER progesterone positive, I would certainly be taking these – was that these drugs AI as they refer but one of the oncologist inhibitors, for as long as I could take them.

But regardless of what these test shows, I don't really understand the utility of these tests. And as this pathologist said in his neighborhood, they are also using the same onco diagnostic test, as we're using here in Indianapolis. So I'm really confused about this because it seems like why take a risk that you don't need to take, you know, by stopping to take after five years, you know, it just doesn't make any sense to me. That's all.

Dr. Ella Noel: Well, I will try to get some clarification for you. Any other questions or comments?

Operator: And we don't have any questions or comments. You may continue.

Dr. Ella Noel: OK. The next policy is the percutaneous vertebral augmentation for osteoporotic vertebral compression fracture. Dr. Whites is the lead CMD on this policy. This is part of a National Work Group. And it is DL38213. This LCD has been modified from its original form. The coverage indications, limitations, and or medical necessity, and sources of information and basics for decision have been updated.

This LCD addresses vertebral augmentation for osteoporotic vertebral compression fracture. Coverage will remain available for medically necessary

procedures, for other conditions not included in this LCD. Any questions, any comments?

Operator: And again, if you would like to provide a comment or ask a question, press star one on your telephone keypad.

And we don't have any comments or questions. You may continue.

Dr. Ella Noel: Thank you. That brings us to the last draft for tonight. This is the implantable continuous glucose monitors. Dr. (Cutler) is the lead CMD. This is part of the National Work Group Policy. And there are a number of DL38686.

This LCD will provide coverage when the following criteria are met, the beneficiary has diabetes, the beneficiary has been using a blood glucose monitor and performing frequent testing, and the beneficiary is insulin treatment with multiple daily injections of insulin, or on a Medicare covered continuous subcutaneous insulin pump.

And the insulin treatment regimen requires frequent adjustments on the basis of testing results. And the patient has seen within six months of the ordering device, the treating practitioner for an in person visit and there is an in person visit with the treating practitioner every six months while being used.

Do we have any questions or comments about this policy at this time?

Operator: OK. And at this time if you would like to provide a comment or ask a question, press star one on your telephone keypad.

And we don't have any comments or questions. You may continue, Ma'am.

Dr. Ella Noel: All right, at this point in time, we can release the public line and continue to talk with the CAC members, (Maria).

Operator: OK. Hold on a second.

Operator: Ladies and gentlemen, this does concludes today's conference call. Thank you for participating. You may now disconnect.