**WPS GHA Contractor Advisory Committee (CAC) Meeting**

**Moderator: Dr. Ella Noel**
**October 19, 2020**
**6:00 pm ET (5:00 pm CT)**

OPERATOR: This is Conference # 7359558

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 speakers' remarks, there will be a question-and-answer session. To ask a question during that time, you will need to press "star" "1" on your telephone. Please be advised that today's conference is being recorded, and if you require any further assistance during the call, please press "star" "0."

I would now like to hand the conference over to your speaker, Dr. Ella Noel. Thank you. Please go ahead.

Ella Noel: Hi, this is Ella Noel. I'm the J8 Contractor Medical Director and I want to welcome you to the J8 Medicare Administrative Contractor Advisory Committee Meeting tonight. We will be doing this through teleconference only due to social distancing requirements. I appreciate your attendance and participation. We will start with the CAC meeting followed by a closed educational meeting with the WPS staff and CAC members.

Reminder, this meeting is being recorded. Continued participation indicates your consent for identification in any discussions about the draft policies presented during the Contractor Advisory Committee meeting tonight. If you do not wish to be identified or we do not have your consent, then I would suggest that you drop off the call.

Tonight we have 5 drafts to present. Four of these drafts, the comment period will end on November 14th. The facet injections policy will end on December 12th of 2020. Please send any written comments to medicarepolicycomments@wpsic.com , and I'll give that address again later.

So, we're going to start first with the Colon Capsule Endoscopy (CCE) policy. This is DL38837. Dr. Robert Kettler is the lead CMD on this policy. Colon capsule endoscopy does not require air inflation or sedation and allows for minimally invasive and painless colon evaluation. The patient swallows a vitamin-sized capsule with water. Photos are strung together to form a video.

Based on the clinical literature and systemic review results combined with the consistent positive safety profile, sensitivity and specificity of colon capsule endoscopy in detecting polyps greater than or equal to 6-millimeters, the evidence supports the recommendation (that) colon capsule endoscopy is a suitable alternative to colonoscopy or to CT colonography as a primary procedure in a patients with major risk for colonoscopy or moderate sedation as a secondary procedure for surveillance of colon polyps in previously diagnosed patients where colonoscopy was incomplete or contraindicated.

In addition, colon capsule endoscopy is suitable as a secondary procedure when incomplete diagnostic colonoscopy was performed for either fecal occult blood test positive or for multitargeted stool DNA positive.

It is not medically reasonable or necessary when the patient has a known or suspected GI obstruction stricture or fistula, cardiac pacemaker or other implanted electromedical device, the patient has a swallowing disorder, contradiction or allergy to any medication or preparation agents used before or during the procedure, when performed in conjunction with CT colonography and when performed for colorectal cancer screening.

Do we have any questions from the CAC members or any comments from the CAC members at this time about this policy?

Hello?

Hello?

Robert?

Operator: OK, sorry. For questions or comments at this time, please press "star" "1" on your telephone keypad. Again for questions or comments at this time, please press "star" "1" on your telephone keypad.

We have our first question coming from the line of Joseph Larosa. Your line is open.

Joseph Larosa: Hi, Dr. Noel. This is Dr. Larosa. I know I'm an OB-GYN but I think that there's indication also for some iliac or ileal disease as well that was not mentioned in your summary. So, I just wanted to make sure that would be included in certain situations.

Ella Noel: All right. Would you send that as a written comment to us, Dr. Larosa?

Joseph Larosa: Sure. I would be happy to.

Ella Noel: Thank you. I appreciate it.

Joseph Larosa: Sure.

Operator: And again for questions or comments, please press "star" "1" on your telephone keypad.

Next line will be from Robert Jackson. Your line is open.

Ella Noel: Hi Dr. Jackson.

Robert Jackson: Hello. What are the – what's the yield of something like this? I mean how often do they miss polyps, how often, I just wonder if it's worth it in terms of, if there's much value to this at all? I have some questions about that. I have no idea on the specifics on this.

