CMS CLFS FACA ADVISORY PANEL – NEW LAB TEST PRICES
2024-07-25

Agenda

https://www.cms.gov/files/document/agenda-cdlt-panel-meeting-july-25-26-2024.pdf

Unofficial Auto Transcript
(THIS DOCUMENT)

Here is a video archive and autotranscripts segmented for the 4 videos.

20240725 CLFS FACA VIDEO ONE (1-58)
https://youtu.be/TjA51_WikNM

20240725 CLFS FACA VIDEO TWO (62-70)
https://youtu.be/Favgw6rdwpw

20240725 CLFS FACA VIDEO THREE (70-103)
https://youtu.be/356m3mmeYX0

20240725 CLFS FACA VIDEO FOUR (104-132 & Holdovers)
https://youtu.be/xvDjMtOwf9g

20240726 CLFS FACA VIDEO FIVE (**0726**, MISC)
https://youtu.be/nw64rEx1kDU

Contents

PART ONE

Unknown Speaker 0:13
marveling, you can go ahead and begin recording. Recording in progress.

Unknown Speaker 0:23
Good morning. Welcome to the Medicare advisory panel and clinical diagnostic laboratory tests meeting. My name is Rashida Arthur and as a member of the Medicare clinical laboratory fee schedule policy team and the Division of ambulatory services. I am the designated federal officer for the CLT panel. I would like to begin by expressing appreciation for those of you who were able to virtually participate via this teleconference. We truly appreciate your flexibility with switching to a virtual only format. We'd also like to extend a warm welcome to members of the Medicare advisory panel who are also clearly present for today's meeting. As you may know, this meeting allows an opportunity for the CDL T panel to provide input and recommendations to the secretary and the administrator of CMS on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System codes being considered for the Medicare payment under the CLF s for the next calendar year. This meeting also provides a forum for the public to respond to direct questions posed by the CLT panel in a real time manner. Please note that we will be discussing only the codes address in our clinical lab fee schedule calendar year 2025 test codes update file, which is found on rsbfs annual laboratory meeting webpage, comments and recommendations on where their codes identified as GAAP. Though code from last year's final determination is a separate and distinct process that we will not be discussing at this meeting. Consistent with the annual clinical lab fee schedule process. After the consideration of the information from the annual lab meeting, public comments and today's CTLT panel recommendations. We generally post preliminary payment determinations on our website in September of each year. We accept additional comments from the public through October of each year. And unlike a new crosswalk, test, the payment amount for new gapful test is not established when we determine the basis for payment because it takes about nine months from the CFS annual public meeting for max to establish Max specific amounts and to report those amounts to CMS. Next slide. On the next page, please. Thank you. In November of each year, we generally finalized the basis of payment for new and substantially revised test codes and the amount of payments through the annual CMS instruction implementing the updated CFS for the next calendar year. The public has an additional 60 days from the date we issue our annual instruction, or in essence the final payment determination to request reconsideration of either the basis of payment or the amount of payment for the new or substantially revised texts. The public may comment on these reconsideration requests at the next CFS annual public meeting. Once a code or lab test has undergone a reconsideration cycle, and CMS has made second final determinations on the code or tests. The payment methodology is then final. For any new test code that will be gap fill we ask our Medicare contractors to develop Max specific gap amounts by April 30 of the following year. These amounts will then be finalized by September 30 of that year. I'd like a test crosswalk to ACLs lab test code. The amounts for the gap field test is not established when we determine the basis for payment because it takes about nine months for our contractors to establish carrier specific amounts. After prices for get filled tests are developed by our Medicare contractors. We will then post on our website and accept comments for 60 days. Later in the year when the gap full payment amounts are posted on the website as final we will accept reconsideration requests on the gap full payment amounts for 3030 days. Once the reconsideration request. Once the reconsideration process is complete for cycle, the determination is final and would not be subject to further reconsideration. Lastly, I'd like to share a few housekeeping Items regarding

today's convening. Please note the following. Next page please. So, as a reminder, the agenda and the code lists may be found on our CMS website. To our standby speakers Next page please. If you are not speaking, please place your phone on mute. We have many speakers today. And so we just want to ensure that everyone, please please please place your phone on a mute if you're not directly speaking. Regarding input from standby speakers, we will seek input from standby speakers only when the CLT panel has questions specifically for those standby speakers. That is standby speakers cannot address the interim co chairs or the panel members directly. They can only speak when a question is specifically posed to them. Another important housekeeping role is to really honor warnings when the discussion or the topic is seems kind of off topic. And so when the discussion begins to deviate from a specific question, the panel interim co chairs or the DFL myself, we can intervene to support with reorienting the discussion and ensuring this the topic stays on discussion stays on topic. So just please keep that in mind as we provide assistance during the meeting, we try to facilitate a smooth meeting. Additionally, like last year's meeting, if during the discussion of a code, a new recommendation is post proposed, the discussion for that specific code will be concluded. And we will move that discussion to the end of the meeting. So if during a discussion, there is a new option that was not previously discussed, we just want to make sure that the panel has an opportunity to really think through that additional option. So that code will just be moved to the very end of the meeting so we can loop back around to have that discussion. We will also keep a list of all of those codes that are moved to the end of the agenda just to ensure that we revisit all of those codes. So again, we hope to have a very efficient meeting we look forward to interacting hearing from the DACA panel as well as the standby speakers. If you have any additional questions during this meeting, please do not hesitate to reach out to members of the division of ambulatory services team. If you have follow up questions or issues after this meeting, please submit all inquiries to the CLT panel Resources box. Next page please. Before I turn the meeting over to our interim co chairs and meeting facilitators, doctors Chris Chang and jokin Linares. I'd like to introduce the management team of the division of ambulatory services. Next page please. Sarah Shari loso, the director and Michelle Cruz Deputy Director. This concludes my introductory and housekeeping comments. Now we will hear a few remarks from Dr. Linares and Dr. Cheung.

Dr Lennerz MGH 8:17
Thank you Dr. Arthur. Great introduction. Good morning, everyone. My name is Joe lenaerts. And I along with Dr. Chris Chang will serve as the interim co chairperson during today's meeting. Again, welcome to the calendar year 2025 a CDO T panel lab meeting, we will seek information and input from our FACA panel. I would like to begin by performing a quick roll call of our panel members. So for each member when you hear your name, please just unmute yourself and acknowledge that you present. I think we have a table for that as well on the slides. But I will start anyway. And so the first panel member is Dr. Bill Celski here. Wonderful. The second is Dr. Chandra present. Perfect third is Dr. Chris Chang. I have seen it before Chris Good morning. Perfect Nick says Dr. Clark here. Wonderful then Dr. Jang. Jennifer, are you here?

Unknown Speaker 9:29
Yes, I'm here. Wonderful. Thank

Dr Lennerz MGH 9:31
you for confirming Yes. Next panel member would be myself and I'm here. Last time I checked and then number seven is Dr. rompler. Mark. Wonderful. Thank you. Panel. member number

eight is Dr. Michelle Shumate, Schoonmaker. Wonderful, thank you. And then number nine is Heather. Miss Heather Chappelle, Heather, you hear, present. Wonderful, now that we don't get the roll call. I believe we have a quorum, or else select a briefing. Note that in addition to the names of the panel members, you can see on the screen the source of the nomination for each panel member. So sometimes it's a bit confusing because that might not be the institution of the panel member. But those are the sources of nomination. So at this time, I'd like to brief the public who's present on the advisory panels process for reviewing and categorizing the coats on the list for for each year. So these are sort of the rules of engagement. So over the years, we've created subcommittees to review the list of quotes. So the purpose for the subcommittee is to maximize the utility of the panel members expertise by streamlining the efficiency of the discussion during the meeting. So we have created two subcommittees for this specific purpose. One is the molecular pathology genomic sequencing subcommittee, or the M O. G, committee or subcommittee for short, and the second subcommittee is referring to chemistry, hematology, immunology and microbiology, or chimp for short as a second. So there's an emoji, molecular subcommittee and then the chimp subcommittee. Each subcommittee has co chairs, and the co chairs for the emoji subcommittee are Dr. Leonard's myself and Dr. Chandra, and the co chairs for the chimp subcommittee adoptable Celski and Dr. Clark. So again, the total number of codes, I think this year over 130, were divided amongst the two subcommittees. And there were discussions of how to approach crosswalk and or gap fill for each of the codes with each subcommittee. After leveraging, of course, the individual panel members expertise, we considered the public comments made during the public meeting, and utilize other pieces of supporting information that was submitted either to CMS or available to us so that we could understand the complexity and the technology of each test. And then finally, it's important to understand that the Subcommittee on individual panel member does not make the sole recommendation for a test to CMS. Because this is a process it is rather so that the full panel makes recommendations on each coat when they vote on their choices for either crosswalk or gap fill, which will occur during the meeting today. And now I'd like to hand it over to Dr. Cheung for a few words of introduction. But for Trump, right, good

Unknown Speaker 12:45
morning. So as stated by Dr. Linus, we have taken the great number of quotes on our list and broken them into categories. In general, we try to maintain consistency within the categories that ama CPT uses in their manuals. Then we look at the type of lab test the specimen and the analyte. All this goes into the decision making process in terms of taking large list of course, like genomic sequencing course as well as the Microbiology and Immunology codes. Furthermore, we also look at the type of specimens, analyze methodologies, resources and indication of the test to name a few. And again, the whole purpose of creating subcategories out of the major categories is that so that you recognize that when we look at ama CPT book is to help promote efficiency during the meeting, and help the panel members quickly begin to look at similar course. You'll notice that for today, we're going to cover many groups across multiple categories. Please follow along using the court lists provided in Appendix three of your agenda. We'll begin with the first code 0445 You were I will help begin the discussion for this code. So 0445 u is a path for Alzheimer's disease that beta amyloid and phospho tau we'll get to the slide. Okay, the first code Yeah. By Axia on test on CSF report as positive or negative for amyloid pathology. And the sub committee recommendation is to crosswalk this to 0358 u which is very similar in this long descriptors. It's very similar to the submitted code. So are there any new options from panel to consider? And the questions from the panel are from CMS

Unknown Speaker 15:01

If there are no additional comments or questions panel members please now cast your vote

Unknown Speaker 15:25
I believe we're waiting for one more response if you do need to abstain that's fine but please indicate

Unknown Speaker 15:58
Okay, we have everybody thank you

Unknown Speaker 16:01
moving to the next code or a to xx or which will be presented by Dr ramp

Unknown Speaker 16:14
mark

Unknown Speaker 16:23
you may unmute yourself.

Unknown Speaker 16:25
Thank you doctor so a 2x x Oh was

Unknown Speaker 16:34
two

Unknown Speaker 16:41
I believe this is for beta amyloid 140 It's a qualitative chemiluminescence assay for CSF

Unknown Speaker 16:57
and it looks like the options are to crosswalk to 0358 you.

Unknown Speaker 17:24
Are there any new options for the panel to consider? And are there any questions or comments from the panel or from CMS?

Unknown Speaker 17:34
Yeah, this is from Sarah from CMS. I just want to confirm your option just because you you you mentioned crosswalking to 0358 you by itself on the table we have a point five multiplier as an option. Is that still what you're putting forward? Or would you like to add the option of just three five au by itself?

Unknown Speaker 17:59
So the option here is 0358 u times point five is the multiplier. Excellent. Okay. And then of course there's the gap fill as well. Yes.

Unknown Speaker 18:16
There are no additional comments or questions on Discord panel members please now cast your vote

Unknown Speaker 18:39

Okay, thank you.

Unknown Speaker 18:41
Next code is a 2x x one also present by Dr. Mark rompler.

Unknown Speaker 18:57
Okay, so this is a 2x x one is another beta Lloyd assay. beta amyloid assay is the same methodology. It's for a different analyte for one dash for two. The options here again, similar to a 2x x Oh, our crop swap to 035 au times point five or gap fill.

Unknown Speaker 19:35
Are there any new options on the panel?

Unknown Speaker 19:38
A lot to consider.

Unknown Speaker 19:39
And are there any questions or comments from the panel of CMS? Okay, if there are no additional comments or questions on this, panel members, please now cast your vote

Unknown Speaker 20:01
Okay, that's complete Thank you.

Unknown Speaker 20:04
You the next code is a 3x x or which is myself is that neurofilament light chain, it was the post crosswalk 0358 u times 0.5 Because the methodology is very similar. The methodologies are very similar to 0358 you accept is only one analyte that's the multiply of 0.5. Then you options for the panel to consider or questions or comments from the panel or from CMS.

Unknown Speaker 20:48
No additional comments or questions on this court panel members please cast your vote

Unknown Speaker 21:07
Thank you.

Unknown Speaker 21:10
Next court is it x it 6x x one presented by Dr. ramp

Unknown Speaker 21:19
so it's x x x one under the immunology category is a test for strep pneumoniae a, an antibody IgG. It's a quantitative test. The panel is proposing app fill. It doesn't see us it doesn't see a comparable cost and resource comparison. 287633 So the options here for voting are a crosswalk 287633 Or a gap fill is the subcommittee recommendation.

Unknown Speaker 21:59
Thank you. Are there any new options on the panel to consider? Or any questions or comments on the panel or from CMS. Gov no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 22:26
Okay, thank you.

