WPS GHA Open Meeting – October 21, 2019

Moderator: Noel, Dr. Ella

October 21, 2019

1:30 PM CT

OPERATOR: This is Conference # 6983707

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the October Draft LCD Open meeting. At this time, all participants are in a listen only mode. I would now like to hand the meeting over to your Chair, Dr. Ella Noel. Thank you, please go ahead.

Dr. Ella Noel: Thank you. I would like to welcome everyone who's attending in person in Madison, Wisconsin and in Omaha, Nebraska, as well as those who are on the phone. This is the WPS Government Health Administrators Draft LCD Open Meeting. As stated earlier, my name is Ella Noel and I'm today's facilitator. I am a J8 Contractor Medical Director at WPS.

I have a couple of announcements to make. I want to remind you that if you are a guest who is at one of the facilities, you need to be accompanied by WPS staff while in the building at all times. If you need to leave the room to exit the building or to use the facilities, please congregate at the back of the room, one of the WPS staff members will be glad to assist you. I would also like to ask that participants identify himself over the phone if speaking and identify any conflict of interest.

Please note that this meeting is recorded and will be posted on the WPS GHA website. Your participation in the meeting implied consent for recording. We will be accepting comments on multiple draft LCDs today, we have thirteen new drafts and three reconsiderations. The drafts are available on our website at wpsgha.com.

I remind you that there are no other topics open to discussion here today. WPS will not be responding to any of the comments during the open meeting. All comments will be compiled and reviewed after the comment period has ended for each draft, which I believe is November tenth of this year. There is a forty-five day comment period that starts when the draft was posted online for public review. In the interest of allowing enough time for all of those who wish to comment, please do not repeat information

already given by another presenter.

We have two speakers giving formal presentations today and these will be limited to ten minutes each, phone comments will be limited to two minutes each. Please send all written comments to medicarepolicycomments@wpsic.com and identify which draft you are responding to for clarity.

So we will go ahead and get started with the first of the sixteen LCDs to be discussed today. This LCD is under my supervision, it's DL36799 MolDX, combinatorial pharmacogenomics limited coverage. This is a limited coverage policy for gene site neural ID genetics and other combinatorial pharmacogenomic panels in the treatment of psychiatric illnesses when ordered by a psychiatrist. Gene site and neuro ID genetics are covered for patients in who A two-gene panel consisting of CYP2C19 and CYP2D6 is reasonable and necessary.

In summary, combinatorial pharmacogenomic testing is considered reasonable and necessary in limited circumstances as described in this local coverage determination as an adjunctive personalized medicine decision making tool once a treating physician, excuse me, has narrowed treatment possibilities to a small group of specific medications based on other considerations, including the patient's diagnosis, the patient's other medical condition, other medications, professional judgment, clinical science and basic science pertinent to the drug, and the patient's preferences in value.

Combinatorial pharmacogenomic testing is not considered reasonable and necessary merely on the basis of a patient having a particular diagnosis. Additionally if the record does reflect that the treating clinician has already considered non-genetic factors to make a preliminary prescribing decisions, pharmacogenomic testing is not considered reasonable and necessary. Rather such testing may be considered reasonable and necessary if a particular treatment is being considered for the patient's diagnosis and there is a significant gene drug interaction of concern.

A combinatorial pharmacogenomic test is a multi-gene panel that examines polymorphism in several or more genes that interacts themselves or encodes proteins that interact with pharmacokinetic or pharmacodynamic manners with medication. These tests may also include some type of an algorithm to generate recommendations or warnings based on the results of the polymorphism identified among the genes tested. Such tests have typically been developed with the intent of allowing physicians to select, avoid, or appropriately dose medication so as to achieve an optimal

response without the need for trial and error or to avoid adverse drug event.

Combinatorial pharmacogenomic testing has been developed to help clinicians select medications and their medication dosages. The evidence is insufficient to suggest that these tests provide a benefit beyond the benefit that would be achieved by testing it two-gene panel consisting of CYP2C19 and CYP2D6.

Additionally, the FDA has released a cautionary statement regarding these tests and these tests are currently not recommended for use by the American Psychiatric Association, a major body representing clinicians who would be treating physicians using such tests to make treatment decisions. In summary, while combinatorial pharmacogenomic tests have been developed to serve a vulnerable population, there is insufficient evidence to suggest that they offer benefits above and beyond either informed prescribing or a single CYP gene test for CYP2D6 polymorphism. MolDX recognizes that the feel the personalized medicine is rapidly evolving so this coverage decision will continue to be reassessed and may be revised or rescinded as new evidence emerges. Do we have any comments in Madison?

Beth Scanlon, RN — No, we do not.

Dr. Ella Noel — Do we have any comments in Omaha?

Dr. Robert Kettler — No comments.

Dr. Ella Noel — Would you check to see if there are any comments on the telephone line please?

Operator — At this time, participants may press star one for any comments. And at this time there are no comments via the phone.

Dr. Ella Noel — Thank you. Since there are no comments we'll proceed to the next draft. This is a MolDX policy that is under my supervision, its DL37915, Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer. This contractor will provide limited coverage for the Oncotype DX AR-V7 nucleus detect to help determine which patients with metastatic prostate cancer may benefit from androgen receptor signaling