Ella Noel: Yes and I don't believe...

Robert Jackson: Anybody knows this?

Ella Noel: the policy has that information in it. I know, I reread the policy this afternoon because it's not my policy and I don't remember seeing that. So, that is an interesting question but based on the literature and review results, it's supposed to be sensitive and specific enough to help detect polyps that are greater than or equal to 6 millimeters. So, I'm sure some of it has to do with preps and that sort of thing but, yes if you want, send that question in and we'll see if we can get answer for you.

Robert Jackson: Yes. Part of the reason I questioned it is that so often we have one study and then let's do another study and let's do another study and we don't add up. You know what I mean? There's no – there's no step to this – there's oftentimes no step to this. In other words, you could just do everything and not gain any further information. So, I just – that's all.

Ella Noel: Yes and I understand what you're saying and they should be following the diagnostic and surveillance purposes, they should be following the criteria that are outlined in the policy. It's a primary procedure in patients with major risks for colonoscopy or moderate sedation and they have to have had a positive fecal occult blood test or a multitarget stool DNA test that's positive.

And then, it's a secondary procedure when surveillance of polyps is needed if the colonoscopy was incomplete or an incomplete colonoscopy was performed for either positive fecal occult blood or a multitarget stool DNA as positive. So... ...

Robert Jackson: OK. So I get that, I guess what I'm getting to is, so they can't have a colonoscopy because they're too sick for some reason. So, why do you need to know that they have polyps when you – and/or cancer when you can't do anything about it? Because if they can't take a colonoscopy, they certainly can't take a colectomy. That's just my way of looking at it, so.

Ella Noel: Yes. I understand where you're coming from. I guess maybe a different example would be somebody is too high risk to take off their blood thinners and you just want to take a peek. I mean I guess you could use a colonoscopy for that as well but maybe, I guess that wasn't that great of an example, never mind.

Robert Jackson: No, I get it. Yes, OK, thanks.

Ella Noel: Yes but I understand what you're saying. It just seems like there can be quite a bit of different testing that can be done and in some patients you do wonder if things are overdone because one test leads to another test.

Robert Jackson: Thank you.

Ella Noel: Any more questions? Thank you.

Operator: Next question will be coming from the line of Dr. Zuhair Yaseen. Your line is open.

Zuhair Yaseen: Yes, this is Dr. Yaseen. I'm a gastroenterologist from Indiana. I think I can answer some of the questions that were brought up as we – we already have the technology for the small bowel disease and we have been using it for years, and if the yield is small for the small bowel disease, but it is – it is very useful. Now this is, I think, we've been waiting for this technology for quite some time and we're all aware of the implication.

I think the questions asked about, well can it missed polyps? Of course, actually if anything, I think it will be complementary to the colonoscopy. Colonoscopy can miss up to between 5 and 20 percent of polyps, depending on the size. So, I think in, if anything, this might be complementary and would probably see more.

And, also I would – I would say there is maybe 2 or 3 percent of people we cannot reach the cecum for many reasons and we struggle and sometimes if you push too hard, you can perforate someone. There are also a lot of patients with anemia of unclear etiology. We can't really tell and it could be a small AVM. We cannot really see it with the bowel – with the colonoscopy.

So as I was listening, it is indicated for certain selected indications. I'm sure there will be precertifications and a lot of hurdles to go through but I personally think this technology already in use, they just perfected it, so we can get it into the right place. And, I think the example that you mentioned about the blood thinners is an excellent one. We have seen that many times people could end up with stroke or even MI by trying to do the colonoscopy.

So, you can see that an AVM or something that's really may not be that serious. So personally, I think it is the questions asked are very – they're excellent and valid but I think from a perspective of a patient, knowing what the etiology of their bleed and from perspective of a GI doctor to decrease cost by doing multiple colonoscopies to look for the same thing it might be helpful. And, I'll stop right here. Thank you.

Ella Noel: Thank you very much for the compliment. We appreciate that.