Unknown Speaker 22:29
Next court is x x presented by Dr. Rambler.

Unknown Speaker 22:40
Okay, this code is another subcategory immunology it's for Alzheimer's is for it's to detect total tau. The subcommittee is recommending a crosswalk to 035 eu with a point five multiplier. And the justification is that both assays are qualitative chemiluminescence assays for CSF. The only difference is that a three five you has two analytes where the testing question is a single analyte So the options are the subcommittee recommendation of a crosswalk to 035 au with a point five multiplier versus the gap fill.

Unknown Speaker 23:29
Thank you. Are there any new options from the panel to consider any questions or comments on the panel or from CMS?

Unknown Speaker 23:44
Okay, if there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 23:56
Okay, thank you

Unknown Speaker 23:59
okay, next code is x x bar to you. This is the code is on melatonin level study sleep level study. There was no presentations the subcommittee recommendation is to crosswalk to 80307 which is

Unknown Speaker 24:27
which describes that instrument chemical chemistry analysis by methodology very similar to the proposed code are there any new options on the panel to consider? Any questions or comments from the panel or from CMS?

Unknown Speaker 25:00
Are there no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 25:15
Okay, thank you.

Unknown Speaker 25:18
Next court is xx six five U. And the presenter is Dr. Vicky Celski.

Unknown Speaker 25:27
XX six five U is a meta genomic next generation sequencing assay for multiple etiologic agents that may or may be found in cerebral spinal fluid. There was a pretty clear crosswalk to 0323

you that was recommended by the committee this was also the crosswalk were recommended by the presenter.

Unknown Speaker 25:55
Danny knew options from the panel to consider any questions or comments on the panel from CMS?

Unknown Speaker 26:09
If there are no additional comments or questions on this code panel members, please now cast your vote.

Unknown Speaker 26:25
Okay, thank you.

Unknown Speaker 26:27
Next code is 86041 reconsideration code and presented by Dr. William Clark.

Unknown Speaker 26:36
Thanks. So this is a code it's 6041 which is acetylcholine receptor binding antibody. The panel recommended recommended 86341 last year and make that recommendation again this year. So the options or abstain gap fill or 86341.

Unknown Speaker 26:59
Thank you, Dr. Clark, the new new options on the panel to consider. Then any questions or comments from the panel from CMS?

Unknown Speaker 27:18
There are no additional comments or questions on this code panel members, please now cast your vote.

Unknown Speaker 27:32
Give

Unknown Speaker 27:34
me the next code. Is it 604 To a reconsideration. Again, we have no present station from the sponsors. Last year, the panel recommended 86341 because and this year that's that's the subcommittee recommends the same it's it cross walking into 86341. Are there any new options for the panel to consider? Are there any questions or comments from the panel or from CMS? Can no additional comments or questions on this code panel members please now cast your vote.

Unknown Speaker 28:30
Thank you.

Unknown Speaker 28:32
The next code is 8604 tree reconsideration code to be presented by Dr. Clock.

Unknown Speaker 28:41

For 86043. The panel recommended a crosswalk of 86053 from last year and we make the same recommendation this year.

Unknown Speaker 28:54
Thank you, Dr. Clark. Are there any new options from the panel to consider? Are there any questions or comments from the panel or from CMS? There are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 29:24
Thank you.

Unknown Speaker 29:26
Next code is 86366 presented by the clock.

Unknown Speaker 29:33
So 86366 was given a recommendation of crosswalk 284586 last year and we make the same recommendation for the share eight or 586 crosswalk.

Unknown Speaker 29:50
Thank you. Are there new options from the panel to consider? Are there questions or comments from the panel or from see Mrs. If there are no additional comments or questions on this court panel members, please now cast your vote

Unknown Speaker 30:19
Thank you.

Unknown Speaker 30:20
We go on to 0431 you presented by Dr. Clark.

Unknown Speaker 30:27
So 480431 you, we recommend a crosswalk 284238. The rationale being it's similar methodology and resources.

Unknown Speaker 30:43
Thank you. Are there any new options from the panel to consider? Either Questions or comments from the panel from CMS.

Unknown Speaker 30:59
There are no additional comments or questions on this court panel members, please now cast your vote

Unknown Speaker 31:17
Thank you.

Unknown Speaker 31:19
Next code is 0432. You presented by Dr. rompler.

Unknown Speaker 31:28

043 kill you is a cow's like protein antibodies performed on serum or CSF. It's a qualitative cell binding assay. So the committee recommended to crosswalk to 84238 because both assays were receptor detection assays and actually comparable resources and effort. So there's actually a couple of different selections here. One is a crosswalk to 843 Eight, and second is a crosswalk to these three codes oh three, four or five you Oh 419 u and Oh 411 u and then finally a gap fill?

Unknown Speaker 32:27
Are there any new options on the panel to consider? Are there any questions or comments from the panel or from CMS?

Unknown Speaker 32:43
The new edition additional comments or questions on this court panel members please now cast your vote.

Unknown Speaker 33:03
Okay, I'll say

Unknown Speaker 33:05
next code is 0443. You are neurofilament light chain ultra sensitive in another essay, serum or CSF. And this is very, we already had one neurofilament light chain crosswalk to 0358 with a multiplier of 0.5. And this is the recommendation from the subcommittee. Are there any new options on the panel to consider? Are there any questions or comments from the panel or from CMS? There are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 34:03
Thank you.

Unknown Speaker 34:04
Next chord is x x three. We want to move the screen to the x x three to you. This is a multiple myeloma quote testing by LC mass spec tandem mass spec. There was no presentation but we've done crosswalk. It's very close to 0077. You immunoglobulin paraprotein. And that's the recommendation of the subcommittee.

Unknown Speaker 34:46
Are there any new options for the panel to consider? Are there any questions or comments from the panel or from CMS? There are no additional costs So questions on this court panel members please now cast your vote

Unknown Speaker 35:16
Thank you.

Unknown Speaker 35:18
It's good. 039 for you. This is a quote for you have a s 16 compounds by liquid

Unknown Speaker 35:33

by liquid chromatography with tender mass spec. The subcommittee recommended a gap fill because last year we had a very similar code presented but since it's still in gap fill, we couldn't crosswalk it to that. So we're to be consistently across we are proposing gap fill again.

Unknown Speaker 35:58
Add any new options from the panel to consider. Are there any questions or comments from the panel or from CMS? There are no additional questions or comments on this court panel members please now cast your vote

Unknown Speaker 36:29
Thank you.

Unknown Speaker 36:31
Next code, is it x 051 to be presented by Dr. Shoemaker.

Unknown Speaker 36:39
Good morning. Yes, this 8x 05 line is a code for a mycobacterium tuberculosis assay with rifampin resistance by amplified purpose technique. The subcommittee recommends a crosswalk to 87556 which is the PCR assay for MTB detection, and then 87641, which is a code for a resistance gene.

Unknown Speaker 37:11
Thank you, Michelle. Are the new options for the panel to consider. Are there any questions or comments from the panel or from CMS? If there are no additional comments or questions on this court panel members, please now cast your vote.

Unknown Speaker 37:44
Thank you.

Unknown Speaker 37:46
Next court is it x o presented by Dr. rompler?

Unknown Speaker 37:59
So 8x 3x

Unknown Speaker 38:01
Oh is again for Alzheimer's,

Unknown Speaker 38:05
it's phosphorylated tau. The recommendation is to crosswalk this to 035 au with a multiplier of point five. And the rationale is that both of these essays are qualitative, chameleon chemiluminescent assays performed in CSF with the exception of a 0358 you has two analytes.

Unknown Speaker 38:42
Are there any new options for the panel to consider? Are there any questions or comments from the panel or from CMS? If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 39:08

Thank you.

Unknown Speaker 39:10
Next code is 8x x 00 to be presented by Dr. byzewski.

Unknown Speaker 39:20
Code x x 00 is an assay for etiologic agents of imagine itis and bacterial vaginosis it uses an algorithmic approach to identify likelihood of bacterial vaginosis. The subcommittee recommended a crosswalk to a similar in AAA code 81514, which is compatible to the recommendation made by several presenters. Thank you.

Unknown Speaker 39:46
Are there any new options from the panel to consider? Are there any questions or comments from the panel or from CMS?

Unknown Speaker 40:02
There are no additional comments or questions on this code panel members, please now cast your vote

Unknown Speaker 40:17
you

Unknown Speaker 40:19
next code is Oh 435 You to be presented by Dr. Shoemaker. Yes, thank

Unknown Speaker 40:29
you. This assay is for a chemotherapeutic drug cytotoxicity assay of cancer stem cells. We agreed the subcommittee agreed with recommendations to crosswalk to 0248. You based on the fact that the assay is similar in description and resources with 0248. You.

Unknown Speaker 40:56
Thank you. Are there new options from the panel to consider? Are there any questions or comments on the panel or from CMS? That no additional comments or questions on this code? Panel members please now cast your vote.

Unknown Speaker 41:23
next code is x x eight for you to be presented by Dr. Schoonmaker.

Unknown Speaker 41:30
Thank you. This assay is for HPV work for E six E seven markers for high risk subtypes. We did not have a presentation for this but the panel or the subcommittee recommended a crosswalk 287624 by virtue that the the eight 764 is similar in discretion to x x eight for you.

Unknown Speaker 42:01
Thank you. Are there any new options for the panel to consider? Are there any questions or comments from the panel or from CMS?

Unknown Speaker 42:18

If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 42:33
Thank you

Unknown Speaker 42:36
next court is x x eight nine you to be presented by Dr. Shoemaker.

Unknown Speaker 42:42
Thank you this this code is for an assay for infectious disease vaginal infection identifying 32 pathogenic organisms by PCR, the panel has record or the subcommittee has recommended a crosswalk 287507 plus 87506. On the basis that 805 or 87507 covers up to 25 targets and 87506 covers six to 11. And so by virtue of the number of targets we met or recommend the crosswalk to 87507 plus 80506.

Unknown Speaker 43:27
Thank you. Are there any new options from the panel to consider? Are there any questions or comments from the panel from CMS

Unknown Speaker 43:46
that no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 44:03
Thank you

Unknown Speaker 44:05
next court is xx nine nine you to be presented by Dr. Clark.

Unknown Speaker 44:12
Thank you. Code x x nine nine U is an amino assay for quantitative determination of infliximab. The committee recommendation is a crosswalk to eight zero to three zero, which is a drug assay for infliximab.

Unknown Speaker 44:33
Thank you. Are there any new options from the panel to consider? Are there any questions or comments from the panel or from CMS?

Unknown Speaker 44:49
There no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 45:28
Okay, thank you

Unknown Speaker 45:30
next coders x x nice seven you to be presented by Dr rompler

Unknown Speaker 45:38
x x nine seven U is a solid tumor assay. It looks at a total panel of 36 or more drugs and is reported as a tumor response prediction for each drug. So the committee recommended a crosswalk to zero to four au on because the assays are comparable in nature, the only difference is that x 697 Us 36 analytes instead of 12 or 0248. You

Unknown Speaker 46:14
Thank you. Are there any new options on the panel to consider?

Unknown Speaker 46:22
Are there any questions or comments from the panel or from CMS?

Unknown Speaker 46:33
If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 46:52
Thank you. Next code is x x nine AU. This is a code for Irritable Bowel Disease immuno assay for adalimumab. And this subcommittee is cross recommending a crosswalk to 80145 as this is code for an essay for adult limits met. At any new options on a panel to consider any questions or comments from the panel from CMS? There are no additional comments or questions on this code panel members please now cast your vote.

Unknown Speaker 47:53
Thank you.

Unknown Speaker 47:55
Next code is 0430 you presented by Dr. Clark

Unknown Speaker 48:03
0430 u is malabsorption evaluation consisting of four analytes. The recommendation is to crosswalk to eight to 103 plus 83993 plus 82653 plus 84376. The rationale being that all four of these codes correspond to the analytes that are in the malabsorption panel and the same methodology and resources would be needed for the individual tests.

Unknown Speaker 48:43
Thank you. Are there any new options on the panel to consider? Are there any questions or comments on the panel from CMS?

Unknown Speaker 49:00
Got no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 49:18
Thank you.

Unknown Speaker 49:20

Next code is 0427 you monocyte distribution with whole blood. The subcommittee recommends a gap fill because this monocyte distribution index the wave is most similar to the red cell distribution with the has no seat CPT code currently, and so we get recommending a gap fill.

Unknown Speaker 49:51
Are there any new options on the panel to consider? Are there any questions or comments from the panel? From CMM s if there are no additional comments or questions on this code, panel members, please now cast your vote

Unknown Speaker 50:30
Okay, thank you

Unknown Speaker 50:33
Nexus X one zero to you to be presented by Dr. rompler.

Unknown Speaker 50:39
X one zero to you is a therapeutic drug monitoring assay. It looks at too much or possibly more compounds in plasma, and the methodology uses LC Ms. Ms. So, the descriptor indicates that it's a qualitative and quantitative assay. The Committee recommends the committee was split and recommends some recommended a gap fill and some recommended a crosswalk to G zero 43. Because the comparison between the proposed crosswalk is not well understood. I do want to know there are a few questions from the committee here to the presenters. Would the committee like to ask those now? Yes.

Unknown Speaker 51:31
Presenter available?