	inhibitor therapy and which may benefit (connection issue) therapy. It is covered in patients with progressive metastatic castrate resistant prostate cancer as defined by the prostate cancer workgroup two guideline. Patients will have failed one androgen receptor signalinge inhibitor, specifically Xtanti or Zytiga. Patients will be considered appropriate for treatment by their treating physician for the alternate androgen receptor signaling inhibitor therapy as a single agent and circulating tumor cells with nuclear expression of AR-V7 protein will be assessed prior to the initiation of therapy. Do we have any comments in Madison?
Beth Scanlon, RN	No comments.
Dr. Ella Noel	Dr. Kettler, do we have any comments in Omaha?
Dr. Robert Kettler	Nope.
Dr. Ella Noel	And can we check to see if there are any comments on the telephone line?
Operator	Phone participants may press star one for any comments at this time. And at this time there are no comments via the phone.
Dr. Ella Noel	Okay, the next is another MolDX policy, again, under my supervision, DL38018, MolDX Decision Diagnosis Melanoma. The decision diagnosis melanoma test is covered only when the following clinical conditions are met. Patient has been diagnosed with clinical stage sentinel lymph node biopsy eligible T1b and T2 cutaneious melanoma tumors, with clinically negative sentinel node basins who are being considered for sentinel lymph node biopsy to determine eligibility for adjunct therapy. Per current NCCN and ASCO guidelines sentinel lymph node biopsy eligible patients are defined as patients with T1a tumors in whom there is significant uncertainty about the adequacy of micro staging or with Breslow depth less than zero point eight millimeters and with (connection issue), lymphovascular invasion or combination of these factors, patients with T1b tumors that are greater than or equal to eight millimeters or less than point eight millimeters with alteration, and patients with T2 tumors. The DecisionDX melanoma test is a thirty-one gene expression profile to determine a cutaneous melanoma patient's risk for metastatic disease. The test classifies patients as having a tumor with low or high risk of developing

	metastases within five years of diagnosis. Patients with a low tumor profile also have a low likelihood of being sentinel lymph node positive, thus the individualized risk profile result of this test can be used to guide the use of sentinel lymph node biopsy in the context of patient specific management plans. The DecisionDX melanoma test will improve net health outcomes by accurately identifying patients who are at risk of developing metastatic disease and would otherwise go undetected, as well as patients with the low likelihood of having a positive sentinel lymph node. Net health outcomes are improved for low risk patients who can consider avoiding a sentinel lymph node biopsy and the associated surgical and anesthesia risk, as well as intensive follow up an exposure to radiation imaging procedures and for high risk patients by improved guidance to perform the sentinel lymph node biopsy. Do we have any responses or comments in Madison?
Beth Scanlon, RN	No. And we have no comments on the MolDX policies in this room.
Dr. Ella Noel	Okay, going forward?
Beth Scanlon, RN	Correct
Dr. Ella Noel	Okay. All right, Dr. Kettler?
Dr. Robert Kettler	There are no comments and there are going to be no comments on the MolDX policies.
Dr. Ella Noel	Okay, then we'll continue to check through one for the phone. Do we have any comments on the phone?
Operator	At this time from participants may press star one for any comments at this time and at this time there are no comments via the phone.
Dr. Ella Noel	Okay. Next is MolDX pharmacogenomics testing, DL38435, again, under my supervision. This is a limited coverage policy for CYP2D6, CYP2C19, CYP2C9, HLA-B*15:02, HLA-A*31:01 multi gene panels and combinatorial pharmacogenomics tests. These tests are generally covered, with few exceptions as described in further detail, to increase safety in the use of specific medications by avoiding potentially harmful

medication or doses.

This LCD provides neither coverage nor non-coverage criteria for pharmacogenomic testing for anti-coagulation dosing, which is addressed by NCD 90.1. The primary focus of this LCD is pharmacogenomics and psychiatric and neurological conditions, though, coverage is addressed for other indications, as well. It goes through to show that single gene testing for the previously mentioned gene will be reasonable and necessary in all of the genes there are two conditions. Are there any comments on the phone about this draft LCD?

Operator As a reminder, phone participants can press star one for any comments. We do have a comment from the line of Kim Gorman. Your line is open.

Kim Gorman Hi. I was interested in understanding better, there's a new policy, it's not an LCD but it's associated with this, it just came out from MolDX last week, that the coverage article that's affiliated with this particular policy. And the policy is about when testing multiple genes at the same time and how that impacts this LCD and also billing appropriately under this LCD.

Dr. Ella Noel As stated earlier, we do not address any questions or comments during this open meeting.

Kim Gorman Correct.

Dr. Ella Noel If you have questions I would send them to medicarepolicycomments@wpsic.com

Kim Gorman Okay, thank you.

Dr. Ella Noel You're welcome. Do we have any other comments?

Operator There are no additional comments at this time.

Dr. Ella Noel Thank you. We will proceed to MolDX: Tests on Allograft Kidney Biopsy Tissue to Assess for Graft Rejection, this is DL38425. This policy concerns the use of molecular diagnostic laboratory tests on allograft kidney biopsy tissue to assess for graft rejection. the molecular microscope diagnostic system is considered reasonable and necessary when a beneficiary meets all the criteria listed in the LCD.

These include presently has a functioning renal allograft such that dialysis is not required or if dialysis is required it is due to acute kidney injury that is expected to resolve, the patient has received an allograft biopsy to assess rejection status, the test is being used on tissue from the allograft biopsy, the combination of histological, immunohistological, and serological data are equivocal as to whether the allograft is undergoing antibody mediated rejection, T cell mediated rejection, or a combination of the two.

The test is ordered by either the pathologist interpreting the biopsy or physician who was part of the transplant team treating the patient. Other validated molecular diagnostic laboratory tests are also considered reasonable and necessary for beneficiaries for meet all five of the above criteria when the test provides incremental information beyond that provided by the combination of histological, immunohistological, and serological data regarding antibody mediated rejection and T cell mediated rejection and/or a combination of the two. Do we have any comments on the phone line about DL38425?

Operator As a reminder, participants may press star one for any comments at this time. And at this time there are no comments via the phone.

Dr. Ella Noel All right. We will proceed to DL38437, MolDX LCD SelectMDx for Prostate Cancer. This is a limited coverage policy for SelectMDx. This is a single site clinical diagnostic laboratory test intended to identify men who have an elevated PSA who are unlikely to have a Gleason grade two or higher prostate cancer.

This test is covered in men who meet the following condition. Their PS is greater than or equal to three, they are able to tolerate prostate biopsy, they're able to try to tolerate treatment, either medical or surgical, for prostate cancer of Gleason grade two or higher, they are considering receiving treatment for cancer if found, they have received a digital rectal exam prior to obtaining urine in accordance with the test developers instructions for obtaining a urine sample.