Robert, do we have anybody else who has indicated they would like to make a comment?

Operator: Not at this time. But again, if you'd like to make a comment or question, please press "star" "1" on your telephone keypad. And, we have George Estill. Your line is open.

George Estill: Yes, so this is George Estill. Just a brief comment to complement the GI doctor, I'm family practice, but I'd been doing colonoscopies for 30 years. I had two scheduled this morning, one was totally normal. The second, once we get in there, he's really high risk and so we really – we did not do the colonoscopy but if we had a more benign test like the capsule and it showed a 2-millimeter, I mean 2-centimer polyp, then the benefits of the procedure would definitely outweighs the risk. So, I guess I am for this.

Ella Noel: Thank you. Do we have anyone else in the queue, Robert?

Operator: Yes. We have the line of Pieter Wiersema. Your line is now open.

Pieter Wiersema: Yes. I think we need to be careful. I agree with the first one I heard, the first doctor that commented, a lot of times the use of this test is pure poppycock. I mean if you have someone that's high risk and you're not going to operate on them, why you're doing this test. You know, why you're doing it?

There's no sense to this at all. Now it is a useful test and I've seen this, the use – I'm a pathologist and I worked for large GI pathology group or GI group reading their biopsies and I've done a lot of experience with this. It's useful, if you have someone particularly that has surgery like gastric surgery and they're having bleeding and they can't find it on gastroscopy, this thing will find these ulcers or whatever, erosions around the area where the surgery done which may be hard to access.

And, as the gastroenterologist pointed out, yes, this is very useful, if you have somebody where you can't – that you can't get to these areas with the scope or you're afraid of using perforation. But anyone is high risk, I mean you can do colonoscopies I guess with light sedation.

But if they're too high risk to do a colonoscopy, what makes you think they're going to be surgical candidates and why should you be doing this test and wasting money when you could be doing other test or using that money

elsewhere for a better healthcare. I just don't understand and I think perhaps this test maybe overused and I think we need to be – it's not simple Betty Crocker Cookbook saying, OK, we got to do this and this and this.

I think it's a clinical judgment call and I think it's between the patient, the doctor and the – and whoever else is involved but certainly – and certainly capsule endoscopies should not be done on somebody who had a poor bowel prep and they couldn't find anything. That's total poppycock, you know, so that shouldn't be done that way and that's all I have to say about this.

Ella Noel: Thanks Pieter. Anyone else?

Operator: Not at this time. And again, if you'd like to ask a question or make a comment, please press "star" "1".

Ella Noel: All right, please send your comments in by November 14th to WPS Medicare Policy Comments. Next, we're going to talk about the Non-invasive Fractional Flow Reserve for Stable Ischemic Heart Disease policy. It is DL38839. Dr. Robert Kettler is the lead CMD on this policy.

Non-invasive fractional flow reserve is derived from computer tomography and relies on computer-assisted processing of coronary computed tomographic angiography images to estimate changes in coronary blood flow related to coronary artery stenosis. It is considered reasonable and necessary in the management of patients with symptomatic stable ischemic heart disease when the CCTA analysis is completed and demonstrates one of the following criteria: left main disease with intermediate coronary stenosis, proximal and mid left anterior descending coronary artery disease with intermediate coronary artery stenosis, proximal and mid left circumflex disease with intermediate coronary stenosis, proximal two-to three-vessel disease with intermediate coronary stenosis in at least two vessels and right coronary disease with intermediate coronary stenosis.

It is not reasonable in the following situations: severe obesity, prior placement of prosthetic valve, known severe aortic stenosis, prior placement of grafts and coronary bypass surgery, suspicion of acute coronary syndrome, intracoronary metallic stent, status post heart transplantation, recent MI of 30 days or less, prior pacemaker or defibrillator lead placement, newly diagnosed systolic heart failure with no prior left heart catheterization, left

main coronary artery disease with intermediated coronary stenosis, nonobstructing stenosis on CTA or catheterization in the past 12 months in the absence of a new symptom complex.