Unknown Speaker 51:33
Yes. John Caicos.

Unknown Speaker 51:37
So, one of the first questions from the committee was, how many drugs were qualitative versus quantitative in this assay?

Unknown Speaker 51:52
All of them are qualitative.

Unknown Speaker 51:55
All of the drugs are qualitative. And so the ask is this assay, a combination of therapeutic drug monitoring versus drugs of abuse testing.

Unknown Speaker 52:08
Most of us in this assay are affecting the cardiovascular system, diabetes, gi agents. So it's mostly almost all of its therapy. There are no drugs.

Unknown Speaker 52:21
So I'm sorry, Mark. And Chris, can I ask a question here? Yes. Thank you. So you just told us that all of the descriptor says it's qualitative and quantitative for these 200 more drugs. And that's, that's why we ask the question, you've just told me these are all qualitative, all 200 are

qualitative. So there's no discrete number, it's just a positive negative. So in therapy, therapeutic drug monitoring is typically a dose adjustment based on the clinical picture plus the quantitative result. So if this is 200, qualitative results, how is this different than a drug screen? So

Unknown Speaker 53:10
a lower range is that therapeutic is a lower balance, but therapeutic reference. So a lot of the drugs a low therapeutic index and a higher density or a low they're going to hide their brain. So our lower bound is the lower limit of the therapeutic range.

Unknown Speaker 53:29
Right, but you're not giving a number. If it's qualitative detection, you're saying present, not present. So the the detection limit is fine. But if your detection limit is the lower end of the therapeutic index, let's say it's five, when you detect it, it could be seven, or it could be 700. And you're still giving the same answer, which is present, and the effects of that drug, you know, because if you need therapeutic drug monitoring, typically, you're concerned about efficacy. So as the number above the therapeutic, you know, minimum effective concentration, but you're also worried about toxicity, which is is the concentration above the upper bound? A qualitative assay does not tell you this. So I'm going to ask again, how is this different than a typical testing for positive and negative? How are you going to do therapeutic dosing decisions based qualitative result?

Unknown Speaker 54:27
So part of part of the test is not just centered on dosing, it's also looking at things like adherence within the range within therapeutic range, because the literature shows that most of the times when a drug is out of the therapeutic range of effectiveness, it's on the lower side, it's toxic, they're likely to have side effects and they're not going to be in the primary care appointment. So this is meant to be in the primary care setting where patients are coming in and checking their medications and their six month old weapons. So it's not necessarily being used to check for critical values. Yeah. Okay, I'll

Unknown Speaker 55:02
stop there. I'll stop there. But

Unknown Speaker 55:05
I actually want to continue on and just ask the question, how does the development of those reference ranges play into the resources needed for the test?

Unknown Speaker 55:15
Okay, that clock and Robert, do you have do you have any more questions?

Unknown Speaker 55:23
I do not I have everything I need to know.

Unknown Speaker 55:25
Thank you. Dr. Ramp. Well, one

Unknown Speaker 55:29

final question was the Dylan You mentioned development of the reference ranges, but I'm unsure about how developing the reference ranges adds to the resources needed to run the test.

Unknown Speaker 55:47
So, in our AC, we have analytical range that the cutoff the cutoff value is their lower bound of salary range. So let's say the contribution the canabis are simply ranges like 80 to 100 and we use know about 80 as a cut off, so if construction is higher than the current which means the country should use wheezing, their superior range that is as except effective dose

Unknown Speaker 56:23
okay

Unknown Speaker 56:27
I have no further questions. Okay. So I guess if there are no additional comments or questions panel members please now cast your vote

Unknown Speaker 56:53
Okay, thank you. Next code is x x eight five you to be presented by Dr clock.

Unknown Speaker 57:02
So x x eight five U is a neurology test consisting of beta amyloid and tau protein by immunoprecipitation, followed by LCMS analysis. The public recommendation was a crosswalk 20247 U, which was an LCMS measurement of two distinct analytes its growth factor binding protein and a sex hormone binding globulin. So that was one crosswalk that was suggested publicly, the scientific committee recommends a different crosswalk, which is 2038 for you, which consists of an LCMS analysis of to analyze but it also includes an amino acid for hemoglobin a one C, and then a calculation of EGFR. And the feeling was that this more accurately represented the methodology and resources. So the the committee recommendation is Oh, three, eight for you.

Unknown Speaker 58:07
Thank you, are there any new options for the panel to consider? Are there any questions or comments from the panel from CMS? No additional comments or questions on this court panel members please now cast your vote.

Unknown Speaker 58:40
Okay, thank you.

Unknown Speaker 58:43
Next code is x x AU, to represent it by Dr. Schoonmaker.

Unknown Speaker 58:50
Yes, x x au is a code for a assay an assay to identify urinary tract infection pathological organisms of 17. To be specific by PCR, the subcommittee recommends a crosswalk to 87507 being similar in the number of targets and in the methodology.

Unknown Speaker 59:18

Thank you. Are there any new options for the panel to consider? Are there any questions or comments on the panel from CMS?

Unknown Speaker 59:34
Dr yet, Dr. Jeong Yeah,

Unknown Speaker 59:37
I just realized on my website with a poor answer the question I mean, the code is different from the code just presented.

Unknown Speaker 59:47
X X eight it you? It

Unknown Speaker 59:49
is okay. All right. That's it nice. Correct. Sorry.

Unknown Speaker 59:53
Okay, sorry

Unknown Speaker 59:54
about that.

Unknown Speaker 59:55
Thank you.

Unknown Speaker 59:57
Okay, if there are no additional comments or questions on This court panel members, please now cast your vote

Unknown Speaker 1:00:12
Thank you. Oh, wait, hold on. Sorry. Thank you. Okay. And I go on. Yeah. Okay. Yes, sorry. Okay.

Unknown Speaker 1:00:22
No problem. Next chord is it 7x x or zero to be presented by Dr. Mazursky.

Unknown Speaker 1:00:33
Eight 7x x zero is an amplify qualitative amplified probe assay to detect the fungal agent pneumocystis Joe vici. The subcommittee recommends a pretty straightforward crosswalk to another qualitative amplified probe assay for fungus 87481.

Unknown Speaker 1:00:57
Thank you. Are there any new options on the panel to consider? Are there any questions or comments from the panel or from CMS? That no additional comments or questions on this code. Panel members please now cast your vote.

Unknown Speaker 1:01:49
We are waiting on one more response. Just check that your vote has read. There we go. Thank you.

Unknown Speaker 1:01:56
Thank you. Eight Seven next code is eight 7x x one to be presented by Dr. Bill Celski.

Unknown Speaker 1:02:06
Eight 7x x one is an HPV assay, qualitative assay that by the descriptor presents a pooled result for multiple high risk types, and then calls out separately several six actually separate high high risk type. So one pooled result and six type specific results. The subcommittee felt like 87624 represented the pool result, and 87625 represented the called out high risk results. I will say that the choices listed on the slide here don't reflect my notes or the SM recommendation that 876 to five would be times two because 87625 is four, three call outs in this the six call outs. So we may have to move this. My notes indicated the subcommittee was 87624 plus 87625 times two. Michelle, you were secondary on this. Do you have any comment?

Unknown Speaker 1:03:19
Um, no, my my notes indicate the same thing, Vicki?

Unknown Speaker 1:03:24
Oh, what we'll do is we'll move this quote to the end of the session so that the recommendation can be updated.

Unknown Speaker 1:03:33
I can I can do it pretty quickly if that's what the group definitely. Rashidi

Unknown Speaker 1:03:38
adopted Arthur, if this is correct. If that's procedurally correct, please go ahead and update the the vote and then we'll vote

Unknown Speaker 1:03:47
yes, as long as the rest of the panel understands the distinction in the recommendation has adequate time to be able to make a

Unknown Speaker 1:03:54
decision.

Unknown Speaker 1:03:58
Okay, are there any questions on the comments from the panel?

Unknown Speaker 1:04:03
So Dr. Bill Celski, that now looks correct. Yes. Okay. Perfect. Thank you.

Unknown Speaker 1:04:08
Glen. Could you do times to where or option number four we're saying 87624 plus 87625? Yes. Thank you. Hence the entire thing times two, correct.

Unknown Speaker 1:04:24
Correct. Thanks.

Unknown Speaker 1:04:29

Any comments from the panel from CMS?

Unknown Speaker 1:04:35
Sorry, Dr. Celski, my math pandas right it? Is it just 8765625 times two, or it's the sum of those two times 287624

Unknown Speaker 1:04:48
plus 87625 times two.

Unknown Speaker 1:04:54
Okay, so as it's written,

Unknown Speaker 1:04:57
yeah, as it's written on the ballot, just

Unknown Speaker 1:04:59
Correct

Unknown Speaker 1:05:00
Thank you very much

Unknown Speaker 1:05:04
okay there are no additional comments or questions on this court panel members please now card your vote

Unknown Speaker 1:05:18
okay thank you

Unknown Speaker 1:05:28
next code is x x i don't see three nine you This is an oncology code with ES two proteins by Eliza testing on no that's not what I have I have x x three nine you vote this wrong they

Unknown Speaker 1:05:55
actually x x four eight you

Unknown Speaker 1:05:59
know I have Trina you my tracker

Dr Lennerz MGH 1:06:04
no I also see x x four eight you

Unknown Speaker 1:06:10
in the board? Yes but

Dr Lennerz MGH 1:06:11
in the tracker as well.

Unknown Speaker 1:06:15
Really? Okay, and my tracker is off

Dr Lennerz MGH 1:06:19
it's number 34 Row 36.

Unknown Speaker 1:06:26
Are wait I know what happened I went through quickly my mistake apologize to everybody. So the next chord is x x for you hepatology code for Nash to be presented by Dr. Shoemaker.

Unknown Speaker 1:06:42
Yes. XX for AU for Nash is a combination of detection of markers by multiple methods reported as a single score for Nash activity and fibrosis. The subcommittee agreed with the recommendations for a crosswalk to 0.5 times 000 3am.

Unknown Speaker 1:07:08
You add any new options on a panel to consider? Are there any questions or comments on the panel from CMS? There are no additional medical questions on this court panel members please now cast your vote

Unknown Speaker 1:07:35
Okay, the

Unknown Speaker 1:07:37
next chord is 0436 you to be presented by Dr. Shoemaker.

Unknown Speaker 1:07:47
This code 0436 U is for an assay to detect 388 proteins using abnormal based proteomics for I believe it's lung cancer reported as a predictive algorithm from the immune checkpoint inhibitor therapy perspective. The recommendation was for a crosswalk to 0249 You, however, because that was gap filled last year and not priced on the 2024 CLF. S. The subcommittee recommends a gap fill

Unknown Speaker 1:08:33
Okay, are there any new options from the panel to consider? There any questions or comments from the panel from CMS?

Unknown Speaker 1:08:43
Can I just ask please, this is Vicki the soundscape of CMS just point point of clarification. We cannot crosswalk to something currently in the gap fill process correct?

Unknown Speaker 1:09:00
That's correct. All right. Thank you

Unknown Speaker 1:09:01
there has to there has to be there has to be a rate on the CLF s for it to be used as a crosswalk.

Unknown Speaker 1:09:09
Thank you.

Unknown Speaker 1:09:11

Any more comments? Okay, if there are no more comments panel members please now cast your vote.

Unknown Speaker 1:09:41
Okay, thank you.

Unknown Speaker 1:09:42
Next code is 0446 You are to be presented by Dr. Schoonmaker.

Unknown Speaker 1:10:00
Dr Shoemaker

Unknown Speaker 1:10:04
Sorry, I had muted myself 0446 You is an assay for autoimmune disease systemic lupus an analysis of 10 cytokine soluble mediator biomarkers by immune assay. The subcommittee recommends a crosswalk to 81490 on the basis that 89481490 is similar in description and resources for the same for another autoimmune assay analysis of 12 biomarkers by the same method. Thank you.

Unknown Speaker 1:10:43
Are there any new options from the panel to consider? There any questions or comments from the panel or CMS? You then no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:11:08
Thank you.

Unknown Speaker 1:11:09
Next code is 0447. You again by Dr. Schoonmaker.

Unknown Speaker 1:11:16
Yes, 0447 u is another autoimmune disease assay for systemic Lupus Lupus analysis of 11 cytokine soluble mediator biomarkers by immuno assay. Again, the crosswalk recommendation is to 81490 on the basis that it is similar and description and resources.

Unknown Speaker 1:11:43
Are there any new options on the panel to consider? Are there any questions or comments from the panel as from CMS? If there are no additional comments or questions on this code panel members, please now cast your vote.

Unknown Speaker 1:12:15
Thank you very much.

Unknown Speaker 1:12:17
Next code is x 103. You to be presented by Dr. rompler.

Unknown Speaker 1:12:25
X 103. U is a therapeutic drug monitoring assay for 90 or more drug substances. It's similar to the last code that I proposed. It's an LCMS assay. It's a qualitative assay performed in plasma.

We believe we addressed all the questions there was some questions initially from the panel members and the panel was split on the recommendation but I believe we resolved those questions in the earlier proposal. That submitted subcommittee recommendation which was split was a gap fill or a crosswalk to g 0483. I just want to check to see if there are any other questions from the panel members before we move on.