The record must reflect that the conditions above are all met prior to the test being ordered. And that at the time the test as ordered the physician's decision as to whether or not to pursue a biopsy is part in part contingent upon the results of the test. SelectMDx is an RT PCR assay of mRNA to measure gene expression of three genes performed on urine obtained following a digital rectal exam.

A report is returned that indicates that the patient is either at very low risk or a report showing the probability the patient will have prostate cancer upon biopsy and that the patient will have prostate cancer with a Gleason score greater than or equal to seven on biopsy. Any questions on the telephone?

Operator — As a reminder, participants may press star one for any comments at this time. And at this time there are no comments via the phone.

Dr. Ella Noel — All right. The next policy DL38433 is a MolDX policy. It is to Decipher Biopsy Prostate Cancer Classifier Assay for men with favorable intermediate risk disease. This is a limited coverage policy for the Decipher Biopsy Prostate Cancer Classifier Assay. The test is considered reasonable and necessary to help identify men with localized favorable intermediate risk disease prostate cancer with a life expectancy of at least ten years who are good candidates for active surveillance. Decipher is covered for men with prostate cancer for the following indication.

A man with localized biochemically recurrent adenocarcinoma of the prostate who has a life expectancy greater than or equal to ten years if he is a candidate for and is considering or being considered one of the following conservative management and yet would be eligible for definitive therapy, radiation therapy yet would be eligible for addition of brachytherapy boosts or radiation therapy and yet would be eligible for the addition of short term androgen deprivation therapy or radiation therapy with short term androgen deprivation therapy yet would be eligible for the use of long term androgen deprivation therapy or radiation with standard androgen deprivation therapy yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy or observation postprostatectomy yet would be eligible for the addition of post-operative adjunct to radiotherapy or salvage radiotherapy post prostatectomy yet would be eligible for the addition of androgen deprivation therapy.

The following criteria must also be met; the assay is performed on formalin fixed paraffin embedded prostate biopsy radical prostatectomy specimens and (connection issue) will be used to determine treatment according to the established practice guidelines and the patient has not received pelvic radiation or androgen depravation therapy prior to the biopsy or radical prostatectomy and the patient is monitored for disease progression according to the established standards of care. Do we have any comments about this LCD on the phone?

Operator At this time participants may press star one for any comments. And at this time there are no comments via the phone.

Dr. Ella Noel All right. We will go to the next draft, DL38427, MolDX Molecular Microscope Diagnostic System for the Heart. This policy concerns the use of Molecular Diagnostic laboratory tests on allograft on endomyocardial biopsy tissue to assess for allograft rejection of the transplanted heart.

This test is considered reasonable and necessary when a beneficiary meets all of these five criteria; presently has a functioning cardiac allograft, has received an allograft biopsy to assess rejection status, the test is being used on tissue from the allograft biopsy, the test is ordered either by the pathologist interpreting the biopsy or physician who's part of the transplant team treating the patient, and the results of the tests are intended to be used to guide the selection or dosing of the immunosuppression.

There is a paucity of large randomized controlled trials in heart transplantations, however, the evidence clearly shows that patients are successfully living with heart transplants and there appears to be little if any question and management of immunosuppression is a critical component of survival following transplantation and assessment of rejection status of the transplant planted heart is a major diagnostic tool used to guide immunosuppression management; moreover, while development in these assessment tools have been largely driven by observational data and expert opinion in recent decades evidence also shows that patients are having improved survival.

The American Society of Transplantation, one of the major medical societies of this field, attribute the increased survival at least in part to the availability of molecular tools such as the molecular microscope diagnostics system for the heart. As the field of transplantation develops MolDX will continue to monitor both the new data and the evolving expert consensus regarding the assessment of rejection status and the management of the immunosuppression using assessment data. Changes in these areas may lead to a modification in the coverage decision in the future.

Do we have any comments on the phone?

Operator As a reminder, participants may press star one for any comments at this time.

And at this time there are no comments via the phone.

Dr. Ella Noel Alright. We will proceed to the next draft DL38441. Molecular diagnosis: Erythrocyte Molecular Antigen Testing. This policy provides limited coverage for molecular phenotyping of erythrocyte antigens performed on FDA approved tests in line with their FDA-approved use for patients who are required or expected to require a blood transfusion meeting at least one of the following criteria: long-term frequent transfusions anticipated to prevent the development of alloantibodies or autoantibodies or other serological reactivity that impedes the exclusion of clinically significant alloantibodies, suspected antibodies against an antigen for which typing sera is not available, and laboratory discrepancies on serological typing.

Do we have any comments on the phone about this draft?

Operator As a reminder, participants may press star one for any comments at this time.

And at this time there are no comments via the phone.

Dr. Ella Noel Next draft DL38443. Razor 14-Gene Lung Cancer Assay. This policy concerns the use of molecular diagnostic laboratory tests as a predictive classifier of non-small cell lung cancer. The Razor 14-Gene Lung Cancer Assay is considered reasonable and necessary when a beneficiary meets these four criteria: the patient has a non-squamous non-small cell lung cancer with a tumor less than five centimeters and there are no positive lymph nodes, the patient is sufficiently healthy to tolerate chemotherapy, adjuvant platinum-containing chemotherapy is being considered for the patient, the test is ordered by a physician who's treating the patient for non-small cell lung cancer, generally a medical oncologist, surgeon, or radiation oncologist to help in the decision of whether or not to recommend adjuvant chemotherapy.

The frequent reoccurrence of non-small cell lung cancer following resection in patients classified as low-risk based on clinical and pathological data motivated the development of a molecular classifier that might be able to more accurately identify which patients are likely to have disease recurrence or metastatic disease. The Razor 14-Gene Lung Cancer Assay is a quantitative PCR analysis designed to be used on formalin-fixed paraffin-embedded lung cancer tissue; it relies on an algorithmic interpretation of the quantitative PCR data on RNA from eleven cancer-related targeted gene.

Observational evidence has shown that the molecular risk stratification with the Razor 14-Gene Lung Cancer Assay enhances risk stratification among

patients with tumors considered low-risk based on clinical and pathological criteria. Since treatment intensity, particularly the decision as to whether or not to pursue adjuvant chemotherapy is based on risk grouping, the information provided by the test provides incremental information and can inform physician management as to improve outcome. Furthermore, early observational perspective evidence suggests that adjuvant chemotherapy given to patients who do not have a low molecular risk improves disease pre-survival to be similar to those with molecular low-risk disease.