Service should be performed in patients that are with stable coronary symptoms. If high-grade stenosis is noted, FFR is not medically necessary as the patient should proceed to catheterization. Small-grade stenosis does not require additional confirmatory data. Medicare will not pay both for a CT-derived fractional flow reserve and fractional flow reserve data obtained by pressure wire at catheterization in the context of the same clinical evaluation or onset of new symptoms.

Do we have any comments on this draft?

Operator: And again, ladies and gentlemen, for questions or comments, please press "star" "1" on your telephone keypad.

No questions or comments coming in. Please continue.

Ella Noel: Great. Next we're going to talk about the Facet Joint Interventions for Pain Management. This is draft DL38841. Dr. Robert Kettler is the lead CMD on this policy. This is the one policy that a comment period is different. This one ends on 12/12/2020. Please send any of your written comments to medicare policycomments@wpsic.com.

Facet joint interventions generally consist of three types of procedures, intraarticular facet joint injection, medial branch block and radiofrequency ablation. These facet joint interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet the listed criteria in the policy. Further information about the procedures and limitations are also part of the policy.

Do we have any questions or comments on this draft?

Operator: For questions or comments at this time, please press "star" "1" on your phone's keypad.

No comments or questions. Please continue.

Ella Noel: OK. Well now, we'll move to the reconsideration on the endoscopic treatment of reflux, DL34659. I am the lead CMD on this policy. A reconsideration request was made to allow laparoscopic hiatal hernia repair prior to transoral incisional fundoplication and to proceed with transoral incisional fundoplication, if the hernia was reduced to 2 centimeters or less.

Previously, there was an exclusion in the LCD that did not allow to transoral incisional fundoplication to be performed if there was a hiatal hernia that looked 2-centimeters or greater.

Any comments or questions on this draft?

Operator: Again, for questions or comments at this time, please press "star" "1" on your telephone keypad.

There's no questions or comments. Please continue.

Ella Noel: Thank you. The last policy tonight is the molecular diagnostics policy. It's titled MolDX: Minimal Residual Disease Testing for Cancer. It's DL38835 and I am the lead CMD on this policy. We will be taking comments until November 14th on this draft. WPS will provide limited coverage for molecular circulating tumor DNA test that detect minimum residual disease in patients with a personal history of cancer.

This is a rapidly evolving area that is both sensitive and a specific method for monitoring the relative amount of tumor-derived genetic material circulating in the blood of a cancer patient. Minimal residual disease testing can be used to diagnose cancer reoccurrence before there is clinical or radiographical evidence of reoccurrence and detect tumor response to therapy by measuring the proportional changes in the amount of available tumor DNA.

Further revision to these coverage decisions are anticipated as the science to the standard of care evolved. Limited coverage is considered if NGS methodology is used in testing, the condition set by NCD 90.2 are fulfilled, or not applicable, the patient has a personal history of cancer, the type and staging of which is within the intended use of the test.

The identification of reoccurrence or progression of disease within the intended use population of the test identified in the NCCN or other

established guidelines is a condition that requires a definitive change in patient management.

The task is demonstrated to identify molecular reoccurrence or progression before there is clinical or radiographical evidence of recurrence or progression and demonstrates sensitivity and specificity of subsequent reoccurrence or progression comparable with radiographical evidence of recurrence or progression. The task is demonstrated to identify reoccurences or progression with sensitivity and specificity that is considerably more accurate than other established forms of surveillance or monitoring.

If the test is to be used for monitoring the therapeutic response, it must demonstrate the clinical (ability) of its results in published literature for the explicit therapy indicated. If similar MR – minimal residual disease test exist in the market and are covered by this contractor, test performance for the test must be comparable to existing test and the test satisfactorily completes the technical assessment that will review and confirm the analytical and clinical validity of the test to ensure conditions above are met.

Do we have any comments or questions about this draft?

Operator: And again, for questions or comments, please press "star" "1" on your phone's keypad. And, by the way, we have Dr. Don Selzer on the line. I think he was – he's asking a question with the previous draft.