Unknown Speaker 1:13:21
Okay

Unknown Speaker 1:13:24
are there any questions or comments from the panel from CMS? If there are no additional comments or questions on this court panel members please now cast your vote.

Unknown Speaker 1:14:05
Waiting on one respect there it is. Thank you.

Unknown Speaker 1:14:09
Next code is 0429. You to be presented by Dr. Vicky Purcell. See,

Unknown Speaker 1:14:17
code 0429. New is another HPV qualitative assay that identifies 14 high risk types of HPV. What's unique about the assays that is configured for oral pharyngeal screening as opposed to genital screening. The subcommittee discussed this and was a little unclear on how the reporting is actually formatted. If the assay presents a pooled result, 87624 would be appropriate if it calls out specific types, some number of eight sevens six to five would be appropriate. What I would like to ask for is if the presenter is available if they could provide some clarification on how reporting of this result actually occurs.

Unknown Speaker 1:15:16
Is the left is proposing submit submitted this code available to answer the question

Unknown Speaker 1:15:32
Dr. Bill Celski, I don't think they are on the call.

Unknown Speaker 1:15:34
I don't think they're on the call either. They would have spoken up I think they made an I am. Hi. Hi, I'm

Unknown Speaker 1:15:41
on the call Sorry, I was having trouble unmuting myself. Can

Unknown Speaker 1:15:46
you please clarify how the assay is configured and reported?

Unknown Speaker 1:15:50
Yes. So the assay is could

Unknown Speaker 1:15:53
you please state your name and organization? Thank you. Sure.

Unknown Speaker 1:15:56
This is Dr. Muhammad Kamal with Omni pathology. So the assay is is configured to report HPV three results HPV 16, HPV 18, and other and the other includes the remaining 12 HPV types. So the oral pharyngeal swab is performed. And it's an it's, it's run on the Roche corpus system and the results on every assay we the the, the doctor will get three results. One positive negative on 16, HPV 16, one positive negative and HPV 18. And then positive negative on other.

Unknown Speaker 1:16:49
Thank you, Dr. Celski, do you have the answer? You're looking?

Unknown Speaker 1:16:52
Yes. Thank you very much. Um, that that was actually what the committee had considered. Therefore, our recommendation would be 87624 plus 87625 times one. Okay, thank you.

Unknown Speaker 1:17:11
Okay, are there any questions or comments from the panel or from CMS? If there are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:17:35
Thank you.

Unknown Speaker 1:17:38
Next court is xx tree nine you. And this is oncology breast cancer test screening for two proteins by Eliza on tear fluid. The recommendation from the subcommittee is a crosswalk 281500 which is a very similar in resources and methodology.

Unknown Speaker 1:18:12
Are there any new options on the panel to consider? Are there questions or comments from the panel from CMS? If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:18:40
Thank you.

Unknown Speaker 1:18:42
Next court is x 101 used to be presented by Dr. Clark.

Unknown Speaker 1:18:49
X was there a wide view is another broad spectrum screening assay by LC ms ms. In this case it's 80 or more psychoactive drug and plasma the we've already discussed the questions and and discussion before the split recommendation is either GAAP fell or geo 483 Thank you

Unknown Speaker 1:19:23
there any questions or comments on the panel from CMS? If there are no additional questions, comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:19:45

Thank you,

Unknown Speaker 1:19:48
school is x x six three you to be presented by Dr rompler x x

Unknown Speaker 1:19:55
x three years. Plasma biochemical assay looks at two analyze tyrosine kinase one a growth factor as it relates to preeclampsia, and then has a predictive algorithm to determine the risk. So the committee recommendation is a crosswalk to 0243 u times two. And the idea behind this recommendation are that both assays are for preeclampsia. They're biochemical on nature, and they're both utilize serum and have predictive algorithms. So the only difference is that x x x three you has twice the amount of analyzers to analyze instead of just one

Unknown Speaker 1:20:39
for the crosswalk.

Unknown Speaker 1:20:44
Are there any new options for the panel to consider? Are there any questions or comments from the panel from CMS? If there are no additional comments or questions on this quote panel members, please now cast your vote.

Unknown Speaker 1:21:18
Next quarters 87593 And to be presented by Dr. Celski.

Unknown Speaker 1:21:28
87593 is a qualitative amplified probe assay for ortho pox virus which includes in pox virus. The recommendation aligns with those by presenters to crosswalk to 87635 which is another qualitative qualitative amplified probe assay for another emerging pathogen SARS cov, two so, recommendation 87635 crosswalk.

Unknown Speaker 1:21:57
Thank you. Are there any new options from the panel to consider? There any questions or comments from the panel or from CMS? If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:22:23
Thank you.

Unknown Speaker 1:22:25
Next code is 044 to you to be presented by Dr. Brzozowski.

Unknown Speaker 1:22:32
044 to you is a lateral flow immunoassay assay or optical immuno assay procedure to detect to biomarker analytes intended to distinguish between different radiologic agents of respiratory infection it's intended for point of care use relatively simple technique Our recommendation is to crosswalk to another optical immuno assay procedure 87811 There is a difference in that this lateral flow immuno assay has to analyze and 87811 has a single analyte but we still felt that it was similar resources required for those assays. So recommendation crosswalk 287811

Unknown Speaker 1:23:23
Thank you. Are there any new options for the panel to consider? Are there any questions or comments from the panel from CMS if there are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:23:56
Okay, thank you.

Unknown Speaker 1:23:59
Next code is x x three u which is swap P FAS night compounds by LC tender mass spec a subcommittee recommended a gap fill folks very similar court last year and since that's doing gap fill we have to be consistent we have to get filled to 394 cross which is three four. Sorry. Question for CMS is three four now you now given a value

Unknown Speaker 1:24:45
actually I'm seeing something we need to check. Because in option it says 349 you but in the descriptor it's 394 you so something got transpose there

Unknown Speaker 1:24:59
now Before you but the 394, you have a value because if not, then we cannot crosswalk to that for this year. And so the recommendation from the committee has to be a gap fill.

Unknown Speaker 1:25:13
This is Dr. Jennifer Chang. I do well open the Quarter Three file from 2024 CPT code found the 2024. It does have a value is $198.74.

Unknown Speaker 1:25:29
But it's not finalized.

Unknown Speaker 1:25:39
If CMS can verify the evidence already on the CRFs, then we can crosswalk to 394. You otherwise were to get fill

Unknown Speaker 1:25:47
in looks like it's on the latest CLF s. Okay.

Unknown Speaker 1:25:51
Well, can CMS verify that?

Unknown Speaker 1:25:54
Yeah, this

Unknown Speaker 1:25:55
is Sarah Sherry, also at CMS, and

Unknown Speaker 1:25:58
we do have a rate for 039

Unknown Speaker 1:26:00

for you.

Unknown Speaker 1:26:02
Okay, thank you. So then the recommendation is then the crosswalk 20394.

Unknown Speaker 1:26:12
And this is Sarah Harding. I just want to state sort of for the record that I did change the recommendation to three nine for you. And therefore what is shown on the screen as 349 you was a transposition is incorrect, but we will update that as well. But you are indeed voting for a crop potential crosswalk of three nine for you, which is that full descriptor? The correct descriptors is on the screen right now.

Unknown Speaker 1:26:47
Thank you, Glen.

Unknown Speaker 1:26:49
Okay, so are there any questions or comments in the panel from CMS? If there are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:27:09
Okay, thank you.

Unknown Speaker 1:27:12
Next code is x one zero for you to be presented by Dr. Randall.

Unknown Speaker 1:27:22
X one zero for you is another therapeutic drug monitoring assay. Similar to the previous three proposed, the only difference here is that it has 110 or more drugs in their resulted qualitatively, the proposal here is excuse me, this subcommittee recommendation. Similar to the other three proposals is the same as a gap fill or a crosswalk to g 0483.

Unknown Speaker 1:27:58
Thank you, are there any new options on the panel to consider? Are there any questions or comments from the panel or from CMS? There are no additional comments or questions on this code panel panel members please now cast your vote

Unknown Speaker 1:28:30
Okay, thank you.

Unknown Speaker 1:28:33
Next chord is x x three one you have multiple myeloma code for liquid chromatography, tandem mass spec of monoclonal proteins and the the subcommittee is recommending a crosswalk to 0077 you because of the similarity in methodology and resources. There were no presentations for us to refer to.

Unknown Speaker 1:29:10
Are there any new options on the panel to consider? Are there any questions or comments from the panel or from CMS? If there are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:29:39
Thank you.

Unknown Speaker 1:29:43
Next call is x x 360. You can be presented by Dr buss ASCII

Unknown Speaker 1:29:51
code x x three six U is a multiplex assay to detect three agents three sexually trained transmitted infection agents. We are recommending a crosswalk 2040 to you, which is a similar qualitative assay. It is for four analytes as opposed to three analytes. However, groupings in multiplexes generally cover a range of three to five so we felt comfortable recommending 040 to you as a crosswalk

Unknown Speaker 1:30:31
and then in new options from the panel to consider any questions or comments from the panel from CMS? If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:30:53
Thank

Unknown Speaker 1:30:55
you next call is x x six six you to be presented by Dr. Shoemaker.

Unknown Speaker 1:31:04
Yes, thank you. This assay is for detection of Neisseria gonorrhea sensitivity to ciprofloxacin, Cipro lots of kin is a point mutation, but the result is an algorithm reporting the probability of floor quinolone resistance. The committee had some questions with this assay as to whether or not it it also did the identification of the Neisseria gonorrhea or if it was just the AMR on positive samples, and whether it was a direct specimen versus in an assay performed on an isolate. There was no presentation but if anybody else from the subcommittee would like to weigh in here, or if there's a sponsor for this code that could provide additional details that would be very helpful.

Unknown Speaker 1:32:00
Is the lead submitting this code on the call? To answer the question?

Unknown Speaker 1:32:16
Dr. Shoemaker, I don't think that the submitting lab is on the call.

Unknown Speaker 1:32:21
Okay, I think then, our recommendation from the subcommittee would be to get Phil this code again, because it's not just the detection of the point mutation as positive or negative, negative, but it's a report out of an algorithm as a probability of resistance. And I don't believe that we had a similar code to recommend a specific crosswalk. Thank you.

Unknown Speaker 1:32:50
Are there any questions or comments to the panel or from CMS?

Dr Lennerz MGH 1:32:54
A quick note here, this is Troy Leonard's in the voting tool. Good one option is at least my version not present. So the 87563 that is on screen is not in the x 6x. You question?

Unknown Speaker 1:33:21
Yeah, that seems to be missing in the

Unknown Speaker 1:33:23
I'm adding it right now. Thank you very much for pointing that out.

Unknown Speaker 1:33:30
And, wow, there we go.

Unknown Speaker 1:33:35
Okay. So both of those codes that 876-418-7563 are for qualitative detection, and, you know, detected or not detected for identification rather than the resist resistance. 87641 is a resistance gene, but again, its presence or absence, it's not reported as a probability of resistance. And so I think that's why we had recommended the gap fill.

Dr Lennerz MGH 1:34:11
I I think I understood the favor for option two by the subcommittee just meant to point out that the other options were not all there. But I think if I understood you correctly, the subcommittee recommends gap fill.

Unknown Speaker 1:34:27
Yes. Dr. Burzynski, did you have any comments on this one?

Unknown Speaker 1:34:33
I think absent any clarity by the sponsor of this code, gap, Phil is probably the the more reasonable option. There's too many questions about what is actually being detected and reported.

Unknown Speaker 1:34:51
Thank you. Thank you.

Unknown Speaker 1:34:56
Are there any additional comments from the panel? Okay then none panel members please cast your vote

Unknown Speaker 1:35:18
Okay, thank you

Unknown Speaker 1:35:21
next code is x x four three you to be presented by Dr. byzewski

Unknown Speaker 1:35:29
So code x x four three u is another HPV code. It is for gene expression of 14 biomarkers. It's seven types of HPV with two markers for total of 17. What was not clear from this descriptor

again is how the report is configured Is it a pooled report is it individual types reported? This would influence what a crosswalk recommendation would be. So absent any clarity on the part of the sponsor, we would recommend gap fill but if the sponsor is available to address this issue, that would be appreciated

Unknown Speaker 1:36:17
as a sponsor on on a call. Yes, we are

Unknown Speaker 1:36:20
here this is a really Gibson with milma medical and in the description it reads that the the last

Unknown Speaker 1:36:41
cervical dysplasia or cancer for each.

Unknown Speaker 1:36:53
biomarkers.

Unknown Speaker 1:36:58
Okay, thank you.

Unknown Speaker 1:36:59
We'll

Unknown Speaker 1:37:03
certainly send that in our sample report.

Unknown Speaker 1:37:09
Thank you adoptable. Celski,

Unknown Speaker 1:37:10
I think the explanation is is sufficient. We discussed that as a possibility for reporting Falk recommendation from the sponsor and we would recommend gap fill.

Unknown Speaker 1:37:29
Thank you. Are there additional comments or questions on this code? Now cast your vote

Unknown Speaker 1:37:46
Okay, thank you.

Unknown Speaker 1:37:49
Next code, is it x 050 to be presented by Dr. Shoemaker.