Any comments on the phone?

Operator As a reminder, participants may press star one for any comments at this time.

And at this time there are no comments via the phone.

Dr. Ella Noel Alright. The next is DL38429. MolDX: Repeat Germline Testing. This Medicare contract [unintelligible] herein identifies general limitations to coverage of DNA and RNA-based testing of germline genetic material of the Medicare beneficiary. This contractor does not consider any laboratory tests that investigates the same germline genetic context for the same genetic information that has already been tested and the same Medicare beneficiary to be reasonable and necessary.

Germline testing using gene panels that contain some genetic content that has already been tested in the same Medicare beneficiary may be considered reasonable and necessary provided that there is established clinical utility present in the remaining non-duplicative genetic components of the test. Unit of service for any one specific germline DNA or RNA-based test is limited to one per lifetime. Examples of germline tests include but are not limited to single-gene and gene panels for hereditary cancer syndrome or cancer predisposition, inherited disorders, and pharmacogenomic BLAST cytochrome P450 testing.

Providers should take reasonable measures to be aware of what, if any, germline testing a beneficiary has had prior to billing for germline testing so as to avoid billing Medicare for services that are not reasonable and necessary. Clinicians to order germline testing may wish to be aware of whether the test that they are ordering is covered under Medicare and they may wish to verify that they are not ordering repeat germline testing. Clinical utility of germline testing in Medicare beneficiaries has previously been established for several conditions; however, as repeated testing in the same genetic information does not by its nature provide new clinical

information this contractor does not believe it is either reasonable or necessary to perform such services more than once.

Do we have any comments on the phone?

Operator As a reminder, participants may press star one on their telephone keypad for any comments at this time.

And at this time there are no comments via the phone.

Dr. Ella Noel Alright. Next, we will do DL38431. MolDX: Signatera and Minimal Residual Disease Testing for Colorectal Cancer. This Medicare contractor will provide limited coverage for this test. Two different kinds of tests will be covered: one is a diagnostic laboratory tests for patients with colon cancer; and two, as a diagnostic laboratory tests for patients who are not known to be with colon cancer.

A single test as used in testing situation number one consists of performing generic sequencing on a solid tumor tissue sample to identify sixteen single nucleotide variants which serve as a clonal representation of the patient's cancer. This is followed by a series of assays run on blood to detect the presence of these clonal sequences, the series of assays comprised of single tests. A single test as used in the second testing situation consists of only an assay to detect the presence of clonal DNA in the patient's blood, each assay is a single test.

Additional tests seen using this may be covered for the clinical indications if on technical assessment it displays similar analytic and clinical validity as Signatera. The initial sequencing of the solid tumor tissue requires only analytic validation, the detection of circulating tumor DNA requires both analytical and clinical validation.

Do we have any comments on this policy on the phone?

Operator At this time participants may press star one for any comments.

And at this time there are no comments via the phone.

Dr. Ella Noel Alright. We are on the last MolDX policy. DL38439. MolDX: AlloSure® Cell-Free DNA Testing. This LCD provides limited coverage for tests performed using the AlloSure® donor-derived Cell-Free DNA Assay. AlloSure® Kidney is covered to assess the probability of allograft rejection in kidney transplant recipients with a clinical suspicion of rejection and to inform clinical

decision-making about [succinct] renal biopsy in such patients at least two weeks post-transplant in conjunction with standard clinical assessment.

AlloSure® Heart is covered when used in conjunction with AlloMap to assess the probability of allograft rejection in heart transplant recipients with clinical suspicion of rejection and to inform clinical decision making about the necessity of heart biopsy in such patients at least fifty-five days post-transplant in conjunction with standard clinical assessments. Collectively this indicates that a test that is able to provide information that will help to inform immunosuppression and rejection management while avoiding an invasive procedure and potentially expanding access to care as clinical utility. It is well-accepted within the renal and cardiac transplant communities that immunosuppression management is an important component of post-transplant care to both optimize graft longevity while avoiding side effects and toxicity of immunosuppressive therapy.

Graft assessment is an important decision tool used to help clinicians optimize immunosuppressive treatment. The gold standards for assessing rejection are solid organ allograft rejection or injury has historically [remains] biopsy in conjunction with serological criteria; however, given the invasive nature and risk associated with a biopsy test that can potentially mitigate the need for a biopsy [unintelligible] providing clinicians with actual information that can be used to help optimize immunosuppressive therapy are reasonable and necessary. Thus, there is adequate evidence to support AlloSure® assays when used in combination provides incremental information to change clinical management in a way that would be expected to improve outcome.

Do we have any comments on this last MolDX policy?

Operator At this time participants may press star one for any comments.

And at this time there are no comments via the phone.

Dr. Ella Noel As previously stated, we have thirteen new draft MolDX LCDs, please send any written comments to Medicare policy comments at wpsic.com. The comment period closes November tenth.

Next, we will go over three reconsideration requests that required revision to established LCDs. The first is DL34633 Erythropoiesis Stimulating Agents. This policy is under my direction, we got a reconsideration request to add a new group paragraph for myelofibrosis. Myelofibrosis is overlapping with MDS on the spectrum, and like MDS is diagnosed by bone

marrow apology. Myelofibrosis can result in symptomatic anemia. We will add a new group, myelofibrosis, and include only one indication in that group as primary myelofibrosis ICD-10 D75.81. This would be appropriate for the use of both J0881 and J0885 Procrit.

Do we have any comments in Madison about the changes to the [ISA] LCD?

Madison Responder — No comments here.

Dr. Ella Noel — Do we have any comments in Omaha?

Omaha Responder — No comment.

Dr. Ella Noel — Do we have any comments on the telephone on the LCD?

Operator — As a reminder, participants may press star one for any comments.

And that this time there are no comments via the phone.