Ella Noel: OK, let’s take Dr. Selzer.

Operator: Dr. Selzer, your line is open.

Ella Noel: Yes, let's take Dr. Selzer first.

Don Selzer: Thank you, yes. Hello, general surgeon from Indiana. I was asking a question about the previous LCD on the management of reflux. And, I wanted to confirm that this authorizes simultaneous surgical hiatal hernia repair to endoscopic management of reflux, specifically the TIP procedure to happen simultaneously?

Ella Noel: Yes.

Don Selzer: Same date of service?

Ella Noel: Same date of service. So, the hiatal hernia repair is laparoscopic and then the GERD repair, the TIF would be done endoscopically.

Don Selzer: OK.

Ella Noel: Yes.

Operator: And the next person will be Dr. Joseph Larosa. Your line is open.

Joseph Larosa: Hi, Dr. Noel. Two questions for you. Last time that we met several months ago we had a lot of MolDX things that were up voting on. Is this the same as those that would encompass all those five or six that we talked about last time or is this specifically for the minimal residual disease testing with cancer, I'm thinking it's the same but I just want to double check on that.

Ella Noel: This is specifically for minimal residual disease.

Joseph Larosa: OK.

Ella Noel: We will be trying to develop foundational policies, so that we can lump, say all the prostate MolDX test into one policy going down the road but this one is specific to this minimal residual testing.

Joseph Larosa: OK. And, then I do want to make a comment and you rattle off that website WPS Medicare Policy but I think it's a full URL, if you could repeat that for me.

Ella Noel: Yes, it's medicarepolicycomments – with an S at the end – @wpsic.com.

Joseph Larosa: WPSIC – let me just repeat that, so it's medicarepolicycomments@wpsic.com. I got it. OK.

Ella Noel: You got it.

Joseph Larosa: Thank you, Ella.

Ella Noel: You're welcome. Robert, is there any more questions or comments?

Operator: Yes. We have Pieter Wiersema on the line. Your line is open.

Pieter Wiersema: Yes. I don't know much about the predictive testing for breast cancer but I do know about melanoma. I also board-certified dermatopathologist and I

recently – well, I thought, I have one client who does a lot of these surgeries for melanomas and he advised me that currently there's molecular testing available that's superior to sentinel lymph node biopsy in terms of predicting recurrence of disease.

In short, this is the testing that's now more and more being done and it's replacing sentinel lymph node biopsy in deciding what treatment is to be made. I believe it's immunotherapy, PD-L1 type of drugs, Keytruda, Opdivo to be used as a – for event reoccurrence and that kind of thing.

So, this type of testing as you said, Dr. Noel or Ella Noel, is coming forth and it's going to be rapidly evolving and use more and more in deciding what – how to guide us in treatment of these challenging diseases. So, having said that, I think it's important to make sure that these tests which incidentally for melanoma will cost about $5,400 to only do it, if it's going to – approve it only if the patient's treatment is going to be affected by the result of the test.

We can't just do it for, oh, I want to know what my prognosis is. I got a thin melanoma, you know, that kind of thing. We want to do it for people that are facing a choice between immunotherapy and no immunotherapy and I think that's important to put that in the LCD. Otherwise, it becomes just the – not really a – good use of the funds from Medicare to be using this test for curiosity sake or somebody, they can pay for that out of their own pocket.

So, this is what I'm getting at and I would appreciate anyone else who has comments about this and let me know what they think about the other testing like for breast and for bladder and for – I'm not familiar with those areas that well. Thank you.

Ella Noel: You're welcome. Thank you.

Do we have any other comments on these draft policies?

Operator: Not at this time but again for questions or comments, please press "star" "1" on your telephone keypad.

Ella Noel: If we have no further comments on the LCD, the people that are listening in on the line can be dropped. We want to keep the physicians, the CAC members present, so that we can proceed with the meeting.

Operator: All right.

Ella Noel: So has the one line been...