Unknown Speaker 1:38:01
Yes, this is an assay PCR for h pylori for drug resistance. And I we had some discussion about this one as well. And I believe the subcommittee we landed on a recommendation of a crosswalk 287150 which is confirmation of a target on a culture spell specimen

Unknown Speaker 1:38:32
by PCR. Okay, thank you.

Unknown Speaker 1:38:37
There any questions or comments from the panel from CMS?

Unknown Speaker 1:38:43
Can I comment please, that we did get clarification by the sponsor that this was an assay performed on an isolate not on a direct specimen. So that just to clarify why 87150 Thank you.

Unknown Speaker 1:39:02
Okay, if there are no additional comments or questions on this court panel members please now cast your vote

Unknown Speaker 1:39:21
think if

Unknown Speaker 1:39:23
the next code is xx five to you to be presented by Dr. Schoonmaker.

Unknown Speaker 1:39:33
Yes, x x five to you is an assay for multiple targets, I believe it's it looks like six reactions and including two proteins and three immunoglobulin assays representing a multiplex antibody assay. We could not find a comparable code to recommend a crosswalk and there was presentation so the subcommittee recommended gap fill.

Unknown Speaker 1:40:07
Then in new options on the panel to consider are there any questions or comments from the panel from CMS? There are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:40:35
Okay, thank you. Next

Unknown Speaker 1:40:37
call is x x six to you to be presented by Dr rompler.

Unknown Speaker 1:40:44
X X X to you is an assay for Alzheimer's and detects phosphorylated tau. In similar to the other tab based assays that were proposed earlier today, the committee is recommending a crosswalk to 035. Eu. There are some differences between the proposed assay and the crosswalk. But the committee doesn't think this is sufficient to two, it's sufficient to warrant a gap fill. So, the crosswalk is suggested to 0358 you.

Unknown Speaker 1:41:25
Thank you, are there any new options on the panel to consider?

Dr Lennerz MGH 1:41:31
I have one one quick question. So this is to analyze correct phosphorylated tau and p tau to 17 Or is this one analyte.

Unknown Speaker 1:41:45
So, this is this is to analyze in the end the previously proposed assays. Earlier today, we saw a couple of proposals that had one analyte which is why we were across walking or suggesting a crosswalk the 0358 U times point five. In this case, there are two analyzers zero through five AU has also has two lights.

Dr Lennerz MGH 1:42:15
That's just wondering because if it's only the phosphorylated tau at position 217 The long code descriptor would look the same Correct?

Unknown Speaker 1:42:28
Is the sponsor in lab or on the call to answer that question?

Unknown Speaker 1:42:40
Hello is this is this 456 or 53?

Unknown Speaker 1:42:45
No six to you 53 Okay,

Unknown Speaker 1:42:49
thank you

Dr Lennerz MGH 1:42:59
I think I think it's okay to test developer is not there and the information provided the sufficient

Unknown Speaker 1:43:10
there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:43:37
Okay, thank you.

Unknown Speaker 1:43:41
The next code is x x seven to you have to be presented by Dr. Schoonmaker.

Unknown Speaker 1:43:49
Yes, x x seven to you is a another assay for infectious disease Mycoplasma genitalium looking at micro led sick sensitivity, it looks like it is a single point mutation, but the reported result is an algorithm that is reported as a probability of the micro led resistance. And again, we did not have any information from the sponsor on this code. And so if a sponsor is available and could provide some information that would be awesome. See,

Unknown Speaker 1:44:31
you okay, is the sponsor lab on the on the call?

Unknown Speaker 1:44:46
Okay, then for the sake of being consistent, the subcommittee would recommend a gap fill for this code again, because the other codes recommended were for the direct detection of

mutation as positive or negative and again, this is an algorithm reported as a probability of resistance. And thus the committee recommendation would be forget Phil. Thank you.

Unknown Speaker 1:45:13
Any questions or comments from the panel from CMS? If there are no additional comments or questions on this code panel members please now cast your vote

Unknown Speaker 1:45:47
Okay, thank you.

Unknown Speaker 1:45:49
Next code is 0441. You to be presented by Dr. Wysocki.

Unknown Speaker 1:45:56
0441. You is a novel white blood cell deformability assay you used in the analysis of an infectious disease etiology, we were not able to find a comparable white blood cell deformability as a code for cross walking, there was a recommendation to use a code for red blood cells, but there's nothing for white blood cells. So we felt that gap fill would be the most appropriate mechanism in this case.

Unknown Speaker 1:46:34
Thank you. Are there any new options on a panel to consider? Are there any questions or comments from the panel from CMS? If there are no additional comments or questions on this code panel members please now cast your vote.

Unknown Speaker 1:47:12
Okay, thank you.

Unknown Speaker 1:47:15
Next code is xx was zero Are you in beta amyloid and total tau by Achaea on CSR and the subcommittee is recommending a crosswalk to 0358. Us This is very similar to the source of by the same idea to analyze on CSV.

Unknown Speaker 1:47:48
And then in new options on the panel to consider are there any questions or comments from the panel or from CMS? If there are no additional comments or questions on this code panel members, please now cast your vote.

Unknown Speaker 1:48:12
Okay, thank you.

Unknown Speaker 1:48:16
The loss of the CIM codes 0420 used to be presented by Dr. BISSELL. Dr. Shoemaker.

Unknown Speaker 1:48:24
Yes, thank you. This code is for an assay looking at mRNA expression profiling by real time quantitative PCR with droplet digital PCR have an analysis of six single nucleotide polymorphisms reported as an algorithm in a risk score for your fear you'll carcinoma. But recommendation we had several recommendations from the public one being 0012 m by itself

and then 0012 m plus 0356 u 0356. You was not priced on the 2024 clinical laboratory fee schedule at least at the time that we were having these discussions and therefore the subcommittee would recommend got Phil for this code

Unknown Speaker 1:49:22
that the new options for the panel to consider. Any questions or comments on the panel from CMS? No additional comments or questions on this code panel members please now cast your vote.

Unknown Speaker 1:49:37
Hey there, I'm

Unknown Speaker 1:49:38
sorry. This is Sarah Sharia law. So

Unknown Speaker 1:49:40
from CMS. I just wanted to clarify that on the current clinical lab fee schedule file. You do have a payment rate for 0356 view eight Thank you

Unknown Speaker 1:50:01
Dr should make does that alter your recommendation?

Unknown Speaker 1:50:07
Um,

Unknown Speaker 1:50:09
Does anybody else want to lay in here? I mean, I think it would I think the rationale was that because that code was not priced at the time that we were doing the analysis that the recommendation was gap fill. So if any of my other subcommittee members would would would like to wait in that would be appreciated.

Unknown Speaker 1:50:31
Any comments from the rest of the panel?

Unknown Speaker 1:50:38
This is Dr. Jennifer gel. I just look at a code of 40356 you and it's not only for the droplet digital PCR they are yes, they all use a cell free DNA. I don't think the for the Code of 0420 you do they use cell free DNA?

Unknown Speaker 1:50:59
Is the present is the sponsor on the call to answer that question? Are you using cell free?

Unknown Speaker 1:51:07
This is DNA derived from a urine sample. So it could be cell pretty or or sell based in here that's, that's been laced. Okay, thank you.

Unknown Speaker 1:51:18
Can you please restate your name and the organization?

Unknown Speaker 1:51:22
Sorry, Jordan, all with Pacific edge.

Unknown Speaker 1:51:24
Thank you.

Unknown Speaker 1:51:32
If there are no additional comments or questions on this code, panel members, please now cast your vote.

Unknown Speaker 1:52:00
Okay, thank you.

Dr Lennerz MGH 1:52:02
And thank you for PowerShell I think this is where it switches over to the emoji subcommittee, correct? Yep, you can take over. Thanks. Wonderful, thank you. Great job that was very smooth. Okay, now, the second number 58. The code is x x nine five, you can hand it to you Dr. Chandra, for presentation.

Unknown Speaker 1:52:25
Thank you, Doctor lenaerts. So this is x x nine five U, which is is in AI based algorithmic analysis of digital pathology, baseline imaging to predict for microsatellite instability. We recommend the crosswalk to code zero to two zero you and this is an alignment with the public.

Unknown Speaker 1:52:53
That's not what I was expecting. That they're going to get.

Unknown Speaker 1:52:58
Excuse me. Excuse me.

Unknown Speaker 1:53:00
Excuse me. Could you please everyone ensure their phones on mute? Right.

Unknown Speaker 1:53:07
Yeah, exactly. And then so so but then they then you answered the question very nicely about that. It could be cell free or you know, or lized. And so yep, yeah. So

Dr Lennerz MGH 1:53:27
okay, I think we're back Dr. Shandra.

Unknown Speaker 1:53:31
Thank you. So we recommend a crosswalk to zero to 220 you This is in line with the presentations that demonstrated similar methodology and resources

Dr Lennerz MGH 1:53:49
Okay, are there any new options from the panel to consider? Or any questions or comments from the panel or from CMS? Hearing none, if there are no additional comments panel members please no cast your vote

Unknown Speaker 1:54:17
Okay, thank you.

Dr Lennerz MGH 1:54:21
Perfect. The next code is x x nine six you and it's also Dr. Chandra presenting.

Unknown Speaker 1:54:29
Thank you Dr. lenaerts. Again, this is an AI based augmentive algorithmic analysis of digital pathology slide imaging this time to assess for histologic features of microsatellite instability and homologous recombination repair deficiency. We agree with the presentations to crosswalk to zero to two zero you due to similar methodology and resources.

Dr Lennerz MGH 1:55:02
Any new options from the panel to consider? Or any other questions from the panel or from CMS? Hearing on if there are no additional comments or question panel members, please cast your vote.

Unknown Speaker 1:55:36
Thank you very much.

Dr Lennerz MGH 1:55:39
Thank you. The next code is 0439 you and I'll be presenting this. The code is a snip based Single Nucleotide Polymorphism as well as methylation essay. In the realm of cardiology as a prediction tool, the subcommittee has reviewed the available information and proposes gap fill as well as another option which is a crosswalk to 81493 Based on the roughly similar amount of genes as well as source material as well as methods and complexity. Are there any new options from the panel to consider? Any questions or comments from the panel or from CMS? Hearing none, there are no additional comments or questions panel members please now cast your vote

Unknown Speaker 1:56:54
Okay, thank you.

Dr Lennerz MGH 1:56:57
Thank you very much. The next code is 0440 you also code in cardiology and this this time around 10 single nucleotide polymorphisms by qPCR digital PCR from whole blood and the subcommittee took into account the complexity and recommends gap fill and as an alternative across 4281493 Because of the closest similarity but number of genes is a little bit different. So the recommendation is gap fill as well as 81493 and other any new options from the panel to consider any questions or comments from the panel or CMS? Hearing none, hello Members please now cast your vote

Thank you. The next coat is x x four six u which is a coronary artery disease cardiology test with a genome wide association study assessing if I get the number right 564,856 single nucleotide polymorphisms include

PART TWO

Dr Lennerz MGH 0:00
genomic risk score for acquired heart disease. There was a little bit of discussion among the panel, there was a crosswalk. That is 0078. You suggested that is Gene analysis. You see here the brief description of 16 genes, but that is of course, substantially lower than what's covered in this essay. So while that's the closest similar crosswalk, the subcommittee has decided to recommend gap fill because of the substantially increased complexity and methodology and no adequate other test to crosswalk to so the subcommittee recommendation is gap fill. Are there any new options from the panel to consider? Any questions from the panel or CMS hearing on there are no other questions or comments on this code panel members please cast your vote

Unknown Speaker 1:11
Okay, thank you.

Dr Lennerz MGH 1:13
Thank you. The next code is x seven, three you and I like to hand it over to Dr. Zhang for presentation.

Unknown Speaker 1:23
Okay, thank you, Joe. So this data Jennifer jam presenting code x x seven three u and this is oncology cap type of tests and the tactics target for the melanoma detecting circulating tumor cells, as well as the morphologic categorization and enumeration based on the antibodies including CD 146, high molecular weight melanoma soldier antigen as well as CD 34 and a CD 45 protein biomarkers on peripheral blood so, our panel recommend to go across code to this 0337 You is because based on the same Milan methodology and antibody use a number of antibody used the only difference is this is for different disease for multiple myeloma as well so different antibody but overall we believe they are they share quite a more similarity than differences. So we recommend cross work to the code of 0337 you That's it, thank you

Dr Lennerz MGH 2:30
thank you are there any new shins from the panel to consider any questions from the panel or from CMS there are no additional comments or questions panel members please cast your vote

Unknown Speaker 3:01
Thank you

Dr Lennerz MGH 3:03
the next code is x x seven five view and Jennifer Dr. Joe back to you.

Unknown Speaker 3:11
Thank you Joe yes as you can see this similar methodology as well as resource just resource as as the previous code and we recommend cross cross cross work to the code 033 at you is it because again a similar methodology as your similar amount of the antibody so this is based on all the the rationale we think this is the closest code we should recommend.

Dr Lennerz MGH 3:44

Thank you any new options from the panel to consider any questions or comments from the panel or from CMS hear no additional comments or questions so panel members please cast your vote

okay, perfect when the next code is x x seven for you. You also an oncology coat and also presented by Dr.