Dr. Ella Noel — Okay. The next is on the category three code LCDs. Dr. Kettler supervises this policy. The draft number is DL35490. There were two reconsideration that are being brought today to the open meeting, one is for 0254T Endovascular repair of iliac artery bifurcation, using bifurcated endograft from the common iliac artery to both the external and internal iliac artery including all selective and/or nonselective catheterization required for device placement and all associated radiological supervision and interpretation, unilateral.

The reconsideration request asserts the evidence supporting the use of the GORE® EXCLUDER® IBE or 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 authors. WPSGHA believes that the author's caution is warranted. Coverage is denied at this time.

The next is for 0355T Gastrointestinal tract imaging intraluminal (e.g. capsule endoscopy), colon, with interpretation and report. The reconsideration asserts current published evidence and FDA approval

supports PillCam™ COLON 2 system as a safe, effective, and clinically meaningful diagnostic option for patients after an incomplete colonoscopy or for patients with evidence of a lower GI bleed with major risk for colonoscopy or moderate sedation.

Wisconsin Physicians 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 author, as well as the associated editorial. WPSGHA believes that the author's caution is warranted. Coverage is denied it this time.

We are supposed to have a presentation from Dr. George Panagakos on PillCam™ COLON 2 system. And I apologize if I butchered your name, Doctor.

Is he at the Madison facility?

Madison Responder: He's on the phone.

Dr. Ella Noel: Oh, he's on the phone. Okay. Do you want to take it away, Doctor?

Is George Panagakos on the phone?

Operator: His line is open.

Dr. George Panagakos: Hello. Can you hear me?

Dr. Ella Noel: Yes, I can hear you. Please go ahead and start. And as previously stated, you will have up to ten minutes to present.

Dr. George Panagakos: Thanks a lot. Thanks for the opportunity to speak with you today, provide a little more color on the evidence behind COLON capsule endoscopy and the specific request being made. I know the time here is limited and I'm going to try to focus on some of the main points, address any major concerns. And I know that some of the feedback on data had already been provided to Medtronic and there will be a letter by the company with a more detailed response to further address.

So, as disclosed here was requested and a little on my background, I'm a radiologist and nuclear medicine physician by training, so as one might expect I have experience and a certain perspective with gastrointestinal

imaging, barium enema, CAT scans, etcetera. And so now I'm a Medical Director with Medtronic and it's interesting to be working as one of their medical directors and to be still involved with patient imaging but with a different twist compared to my prior experience.

So, if we could go to the second slide please. And again, if it seems I can't see a screen or anything, so if it seems as if you can't hear me well or if it seems like I'm speaking on a slide that is not the actual slide please just let me know and I can regroup. So, the COLON II capsule endoscopy systems is indicated for detection in colon polyps in patients after incomplete optical colonoscopy with adequate preparation when evaluation of the colon was not technically possible in patients with evidence of gastrointestinal bleeding of lower GI origin.

And this applies particularly to patients with major risks for a colonoscopy or moderate sedation but who could tolerate colonoscopy in moderate sedation in the event that a clinically significant colon abnormality was identified on capsule endoscopy. So, I wanted to take a moment to emphasize that the coverage currently being requested from WPS is not coverage for a generalized screening indication, it's specific to two particular subgroups that are at increased risk.

So, if we could go on to the third slide please. So, the content on this slide is further highlighting what we just discussed regarding the specific subgroups we've been discussing. I'm going to touch quickly on reasons why these particular subgroups--why they're at increased risk and why they're relevant, and then we're going to move into some of the key relevant data regarding efficacy of the COLON capsule system.

So, if we can go to the fourth slide please. So, a little of the information on the subgroups and sort of setting the stage for why this is important, there was a study from Hussey and others from UEG Journal of 2018 mentioning rates of incomplete colonoscopy can range from two percent to nineteen percent. Depending on what specific article you're looking at these numbers may vary slightly; for example, another publication by [Nearings] and other's Endoscopy 2010 mentioned cecal intubation is not achieved in two to twenty-three percent of colonoscopies.

And one reason that this particular group is of concern, why this is concerning to have an incomplete colonoscopy, is based on the frequency with which advanced neoplasia is found in the proximal colon. In fact, in an article by [Spanda] and others that I'm going to be talking about later from Gut 2015 it mentions thirty-three to fifty percent of advanced neoplasia being located in the proximal colon; so also, compliance with colonoscopy

follow-up after an incomplete optical colonoscopy can be problematic.

So, in that same study I was referring to before by [Nearings], within a one-point five-year follow-up period only fifty-four percent of patients who were reported to have achieved complete colonic evaluation after the incomplete colonoscopy and four percent of patients were reported to have advanced neoplasia on follow-up exams; so not just any neoplasia, but specifically advanced neoplasia I'm referring to. So, obviously, colorectal cancer is a very deadly cancer potentially, but with a relatively high five-year survival when patients are diagnosed with localized stage disease this underscores the importance of the early detection and the importance of not leaving things incomplete, so to speak.

So, before we move on I'm going to mention specifically the other subgroup we're talking about, there's some patients who might benefit from colonic evaluation but who are elevated risk for complications associated with colonoscopies. There's published information from Day and others, GIE 2011, for example, that speaks to this topic. I don't want to spend too much more time on this topic and beat a dead horse, so to speak, regarding the particular importance in specific subgroups, I'm confident that WPS is already aware of the importance of this concept as illustrated by coverage for CT colonography with a similar indication, but if anyone has any specific questions related to these subgroups please don't hesitate to ask.

So, if we can move on to the fifth slide please. So, to get into a little bit of the specific data, in a prospective study by [Baltz] and others, World Journal of Gastroenterology 2018 we have data from seventy-four patients who underwent COLON capsule after incomplete colonoscopies, this data was analyzed, it was reported that ninety-three percent of incomplete colonoscopies could be complemented by COLON capsule. Twenty-eight percent of patients were reported to have had significant polyps. And if you're interested the authors mention that according to previous studies significant polyps were defined by size greater than or equal to six millimeters or a number greater than or equal to three.

Dr. George Panagakos: Eighty-six percent of significant polyps we're not reached by the optical colonoscopy, and note, there was one note carcinoma detected, which presented as a twenty six millimeter sequel polyp, and as you might imagine, the sequel being such a disproportion that colonoscopy would likely not see a need in the case of an incomplete colonoscopy.

So the next slide, slide six please .So, there are several studies comparing results from colon capsule with those of CTC, CT colonography equivalency

are at times two period (inaudible) capsule compared to CTC, regarding certain endpoints. I know we don't have time to dive too deeply into all of them. So, I'm going to focus on a couple of studies that I think might be useful for me to highlight.

If you look at the left side of the screen, it should be data from a study from Spada and others, from Gussman two thousand fifteen. On the right, we have study by Ron Dnavdi and others published in CGH two thousand fourteen. So, just two, sort of take them one at a time and just highlight some of the main points.

In the study on the left, we had a prospective blinded cohort study of a hundred patients, and ninety-seven of them being analyzed. They had previous incomplete colonoscopy. So, if you see, IC, Incomplete Colonoscopy, they underwent, both, a colon capsule and CPC and then followed by optical colonoscopy to verify results of what were considered positive in the C- the colon capsule in the CTC subgroups.

I'm not going to spend time going over every single point on this slide. I know it's a rather busy slide, so please forgive me for that. But, if you look at the group, let's focus, for example at the group in greater than or equal to six-millimeter polyps, you can see that colon capsule was found to identify them in twenty-four patients, where as in CT colonography to be only in twelve patients. So, if you look, specifically, they had a relative sensitivity of capsule colonoscopy in comparison with CT colonography. And, you can see there in the upper right hand, it's listed in green, 2.0, and you can look at the confidence intervals there. There's also similar data for polyps greater than or equal to ten millimeters, where a trend was noted, but if you look, you might see that the confidence intervals there do not that they include one. So, there was a trend, but that one did not necessarily reach statistical significance support, specific to the subgroup, where it was specific to greater than or equal to ten millimeters polyps.

So, if you, if we switch to the study on the right now, this is a study with fifty patients, with positive (inaudible) immuno-histochemical test comparing accuracy and patient preference for CTC and colon capsules optical colonoscopy was used as a reference. And, you can see there, again, let's focus on the greater than or equal to six millimeters polyps, you can see sensitivities and specificities of capsule endoscopy versus CTC. You can see eighty-eight points two percent for, both, capsule colonoscopy and CTC. You can see the specificity slightly higher in these two lifted specificities for colon capsules at eighty-seven points eight percent compared to eighty-four points eight percent. And then furthermore, regarding patient preference, seventy eight percent of patients were

reported to have preferred colon capsule to CTC. There was report of bloating and mild abdominal pain associated with CTC.

So, moving on to the next slide, that should be side seven.

Dr. Ella Noel You have less than thirty seconds left.

Dr. George Panagakos Less than how much?

Dr. Ella Noel Thirty seconds left. You have less than thirty.

Dr. George Panagakos Got you. So here, we have data that talks about patients at increased risk or who refuse colonoscopy, I'm not going to go into the details, but this is some of the data.

And if we go on to slide eight, we have data specific to patients with failed colonoscopy, or if risk factors comorbidities making colonoscopy with anesthesia contraindicated.

So, in summary, if we go to the last slide on here, it's - there's evidence of equivalency or superiority in diagnostic results compared to CPC in different patient cohorts/studies. There's also the benefit of (inaudible) radiation exposure that can be associated with CPC. And, it is requested that coverage like the WPS CPC retired LCD be considered.

There are two more slides on reference, I apologize, they maybe in hidden mode. So, to access them, if you're interested in a specific reference, you may have to go out of presentation mode. And find them there.

Dr. Ella Noel All right, thank you.

Dr. George Panagakos I'll be happy to take any questions.

Dr. Ella Noel We don't allow them.

Dr. George Panagakos Okay.

Dr. Ella Noel So, thank you for your presentation. Do we have any comments in the room in Madison?

Beth Scanlon, RN	No comments.
Dr. Ella Noel	Dr. Kettler, do you have any comments in Omaha?
Dr. Robert Kettler	No comments.
Dr. Ella Noel	And, do we have any comments on the phone?
Operator	At this time, as a reminder, participants may press star one on the telephone keypad for any comments, at this time. At that this time, there are no comments via thee phone.
Dr. Ella Noel	Okay. So next, we will go to the reconsideration request known as DL37228. This is supervised by Dr. Holzmacher. This is the wound care LCD reconsideration request with the receipt to expand the list of allowable conditions in the LCD to include diabetic foot ulcers, chronic non-pressure ulcers, limited to break down the skin and stage two ulcers for the service of the debridement CPT codes 97597and 97598, reconsideration also request diabetic foot ulcers listed separately, and stage two ulcers be listed under coverage guidelines. There is revision of language for clarification and coverage guidance associated information to expand therapist, acting within their scope of practice and licensure, may provide the debridement services,97597/97598, revision of language to include therapists were previously listed as physical therapists, documentation clarification to include physician orders for therapy/wound care services ending signed plan of treatment, also known as a plan of care detailing treatment modalities for therapy and wound care services must be established, before treatment. Overall conclusion, in regards diabetic foot ulceration, no study was presented to show clear evidence that debridement improves ulcer healing. One study suggests high frequency debridement improves ulcer healing. There is no data analysis to support this finding and shows statistical significance. One study evaluates DPI and indirectly measures effective debridement on diabetic foot ulcers. It is noted, however, that all ulcer debrided were classified as neuropathic. Two studies repeatedly described pressure keratosis aka callus debridement to prevent diabetic ulcer. The provider requested for diabetic and non-pressure ulcers. Stage two ulcers, no study that specifically

addressed stage two debridement, no study discussed outcomes of debridement in any stage. Studies presented referred to a Class C evidence in support of debridement and debridement may decrease the time to healing. Non-pressure limited to break down of skin, no studies presenting presented addressing debridement for this, frequent discussion of treatment of pressure keratosis to prevent ulcers. Recommendation no change to current LCD coverage guidelines.