Unknown Speaker 4:37
Jim. Thank you Joe. So for coders x x seven for you, as you can read this a similar methodology just a slightly different antibody combinations compared to the previous code. Therefore, again, we recommend a code crosswalk to the code of 033 AGU. We think this is most appropriate to code today. choose four core OS. Org based on the combination of the methodology, specimen resource as well as the antibody numbers. Thank you.

Dr Lennerz MGH 5:12
Are there any new code suggestions or new options from the panel to consider? Any questions or comments from the panel or from CMS? Hearing on panel members, please cast your vote.

Unknown Speaker 5:56
Okay,

Unknown Speaker 5:56
thank you very much.

Dr Lennerz MGH 5:57
Perfect. Thank you, sir. The next code is 0355 view, which is an apple L one, chronic kidney disease risk variant. The panel has reviewed the available information that was submitted as well as the presentation and content submitted, I think by quest by acla. And it might have been one other group that was very helpful, and the subcommittee agrees with the recommendation to vote for gap fill, because there's no other tests that would fulfill the method and complexities. So the recommendation of the subcommittee is gap fill. Are there any new options from the panel to consider? Hearing none, any questions or comments from the panel or from CMS? There are no other questions, panel members, please cast your vote.

Now as these votes are coming in, real quick, how long are we going? Just looking that was exactly half of the tracker. But I don't know was it till 12.

Unknown Speaker 7:21
We are we are scheduled to go until 1230. However, if you if you'd like to do early break and allow folks on line longer lunch, we could stop now and still come back by 115. I leave it to the panel co chairs

Dr Lennerz MGH 7:47
and just received two questions from colleagues. I think this is definitely I don't want to call it intense. But you know, we don't want to make any mistakes. Because you know, a couple of May we can do maybe till 1215 and then take a break, then it would be a full hour break. Would that work for everyone? Chris, what do you think? Yeah, agree. Let's go till 1215. And then I think we take a break because there's still a lot of codes to go and, you know, I think it's it's okay to take a break and at 1215.

Unknown Speaker 8:30
Perfect. Well, we do we have to go ahead. Thank

Dr Lennerz MGH 8:34
you. And you have all the votes for 0355. You correct? Yes, sir. Perfect. Thank you for confirming the next code is x x eight, three, you and other Chappelle is presenting the code.

Unknown Speaker 8:54
Thanks, Joe. This is a code for Nexus syndrome, which is UB a one gene mutations targeted variant analysis with multiple variants listed in the descriptor. There was no presentation or recommendation from the lab, I believe on this one. And so we selected from one of a number of codes that exist on the current CLF s for Gene analysis targeted variant analysis for common variants in a gene. So we're recommending a crosswalk to 81233. If the lab is on, they're welcome to comment on this recommendation. We did not hear from them previously.

Dr Lennerz MGH 9:51
And I just asked if the laboratorial developer is available. Again, we're talking x x eight three You, which is code number 67? Hearing none, any other new options from the panel to consider any questions or comments from the panel or from CMS? Yeah,

Unknown Speaker 10:19
we're here and race.

Dr Lennerz MGH 10:21
Dr. Cohn, are you from the laboratory for the code xx a three you?

Unknown Speaker 10:28
Apologies. raised hand by mistake. Sorry.

Dr Lennerz MGH 10:31
No problem. Thanks for being here. Any other questions or comments on code number 67x X eight three you hear none. Hearing none, panel members, please now cast your vote

Okay. Thank you. The next code is 0437 you and Dr. Chandra is presenting this code.

Unknown Speaker 11:11
Thank you Dr. Ienaerts. This is a psychiatry assay utilizing messenger RNA gene expression profiling, and RNA sequencing of 15 biomarkers. Again, code 0437. You we agree with the cross flock recommendation of zero to nine three you do too similar methodology and resources.

Dr Lennerz MGH 11:43
Perfect. Thank you, Dr. Chandra, any new options from the panel to consider any questions or comments from the panel or from CMS hearing on panel members please cast your vote

Okay, thank you. Thank you. The next code is x x three seven you and I handed back over to you Dr. Chandra.

Unknown Speaker 12:18
Thank you Dr. lenaerts. XX three seven U is a rheumatology autoimmune rumor rheumatoid arthritis assay utilizing next generation sequencing, gene expression profiling of whole blood with analysis as you can see here, again, we agree with the crosswalk recommendation of 0203 you do to similar methodology and resources.

Dr Lennerz MGH 12:49
Perfect. Any new options from the panel to consider? Any questions or comments from the panel or from CMS? Hearing on panel members please cast your vote

perfect the next code is 0428 You and handed over to at the Chapelle

Unknown Speaker 13:24
thanks. This is an oncology code targeted hybrid capture genomic sequence analysis panel of 56 or more genes looking for sequence variants specific to breast cancer also includes besides sequence variants, copy number amplifications rearrangements, MSI and tumor mutation burden. So this code has been recommended crosswalk to 81464. These codes are similar in methodology and resources, and the panel recommends and agrees with the crosswalk to 81464 for this code.

Dr Lennerz MGH 14:06
Thank you have any new options from the panel to consider? Any questions or comments from the panel or from CMS? Hearing on panel members, please cast your vote.

Okay, thank you. Next code is x x three for you. And I hand it over to Jennifer.

Unknown Speaker 14:35
Thank you, Joe. So for the code x x three for you is oncology tests for the current rectal cancer and the use of cell free DNA as a methylation based quantitative PCR test and the report as the presence or absence of the circulating tumor cells and panel recommend to cross walk to the code 8132 to seven based on the same resource cell free DNA as well as similar methodology with the methylation basic PCR test. Also the reporter is the same pattern as presence or absence. Therefore, we recommend code 8213272 crosswalk. Thank you.

Dr Lennerz MGH 15:22
Perfect, thank you any new options from the panel to consider? Any questions from the panel or from CMS? Hearing none, then panel members, please cast your vote now.

Okay. Okay. As previously agreed upon, I think we will take a break now. And I hand it over to Dr. Arthur. I think we will continue at 115. Is that correct?

Unknown Speaker 15:57
Yes, that is correct. So at this time, we asked standby speakers if you do decide to disconnect to ensure you're connected by 1pm just to ensure that you're able to speak and be heard. But you can always just put your video make sure your video is off and play on mute and keep it on during the lunch break just to ensure that you don't have any kind of issues. And we will reconvene at 115 We'll start the second session of the day. Have a great lunch everyone.

Unknown Speaker 16:35

recording stopped.

Unknown Speaker 16:36
Glenn, could you progress? Uh, thank you so much.

Unknown Speaker 16:43
Hey, there, sorry about that. That's

Unknown Speaker 16:45
all the time sounds Good.

Transcribed by https://otter.ai

PART THREE

Opens with 30 minute roundtable on process improvements

Unknown Speaker 0:37
All right, we're gonna get votes and maybe 60 to 90 more seconds to reconnect to the meeting and we'll begin shortly.

Unknown Speaker 1:53
Dr Arthur, question, Should we do another roll call real quick or? Yes, yep, yep, we'll do another roll call once we get back to everyone worthy. Yeah.

Unknown Speaker 2:05
Marlon we're probably going to start recording in about 30 More seconds okay.

Unknown Speaker 3:27
Okay, my rollin we can go ahead and

Unknown Speaker 3:30
record begin recording

Unknown Speaker 3:34
recording in progress. Thank you so much. So before we continue with our session, I just want to allow the panel co chairs to do a quick roll call of the CLT panel members.

Unknown Speaker 3:52
Perfect. Thank you Dr. Arthur. I go through the list again. Dr. Bill Celski still there. Wonderful. Dr. Chandra. Present. Wonderful, Dr. Chong.

Unknown Speaker 4:07
Book the clock here, Dr. Jim? Yeah. I'm also here then Dr. rompler.

Unknown Speaker 4:18
Mark rompler Are you there?

Unknown Speaker 4:29
Think he's on the Zoom mark.

Unknown Speaker 4:39
Let me just check. Michelle Schoemaker Dr. Marshall marker. Are you here to present

Unknown Speaker 4:45
and have the Chappelle

Unknown Speaker 4:48
present?

Unknown Speaker 4:49
Okay, let's double check mark but the rumpler you here

Unknown Speaker 5:02
seats in the zoo?

Unknown Speaker 5:09
I think we would eight out of nine, we might still have a quorum, but he might show up in a minute, right? Yes.

Unknown Speaker 5:16
He may be having some tech issues, we'll see if you're able to join.

Unknown Speaker 5:21
So we still have a quorum, but I did want to note that just consistent with our agenda, before we dive back into the review of codes, there actually is a session

Unknown Speaker 5:33
that CMS will be facilitating related to panel discussions on the topic of CTLT rate setting process. And so just wanted to allow members of the team to go ahead and facilitate that conversation before we dive back into the review of codes.

Unknown Speaker 5:52
Okay. So Glen, if you could progress the slide to the end of the presentation where there should be a couple of slides that states CLT panel discussion for day one?

Unknown Speaker 6:20
Yep, that's it. Perfect. Thank you so much. Until now, we're gonna hand it over to Sarah Harding and Sarah Shari loadstone.

Unknown Speaker 6:28
Thank you, Rashida. It's fine. It's, it's like you can see the future

Unknown Speaker 6:32
of what's going to be discussed tomorrow.

Unknown Speaker 6:36
So just to add a little bit of context, we get a lot of feedback, a lot of comments on

Unknown Speaker 6:44
really how the overall rate setting process works. It's there's obviously a lot of moving pieces. There a lot of meetings, a lot of discussions, a lot of public comment periods. But especially in the last several years, we've gotten kind of a theme of comments of, you know, what, what exactly are you looking for what kind of information would really help

Unknown Speaker 7:09
in setting payment rates. And so we wanted to take advantage of having the panel all together,

Unknown Speaker 7:17
as well as

Unknown Speaker 7:20
those stakeholders who were able to join, to just have a very informal conversation, highlighting a couple of questions that we felt would be

Unknown Speaker 7:33
good to have in this sort of setting.

Unknown Speaker 7:37
So we've we've slotted about half an hour for this, but we do have extra time tomorrow, if if the conversation runs over, I will note,

Unknown Speaker 7:46
obviously, this format of kind of this particular meeting, really does not lend itself to a back and forth between

Unknown Speaker 7:55
the panel members and then just the public who are in listening mode. And we understand that we understand this isn't a, you know, true kind of open forum. But still felt it was a valuable opportunity to let the panel kind of discuss on their own while this process has been fresh in their mind, since they've all been working toward this meeting,

Unknown Speaker 8:23
to just again on a public display, talk about some of the challenges that

Unknown Speaker 8:29
that each of them have, and potentially ways that we can we can improve the process. The other disclaimer is we don't have formal plans for this discussion. So so nobody should should freak out or panic if if some, you know, crazy idea gets put out there, we're really just looking for that kind of feedback.

Unknown Speaker 8:50
Or for general feedback and, you know, potentially to evolve into either a broader public comment,

Unknown Speaker 9:00
process or opportunities to submit, you know, questions into the agency. But, again, we're still trying to narrow what those questions would be, so that we ask the right questions and get the right information back.

Unknown Speaker 9:19
Again, members of the public if you do have a burning question, you can certainly use the q&a or the or the chat function. I think the q&a is the way to go.

Unknown Speaker 9:30
But like I said, this, this really is an informal conversation and opportunity for the panel to give some feedback.

Unknown Speaker 9:39
So the first question that we were hoping to get some feedback on is just what difficulties arise when discussing potential crosswalks for new tests.

Unknown Speaker 10:03
Sarah, are you looking for public feedback or panelist feedback are both handled feedback, please from your role as a panel panelist, you know, looking through all the information that we get that is submitted, you know, from the public meeting until this time? What are what are some difficulties that arise when, in your subcommittee discussions, or just as an individual looking through all the information? No, sure, I'll start because I've been part of this process for a while now. And I've been, I've been glad to be able to be a participant, and I've learned a lot through it. Um, I think the number one challenge is when, you know, sponsors don't provide any information, and then we're kind of left to our own devices to have to figure out what does the comparability mean and is it comparable in terms of method or intended use, or, you know, number of targets versus number of report outs?

Unknown Speaker 11:02
You know, we do try as panel numbers really, really hard to to be consistent year over year in our recommendations and to understand what goes into

Unknown Speaker 11:15
developing and performing these these new tasks day over day over day and especially if they're brand new. Having like some either professional society input or input from the sponsors, is very, very helpful.

Unknown Speaker 11:30
And I'll stop there.

Unknown Speaker 11:36
I'm gonna, I'm gonna add to what Michelle said because it piggybacks really well.

Unknown Speaker 11:42
The information from the sponsors, this is Vicki buss, Celski is extremely helpful. But if we could actually see reports that are generated from these assays, that goes a long way toward helping us understand what information is actually being assay paid for in in in the proposal, and that multiple times in this particular group of codes that we looked at this year, if we had had a report from the sponsor, that would have helped a lot.

Unknown Speaker 12:17
Hi, this daughter, Jennifer JAL, yes, I totally agree with the other previous two colleagues. And yeah, and also for the public meeting in June, for the code I have, I am responsible, half of them don't show up. And I want to say I really want to thank for all the sponsors and a public company who actually showed up on the meeting and gave an excellent presentation, which really helped me tremendously. And as I said, you know, I, I just just like other panelists, I have a difficulty to decide whether GAAP GAAP fail or cross work on the codes which do not have presentation. That actually, I was told I should use the, you know, internet website information, but I don't think that's sufficient.