We have a speaker, who wishes to do a presentation from the Alliance of Wound Care Stakeholder. Are they on the telephone? And, again, they will have a ten limit, ten minutes time limit for their presentation.

Karen Ravitz, JD — Can you hear me? Hello.

Dr. Ella Noel — Hello.

Karen Ravitz, JD — Can you hear me?

Dr. Ella Noel — Yes, I can hear you.

Karen Ravitz, JD — Fantastic. Good afternoon. Thank you for the opportunity to provide this presentation on behalf of the Alliance of Wound Care Stakeholders. My name is Karen Ravitz, and I'm the Health Policy Advisor for the Alliance, and will be addressing our concerns with the WPS reconsideration decision. I have no financial conflicts today.

The Alliance is a nonprofit multi-disciplinary trade association of physicians, medical specialty societies, clinical and patient associations, whose mission is to promote evidence based quality care and access to products and services for people with chronic wounds, including diabetic foot (inaudible) pressure and arterial ulcers. Our clinical specialty societies and organizations not only possess expert knowledge in treating complex chronic wounds, but also in wound care research.

The Alliance has been on the record four time to address our concerns with how WPS is limiting coverage on debridement and not providing the adequate scientific evidence for the support. We've provided comments to the draft LCD in June twenty seventeen, followed it up with those formal letters and emails in June and October twenty eighteen, as well as in February twenty nineteen, requesting clarification of clinically inaccurate information in the final LCD

After reading WPS decision to not update its one care LCD by adopting the recommendations that, both, the Alliance and our members have raised in our letters and the reconsideration request, the Alliance once more must reiterate our concerns, both, in this public forum and later in our formal comments with this flawed policy. We have many concerns, but we'll address only two of them today.

Our primary concern is the WPS eliminated a significant number of codes related to debridement of other chronic non pressure ulcers, when the severity is classified as limited to break down of skin, without providing adequate evidence for eliminating these codes, as well as, WPS specifically identifying conditions, which must be present in order to provide a debridement, yet, left out conditions that should be included, such as the diabetic foot ulcer, again, without providing evidence to support the decision to leave out these conditions. We've requested evidence and justifications for both issues in our letters, and WPS it's failed to respond to us with this information, instead stating that the information is contained in the bibliography.

Our Alliance members are experts in this field. We represent almost every clinical association and specialty society whose members treat patients with wounds. Many of these organizations have clinical practice guidelines, which support debridement as the standard of care when treating patients with chronic plans. While WPS is provided some evidence in its LCD, our members have informed us that none of the evidence is compelling to demonstrate the debridement procedures which WPS has eliminated are either unsafe or ineffective.

WPS has also not brought forth expert consensus among clinicians and scientists that debridement of these types of ulcers are not medically necessary. These are the standards that WPS must prove when citing evidence for a reduction in coverage for a certain item or procedure. Yet, WPS specifically identify certain procedures, which are acceptable for debridement and do not list others, such as diabetic foot ulcers, without providing evidence to justify their decision to include some and exclude others, despite debridement being considered the standard of care.

The Alliance has requested this information in our emails and letters yet, it has not been provided to us or in the draft LCD. Our members are appalled at this policy, and simply stated: it contrasts standards of care and is unacceptable.

Debridement is a well-known and utilize procedure in the treatment of

chronic wound care, it's effective, and it's necessary. There is evidence to support its use that, both, we and our clinical association members have submitted to WPS.

There are numerous review articles on the preparation of the chronic wound bed to support healing and clinical practice guidelines adopted by professional societies in United States, that address the fundamental importance of debridement and the management of chronic wounds, which we have provided to you, such as but not limited to wound bed preparation, a systematic approach to management, that was published in Wound Repair and Regeneration Debridement Controlling Neurotic Cellular Burden, published in advances in skin wound care, just to name a few.

In addition to what we have already submitted, there other examples of evidence on the importance of debridement, including, for diabetic foot ulcers. For instance, in twenty sixteen the Wound Healing Society published clinical practice guidelines, regarding diabetic foot ulcers. In their guidelines, which were published in Wound Repair and Regeneration, it is clearly stated that, to control infection, only product or devitalized tissue needs to be removed by debridement.

Furthermore and guideline four point two, in the Wound Healing Society's Guidelines, it clearly states that initial debridement is required to remove the obviously neurotic tissue, excessive bacterial burden, and cellular burden of dead incessant cells. Maintenance for debridement is needed to maintain the appearance and redness of the wound bed for healing and that more than one debridement method may be appropriate.

We submit the diabetic foot ulcers must be specifically listed as one of the covered diagnoses for debridement as they are the most prevalent diagnosis. They should not simply be contained within the neuropathic ulcer category, as not on all neuropathic ulcers are diabetic foot ulcers. The Wound Healing Society Guidelines are clear. Debridement is mandatory for diabetic foot ulcers; failure to perform this, violates the standards of care. WPS failure to cover it, also, violates the standards of care.

There are other clinical practice guidelines that exists that provide the same type of guidance. Debridement is required for the management and treatment of chronic wounds. Debridement is considered the correct standard of care when treating patients with these types of wounds, yet WPS has been dismissive of any evidence that has been provided to it, with respect to this policy.

Diabetic foot ulcers are one of many examples of conditions, which need to

be listed in the WPS policy. While debridement is a well-known recognized part of the standard of care for chronic wound care treatment, there may not be the type to study specific enough to support specific language in this policy or to the codes that have been eliminated from this policy. Yet experts agree and have tried to express this to WPS that the policy of not allowing many patients, who should be receiving debridement, to obtain them, simply by the omission of the many codes from this policy, and the lack of specific indications in the list of conditions, which must be present.

We urge WPS to listen to the experts who treat these patients every day. This policy is negatively impacting the care that our members provide to their patients in the WPS jurisdiction. Chronic non-pressure ulcers, when the severity is classified as limited to break down of skin must be covered under this policy.

We request that the codes that were contained in the WPS LCD prior to the wound care policy being finalized in twenty eighteen that they are reinstated. If WPS finds the need to list out conditions that must be present to receive a debridement, which we do not agree with, then at the very least, we request the diabetic foot ulcers and several other conditions be added to the list of conditions that need to be present for debridement to be covered.