Unknown Speaker 13:07
That's my opinion for that.

Unknown Speaker 13:10
Yeah. Chandra,

Unknown Speaker 13:13
go ahead. Go ahead. Michelle, please. I was just going to add on that, you know, we've had a couple of codes come up today where, like, in the past, if something was, had been gap filled the prior year, and it was not priced. By the time we get to this meeting, then we weren't, I mean, the policy was to not recommend a gap fill to something that was zero.

Unknown Speaker 13:39
And so if you know when two coats come up, and they're similar, but in two years, we would have to recommend gap fill those two years, two years in a row. And I think what happened this year was that the the third quarter pricing came out. But we had already done our work and made our recommendations after the June meeting, and prior to this meeting, and so I don't think all of us were aware that some of the ones that were zero last year, were actually priced this year.

Unknown Speaker 14:10
And so, you know, I think that's a that's an area that I think is ripe for some policy development from the CMS folks. Thank you.

Unknown Speaker 14:21
This is pretty cool. Chandra, I agree wholeheartedly with all of the comments. And I wonder whether it should be a requirement for any sponsor that has introduced a new CPT code that they shouldn't be responsible and accountable for presenting information about the assay so that we can make a meaningful recommendation. In those instances where there are presentations. That's great. I again, I agree with the comments, and especially when there are recommendations from not only the sponsor, but other clinical lab society that are in full alignment on

Unknown Speaker 15:00
Um, that, that, to me, that kind of alignment is not only very helpful, but powerful too, you know, when reviewing these codes and making a final recommendation

Unknown Speaker 15:19
this is Heather Shopko.

Unknown Speaker 15:21
Just wanted to say that I completely concur with with everyone, I do think the idea of requiring submission

Unknown Speaker 15:32
for your new code requiring that you send materials to describe the assay and the methodology and the resources. And also a result report

Unknown Speaker 15:46

should be something that is strongly considered, it's very difficult to do this work well, without those kinds of details, it's almost possible in many cases, just by a test description.

Unknown Speaker 16:13
And so we're having a moment of silence, I just want to take the opportunity to really thank the CMS staff, they've bent over backwards to gather all of this information and pull it together for us and really help us through the process. And I don't want that to go, you know, unrecognized.

Unknown Speaker 16:39
I'm gonna chime in here too, for those of us like Michelle, and myself and Bill, who have been part of this process for a while now, from the early days where we were left shuffling through CPT books, to the current process where this incredible table is laid out with all of the information makes it so much more efficient and reasonable. That emphasize, again, if we don't have information on these new codes, we can't really make a reasonable suggestion or recommend recommendation, I believe that a lot of this information is provided to the PCC when they make the decision to add a new code. So I find it kind of confusing that we that we don't have access to that information as well.

Unknown Speaker 17:48
Okay, this is very helpful. Thank you.

Unknown Speaker 17:52
And I will note that that,

Unknown Speaker 17:56
you know, as a, as a government agency, we do have to walk a very thin line

Unknown Speaker 18:02
around what is required information.

Unknown Speaker 18:06
versus, you know, we, we, we don't want it to become burdensome on labs, obviously. And so we do, try and balance that out to say, here's the information that would be helpful.

Unknown Speaker 18:22
But

Unknown Speaker 18:25
requiring it, I think, would would, as Dr. schoomaker said it would it would that would require some policy change, but it is not. That doesn't mean it's it's it's out, it just is a little more difficult to get there.

Unknown Speaker 18:39
So the next question, we had asked the panel, and we sent these these questions to the panel last week, just so they could be stewing on them, because obviously, they haven't had enough to do in the last several days.

Unknown Speaker 18:54

What information and I think you guys answered this, in part already in terms of getting reports, you know, outcomes of each test, but is there other information that would aid in the crosswalk process? Or rather than rate setting process? That is that the tends to be missing?

Unknown Speaker 19:19
I mean, again, I'll go ahead and start because I'm so shy.

Unknown Speaker 19:23
I, I believe that, you know, some guidelines around what crosswalking actually means, because it's you're looking for something that's comparable, right? Is it comparable in intended use? Is it comparable in like counting number of targets? Is it comparable in method or you know, in the code sets themselves or not? They're built differently between different specialties. And it's sometimes it makes it hard for us to,

Unknown Speaker 19:55
you know, try to find what's comparable

Unknown Speaker 19:59
from

Unknown Speaker 20:00
Um, CPT descriptors?

Unknown Speaker 20:11
Hi, this is Jennifer. So, um, I will say, this year for the public presentation, we did give them template, right? You know, we asked for the resource or the rationale and so on so forth. I think that wherever they present are the things we would like to have.

Unknown Speaker 20:30
That's all, I had adequate information for the code that has been presented for me to discuss or for me to make a decision and discuss those codes with my panel colleagues. So I think wherever templates you provide to them is our that information we like to have?

Unknown Speaker 21:06
Any others who might like to weigh in,

Unknown Speaker 21:10
on, let me say that just something as simple as a package insert or an IFU that the sponsor has would go a long way toward providing some of this information. And I say that a participant is saying that perhaps CMS could facilitate sharing of materials. I think if you could recommend supplemental materials to send in with the template, that might be a good way to facilitate the panel members having access to it easily, without having to go do a Google search and find it ourselves.

Unknown Speaker 21:48
Yeah, Vicki, that's awesome. And whatever the equivalent of pi for the for an LD T, for example, would be helpful as well.

Unknown Speaker 22:14

This is a heather again,

Unknown Speaker 22:17
just because this year is the first year that I have been on both sides of this, I've been on this panel for I think this is my fourth year. And I just submitted to the AMA as part of my day job for new codes. And it was my first time experiencing the process from that perspective. And I've shared this with the panel and and the CMS folks previously. But I think it's important that there's better coordination, as much as possible between the AMA and CMS, for instance, the AMA, you know, while you're going through that process is sending you email updates about where your codes are in the process, and then all the sudden you get your codes have been accepted, they're moving on. And then it's radio silence. If there was a way for the individuals who actually were responsible for submitting those codes to get a message from CMS to say, here are the next steps. And if you don't provide information, you're more likely to get

Unknown Speaker 23:25
to not get what you want, or what your looks or what you think your tests should be crosswalk to, because the panel won't have the information they need. I think if there was that connection, we'd may have a better chance of making sure labs get get materials into us.

Unknown Speaker 24:07
All right. Well, thank you. This is this. This is very helpful. Um,

Unknown Speaker 24:12
the last question. We have seven or eight minutes left for this discussion.

Unknown Speaker 24:20
It really builds on something Dr. Shoemaker said

Unknown Speaker 24:25
of whether CMS ought to develop specific criteria for determining comparability. That's a big question. And it's something that we really are wrestling with. I know we've talked to different organizations about because there are many different ways right to compare a test

Unknown Speaker 24:45
and we see them across the recommendations we get from labs, right there are tests that are they argue are comparable, either by methodology or the resources or development or whatever it may be, um,

Unknown Speaker 25:00
but it is not defined in our statute.

Unknown Speaker 25:04
And so yeah, so I will I will open that up as kind of our last question that that we won't answer today, obviously, but is, you know, shouldn't should, should we go ahead and try to develop specific criteria for determining comparability? And if your answer is yes, what what would be some of those criteria?

Unknown Speaker 25:46
Okay, again, to to break the radio silence.

Unknown Speaker 25:52
There's there's intended use and this is not CMS has issue I mean, honestly, like, when you look at the CPT code book, and the different sub specialties have defined how they develop codes and descriptors differently, markedly differently.

Unknown Speaker 26:12
And, you know, they are developed by intended use, or by number of targets, or by whether or not there's an algorithm that we may or may not understand, or are you reporting a qualitative quantitative probability risk or result? I did, I think we have had some conversations about this in the past. And I do have some notes that I can share with you guys. When I, when I can't have an opportunity to dig them out again.

Unknown Speaker 26:47
But it is it is it becomes a challenge, especially when we're trying to be consistent between the subgroups, and this in the

Unknown Speaker 26:57
and the specialties.

Unknown Speaker 27:00
Because just because of the way the codes are developed and

Unknown Speaker 27:04
described,

Unknown Speaker 27:07
can I add to this, that PLA s are a bit of a free for all to

Unknown Speaker 27:13
even locating the PLA that might be a reasonable crosswalk, the way they're configured in the codebook is difficult. But the descriptors don't match these standards or guidelines, or whatever they are that CPT convention follows. So going back to asking the sponsors to provide as much information about the assay how it's reported, how it's intended to be used, is probably going to be the only thing that we can do that's going to make this process go more smoothly and avoid gap fills except where they're necessary.

Unknown Speaker 27:58
Dr. bclc had great timing. And we had a comment actually come in that

Unknown Speaker 28:04
mirrored exactly what you just said. So.

Unknown Speaker 28:08
So yes, we can we can definitely try and

Unknown Speaker 28:13
you know, sit down with the AMA and see if some of the some of the gap can be closed with some of the information they do collect. So thank you.

Unknown Speaker 28:28
Yeah, I think another another challenge that we haven't some of the information, too, is is what is analytical and in a black box versus what is actually the clinically reported information.

Unknown Speaker 28:41
In general, and some of my payer colleagues, please speak up if I'm, if I'm misinterpreting this.

Unknown Speaker 28:50
Payers tend to they want to pay for the clinically important information if you need to, if you need to test 17 targets to get one answer. The answer is what's clinically significant, right? And maybe another test does it with three targets. And so do we, at that point, do we crosswalk based on what's reported out versus what's actually being done in the box?

Unknown Speaker 29:44
Recognize I'm letting the silences get on the uncomfortable side so I won't. I won't let them drop to force anyone to say anything.

Unknown Speaker 29:56
But this again, this is all really helpful until

Unknown Speaker 30:00
Give us some ideas of ways to improve things that,

Unknown Speaker 30:04
you know, we need to maybe think bigger picture with. But I guess I'll just ask, Does anybody else have anything they want to say before we get back to the meeting?

Unknown Speaker 30:23
Okay.

Unknown Speaker 30:25
Well, thank you. Um, I am going to turn this then back over to Dr. Arthur. Thank you very much, everyone.

Unknown Speaker 30:35
Thank you, Sarah.

Unknown Speaker 30:37
And we really appreciate the honest feedback, we definitely want to be able to use that information, hopefully, somewhere in the future. So we appreciate any feedback we can get.

Unknown Speaker 30:48
So we will continue with our review of codes.

Unknown Speaker 30:54
Glenn, could you bring the slide up? I believe we're on item number 72.

Unknown Speaker 31:05

Maybe just for the record real quick, Mark, you're here. Correct. Dr. rompler?

Unknown Speaker 31:12
Yes, I'm here. Wonderful. Thank you.

Unknown Speaker 31:18
I'm going to turn it back over to the deck winners. Thank you. Thanks a lot. Okay, the next code is x x eight seven U and that will be presented by Dr. Chandra.

Unknown Speaker 31:33
Thank you Dr. lenaerts.

Unknown Speaker 31:36
XX eight seven U is a cell free code that combines combined cell free DNA alterations with methylation analysis by real time PCR and combines that with Eliza testing

Unknown Speaker 31:55
and

Unknown Speaker 31:57
due to the complexity of the assay, unfortunately, there was no comparable CPT code to crosswalk this test code to So our recommendation is gap fill.

Unknown Speaker 32:14
Perfect. Any new options from the panel?

Unknown Speaker 32:19
Any questions or comments from the panel or from CMS?

Unknown Speaker 32:27
Hearing none,

Unknown Speaker 32:29
then I finally asked the panel to cast the vote now.

Unknown Speaker 32:47
Okay, thank you.

Unknown Speaker 32:49
Thanks a lot. The next code is x x eight. Oh, you. That's also Dr. Chandra.

Unknown Speaker 32:56
Thank you, Dr. Leonard's x x eight o u is a cell free

Unknown Speaker 33:03
DNA analysis CPT code. In the context of blood based testing for colorectal cancer. There wasn't any much more detail that was given in the long description. There was no public recommendation or presentation. And as a result, we would recommend gap fill for this code.

Unknown Speaker 33:32
And in your options from the panel to consider.

Unknown Speaker 33:37
Any other questions or comments from the panel or from CMS?

Unknown Speaker 33:43
Hearing none, then I asked the panel members to please cast your vote now.

Unknown Speaker 33:55
Okay, thank you.

Unknown Speaker 33:59
Perfect. Thank you. The next code is x x seven. Oh, you and Aubrey presenting this. This is a cell free DNA sequencing essay. So genomic testing procedure. And the recommended as well as the subcommittee recommended code is a crosswalk to 81422 based on the comparison of the testing complex complexity and the technology used.

Unknown Speaker 34:27
course there's also the other option of CAP filling, but that's the main recommendation from the subcommittee. Are there any new options from the panel to consider?

Unknown Speaker 34:40
Any questions or comments from the panel or from CMS?

Unknown Speaker 34:48
Hearing none, then asked the panel to cast a vote now.

Unknown Speaker 35:17
are waiting on one response. Just make sure you made a selection of leaves

Unknown Speaker 35:26
there we go, thank you.