The Alliance also has another serious concern with this policy. According to the program integrity manuals the mass shall insure that all LCDs do not conflict with statutes, rulings, regulations, national coverage payment and encoding policies. Yet, WPS seems to have taken liberties with CPT codes that have already been established by the AMA and accepted by CMS.

WPS does not have the discretion to change CPT code descriptors and cover certain items within the code, while denying others. This is in direct violation of the program integrity manual. For example, the LCD states the following:

The following services maybe done during wound care services and can be medically necessary, but they are not considered when debridement service, and wound debridement CPT code should not be used. And specifically, it is listed: removal of necrotic tissue by cleansing, scraping, other than by a scalpel or curette, chemical application or wet to dry or dry to wet dressing, and further, it goes on to say, removal of non-tissue integrated fiber an exudate crust biofilm or other materials from a wound, without removal of tissue, does not meet the definition of any debridement code.

WPS states that fibrin is not covered for debridement, when it is clearly listed in the code descriptor. Similarly, 97597 clearly list four steps when selective debridement is performed yet WPS limits the removal of neurotic issue to a scalpel or curette. The Alliance has asked on multiple occasions for WPS to adhere to the CPT code descriptor language. WPS needs to revise its policies, so that is consistent with the CPT code descriptors and not be in violation of the program integrity manual. The Alliance will be submitting formal comments, which will be more details.

But in closing, I asked that WPS pay special attention to and accept the findings of an expert consensus panel addressing the best practices and wound debridement for diabetic foot ulcers, that will be published in peer review journals, in February twenty, twenty. This panel is composed of the leading researchers and experts from our Alliance physician association members, such as the Society for Vascular Surgery, the American Podiatric Medical Association, the American Diabetes Association, the American College of Foot and Ankle Surgeons.

The panel review the basic science of debridement, existing clinical literature, current society guidelines, and make recommendations on appropriate indications and methods for debridement.

Dr. Armstrong, who is a Professor of Surgery and Director at the Southwestern Academic Limb Salvage Alliance, (cross talk), and a participant in that consensus panel noted: good quality surgical debridement is the cornerstone of good wound healing, without this, it is not too strong to say that we are risking limbs and lives.

We hope that WPS does the right thing and revise this policy. Thank you.

Dr. Ella Noel Thank you. Do we have any comments in the room in Madison?

Beth Scanlon, RN No.

Dr. Ella Noel Do we have any comments in the room in Omaha?

Dr. Robert Kettler We do.

Dr. Ella Noel Okay.

Julie Orzali Hi. This is Julie Orzali. I'm the Vice President of Government Affairs and Reimbursement for Healogics. We are wound care management company, And, we are in full support and in agreement with the comments made by our Alliance for Wound Care Stakeholders. And being respectful to WPS's the statement that they did not want similar comments to be reiterated again by other commenters, we decided not to provide testimony, but we're in full agreement with the Alliance comments, questions, and concerns. Thank you.

Dr. Ella Noel Thank you. And if you would send us written comments to WPS's Medicare Policy Comments Website at: wpsic.com, we would appreciate it.

Julie Orzali Sure.

Dr. Ella Noel Are there any more comments in the room in Omaha?

Dr. Robert Kettler Nope, that's it.

Dr. Ella Noel Do we have any comments on the phone?

Operator As a reminder, participants may press star one for any comments via the phone. You have a comment from Stephen Postal. Your line is now open.

Stephen Postal Hi. Yes, this is Steve Postal. I'm a Senior Specialist of Regulatory Affairs at the American Physical Therapy Association, and in respects to the rules to not reiterated previous comments, I just wanted to go on the record in support of the Alliance's comments, and we will be submitting comments, as well.

Dr. Ella Noel Thank you, any other phone comments?

Operator We do have another phone comment from Jule Crider. Your line is now open.

Jule Crider Hi. My name is Jule Crider; I'm the Executive Association for the American Association of Wound Care Management. Again, indifference to the request not to repeat comments, I will fully support those offered by the Alliance. Further, I would ask that at the upcoming CAC meeting, I understand we are not allowed to provide comments for that meeting, I would request that the members of that committee please review the Clinical Practice Guidelines from the Infectious Disease Society, the Society for Vascular

Surgery, the International Working Group on Diabetic Foot, the Wound Healing Society, and the Wound International, all state the importance of debridement and make strong recommendations for debridement as part of the basic clinical practice for the care of wounds.

Dr. Ella Noel Ma'am, could you submit those to Medicare Policy Comments at wpsic.com?

Jule Crider I will.

Dr. Ella Noel Thank you, anymore telephone comment?

Operator At this time, there are no for the telephone comments. We have one that just came in from Scott Haag, please. Your line is open.

Dr. Ella Noel (Cross talk). Okay, Thank you.

Scott Haag Good afternoon all, Scott Haag, Director of Health Policy for the American Podiatric Medical Association. Again, we agree with the Alliance's comments. I just want to also add to the extent it wasn't stated that the national coverage determination, also, states that the standard wound care, includes optimization of nutritional status, debridement by any means to remove, divitalized tissue, maintenance of a clean moist bed of granulation tissue, with appropriate moist dressings, and necessary treatment to resolve any infection that may be present.

If you may or did submit this, I believe the Alliance may have noted this, as well, and we were said- told in the response of the LCD that this reference is not relevant to the request. So, we just want to say that we disagree with that and support the previous comments that have been made by the Alliance and others.
Thank you.

Dr. Ella Noel Thank you. Anymore telephone comments?

Operator They are no further telephone comments, at this time.

Dr. Ella Noel Great. I want to thank everyone for their participation on the phone, and in Madison, and in Omaha. Please send all written comments on any of the drafts presented today to: Medicare Policy Comments at wpsic.com. The comment period will be closing November tenth. We do not respond individual comments, but they will be noted in the response to comments

document, that is linked to the LCD. Thank you everyone and have safe travels home.
Goodbye.

Operator Ladies and gentlemen, this concludes today's meeting. Thank you for participating. You may now disconnect.