Unknown Speaker 35:29
Perfect. next code is x x seven six you also a cell free DNA sequencing procedure, obstetrics. So single gene non invasive prenatal test for a number of targets, those are listed here, as well as some of the algorithms attached to it, including a fetal risk score for certain conditions. And

Unknown Speaker 35:55
similar to the recommendation that was proposed, as well as after review by the subcommittee, we agreed that there's no code that would reflect the technology and the complexity, one for one. Therefore, the subcommittee's panel recommendation is gap filling rather than a crosswalk? Are there any new options from the panel to consider?

Unknown Speaker 36:21
Hearing none, any other questions or comments from the panel or from CMS?

Unknown Speaker 36:29

Okay, then ask the panel to castable please.

Unknown Speaker 36:41
Okay,

Unknown Speaker 36:43
perfect, thank you. The next code is x x eight to you, which is also genomic sequencing procedure. In this case, next gen sequencing based analysis of circulating cell free DNA for red blood cell antigen detection. And based on the complexity of the procedure, the closest similar code would be 81422. And that was also proposed, I believe, by the Tara as well as several other presenters. Thank you. That was very helpful. Your explanations have helped the subcommittee and so the crosswalk recommendation is 81422. And I opened it up whether there are any new options from the panel for consideration.

Unknown Speaker 37:33
Or any other questions or comments from the panel or CMS?

Unknown Speaker 37:38
Hearing none, then I asked the panel members to castable please.

Unknown Speaker 37:52
Okay, thank you.

Unknown Speaker 37:55
Thank you very much. The next code is x x five o u n A ask Dr. Zhang to present this. Thank you, Joe. Okay, so for code x x five zero u is oncology code for the author on oropharyngeal carcinoma and detection is with applying the methodology of a minimum residual residual disease by next generation sequencing. And also on top of they also identify cell free HPV 16 and 18 DNA from plasma. So, um, well,

Unknown Speaker 38:33
we kind of torn so at this point, we just, we will have options between gap fields as well as another code, we recommend a 0356 u plus a 7625. The rationale for that is, first of all, being for our personnel module, we couldn't find any code for the minimal residual disease by next generation sequencing. Now for recommended 0356 You which is the as you can see, the descriptor on the right side is word on the DNA biomarkers use different methodology droplet digital PCR for cell free DNA and algorithm report and also on top of that with the a 7625, which is for HPV 16 and 18. So, I'm open for any suggestions, if any, you know new code can be implemented.

Unknown Speaker 39:36
Okay, I will give back to Joe. Thank you. Thank you.

Unknown Speaker 39:40
Are there any other questions or comments?

Unknown Speaker 39:45
If not, then, panel members please cast your vote.

Unknown Speaker 40:03
Okay, thank you.

Unknown Speaker 40:07
Perfect. And I will present the next two codes because they are thematically related. So that's 81462 and 81464. And this one code in between missing, and that is because both of these codes that's not shown here, but I think it's mentioned in the appendix were reconsidered. So these are reconsideration codes that

Unknown Speaker 40:30
were submitted for price setting. And there's a few codes later in the meeting that relate to the complexity and the subcommittee recommendations as well. So let's start with the 81462. So briefly, this is

Unknown Speaker 40:47
a cell free DNA code that contains among many things, DNA and or RNA analysis, copy number variants as well as rearrangements. And based on the review and taking into account the complexity also among these codes. The panel recommends a two times 81445 recommendation.

Unknown Speaker 41:14
Of course capsule is another option. But in terms of grading the different complexities of the codes two times 81445 was the preferred recommendation.

Unknown Speaker 41:29
Are there any other new options from the panel to consider?

Unknown Speaker 41:37
Any questions or comments from the panel or from CMS?

Unknown Speaker 41:44
If not, then ask the panel to now castable please.

Unknown Speaker 41:55
Thank you.

Unknown Speaker 41:58
Next code 81464 is cell free DNA DNA analysis or Combined DNA and RNA analysis, copy number microsatellite, instability, stability, tumor mutational burden and rearrangements. So this is the highest complexity of the three codes. And after review with the subcommittee, there's no

Unknown Speaker 42:21
preference in terms of a modifier for another code. But the subcommittee recommended that we should use the gap fill method to

Unknown Speaker 42:30
adequately reflect the complexity of this highest complexity cell free DNA genomic processing code and any new options from the panel to consider.

Unknown Speaker 42:44
Any questions or comments from the panel or from CMS?

Unknown Speaker 42:51
Hearing none, then please ask the panel to cast your vote.

Unknown Speaker 43:20
We have everyone

Unknown Speaker 43:24
we do. Thank you. Wonderful. Thank you. And the next code is all for to to you and I hand it over to Heather Chapelle.

Unknown Speaker 43:35
Thanks. This is a cell free circulating DNA oncology test and solid tumor. It is a biomarker comparison.

Unknown Speaker 43:46
Looking at previous baseline pretreatment, cfdna analysis and reporting any quantitative changes from baseline.

Unknown Speaker 43:58
The panel subcommittee recommends gap fill. This was also the recommendation by the lab and multiple stakeholders so for this code, we recommend gap fill.

Unknown Speaker 44:13
Thank you. Any new options from the panel to consider?

Unknown Speaker 44:20
Any other questions or comments from the panel of CMS

Unknown Speaker 44:26
and panel members please cast your vote

Unknown Speaker 44:37
Okay, thank you. Perfect. Next one is x x four one you and I handed over to Dr. John for this code. Thank you, Joe. So will code x x following you and as you can see, this is the oncology test again and we're using the whole blood or bucho specimen buccal swab specimen and identify the DNA

Unknown Speaker 45:00
With this snip genotyping by real time PCR of 24 genes, so, we break with thinking about the coat crossword to code 0055 u, which is shares a similar specimen as well as a methodology. Now, the only interesting thing is because the core code is 0055 U is for cardiology disease, and this code is for oncology

Unknown Speaker 45:29
study test. So, I think either gap field or crosswalk to 005 You

Unknown Speaker 45:38
are E coli should be considered. So, I will leave the question to the panel and this was our CMS members Thank you. Perfect any new options from the panel to consider

Unknown Speaker 45:55
any questions or comments from the panel or CNS?

Unknown Speaker 46:00
If not, then panel members please cast your vote

Unknown Speaker 46:14
Okay, thank you. Perfect the next code is x x six nine U and it's also Dr. Jiang presenting it thank you. So for code x x six nine U and

Unknown Speaker 46:29
basically, we recommend across code to the zero to one way you because share the similar methodology.

Unknown Speaker 46:38
I think the only difference is the specimen one is the plasma free DNA Cell free DNA Cell free iring versus FF paraffin blocks

Unknown Speaker 46:51
formalin fixed paraffin embedded specimen. So other than that, I think they're pretty compatible.

Unknown Speaker 47:00
That's our recommendation.

Unknown Speaker 47:03
Perfect any new options from the panel?

Unknown Speaker 47:08
Any questions or comments from the panel or from CMS

Unknown Speaker 47:14
hearing on then

Unknown Speaker 47:17
the panel please cast your vote

Unknown Speaker 47:27
Okay, thank you.

Unknown Speaker 47:29
Perfect. The next one is x x seven seven U and it's also Dr. Joe. Thank you, Joe. So, this is that for code x x seven seven u this is the code for the pen solid tumor and with the platform and next generation sequencing analysis of the tumor methylation markers, they are using a specimen is the cell free DNA and with the algorithm reporting so we feel like they are pretty compatible with the code 0405 view the only difference is that the reporting for The X X seven

seven U is algorithm report but the for the 0405 view is pretty much Kwang Chol qualitative detected or not detected. Therefore, we recommend we recommend use the 0405 Your times to in addition because they are using additional experiments on the X X seven seven you so reporting as well as additional specimen

Unknown Speaker 48:36
Thank you, Jennifer.

Unknown Speaker 48:38
Any new options from the panel?

Unknown Speaker 48:43
Any questions or comments from the panel or CMS

Unknown Speaker 48:49
Hearing none, then please panel move to vote.

Unknown Speaker 49:08
Thank you.

Unknown Speaker 49:10
Perfect next code is 815 6x and this is Heather Chapelle presenting the code

Unknown Speaker 49:20
this is a code in transplantation medicine, measuring Allah graft rejection and kidney transplants and Mr. And a gene expression profiling assay with an algorithm using whole blood and

Unknown Speaker 49:39
we have recommended as a subcommittee a crosswalk to 81595. This is in agreement with the recommendation by both the lab and the acla.

Unknown Speaker 49:56
Perfect, thank you any new options from the panel?

Unknown Speaker 50:01
Any questions or comments from the panel or will CMS

Unknown Speaker 50:09
Hearing none,

Unknown Speaker 50:11
then panel members please cast your vote now.

Unknown Speaker 50:27
Perfect next code is x x seven AQ and it's also have a Chappelle presenting.

Unknown Speaker 50:35

This is another transplantation medicine code. Its quantification of donor derived cell free DNA using next gen sequencing and reported as a percentage of donor derived cell free DNA. We have crosswalk recommended a crosswalk for this code 230331. You

Unknown Speaker 50:59
There is a similar methodology in terms of the genome mapping or and similar specimen type and reporting. So, crosswalk 20331 You recommended by the subcommittee?

Unknown Speaker 51:18
Thank you any new options not listed here from the panel?

Unknown Speaker 51:27
Hearing none any questions or comments from the panel or from CMS?

Unknown Speaker 51:35
There are no additional comments or questions panel members please cast your vote

Unknown Speaker 51:52
perfect. The next code is x x nine three you

Unknown Speaker 51:58
and I believe also have the Chappelle Yes. Yes. Yeah, I have the next several. This is transplantation medicine again quantification of donor derived cell free DNA.

Unknown Speaker 52:10
And we have as a subcommittee recommended gap fill for this code. There's no clear crosswalk.

Unknown Speaker 52:21
There was no clear crosswalk identified. We also did not receive any lab or stakeholder comments

Unknown Speaker 52:32
or

Unknown Speaker 52:33
sorry recommended capital.

Unknown Speaker 52:37
Any new options or new suggestions from the panel?

Unknown Speaker 52:43
Any questions or comments from the panel or from CMS?

Unknown Speaker 52:49
Hearing none, then panel please cast your vote

Unknown Speaker 52:58
Thank you, X code x 694. You also have

Unknown Speaker 53:03
another transplantation medicine code quantification of donor Dr cell free DNA. Just another approach again we could not identify an existing price code to crosswalk to there were no lab or stakeholder comments or information provided. So the subcommittee recommends gap fill for this code.

Unknown Speaker 53:31
Any new options from the panel to consider

Unknown Speaker 53:37
the code Questions or comments from the panel or from CMS

Unknown Speaker 53:44
Hearing none panel members please cast your vote.

Unknown Speaker 54:01
The next code is all four to five you and it's also Heather Chapelle presenting.

Unknown Speaker 54:08
This is genome code rapid sequence analysis for each comparator genome.

Unknown Speaker 54:16
Based on the subcommittee's review, we did not feel that the explanation by the lab for the 1.51 modifier is based on previous CMS gap fill pricing exercise. It's it basically they used a previous CMS gap fill

Unknown Speaker 54:39
code to come up with a 1.51 modifier. So it was not as it was explained to us by the lab. based on actual differences in methodology or resources required for this assay. It was more described

Unknown Speaker 55:00
As using a previously gap filled code to come up with a similar modifier for comparator genome.

Unknown Speaker 55:08
And so the cross the committee's recommendation is to gap fill this code.

Unknown Speaker 55:16
Although the lab did provide a crosswalk of 814 to six times 1.51, and I don't know if anyone's on the lab, or they want to comment or explain further why they believe 1.51 modifier is reflects the methodology effort and resources for this assay.

Unknown Speaker 55:40
Is someone from the lab available? I see Russell off singer? Yeah. Can you hear me? Yes, we can. Do you mind introducing yourself?

Unknown Speaker 55:51
Yeah, sure. Thank you. Yeah, this is Russell Knopf singer from Rady Children's Institute for Genomic Medicine. And, oh, four to five years who is is our code. And so to try to,

Unknown Speaker 56:04
to try to add clarity beyond that document that we had kind of sent post the initial meeting on this hearing on this. We have a code that's oh nine for you. That is for rapid whole genome sequencing. And it's it was priced, it was priced by gap fill several years ago. And they landed on a price point that was 51%, higher than code 814 to five, which is standard clinical, diagnostic, whole genome sequencing. And that price point was landed upon based on the differential expenses and materials that go into providing the test in a rapid form factor versus an ultra rapid or excuse me invested versus a standard form factor. And so there's an equivalent code oh nine for you. That is radius PLA code for rapid whole genome sequencing. And so what we were trying to ask for here or recommending is that because the nature of the relationship between oh nine, four years, and 81425 is identical to the comparison between old four to five you and 814 to six, that we thought the same relationship should hold true because the same additional expense base holds to and the same additional clinical utility downstream of rapid testing versus standard turnaround testing holds true. And so that's where the 1.51 came from. And it seemed, seemed like a pretty logical presentation, but it clearly led to a bit of confusion. So I apologize for that.

Unknown Speaker 58:00
So just for clarification for the panel. So the 81426 times 1.51 was a relational factorization of the price, based on the technical difference from your oh nine for you, rapid genome versus the non rapid version of that.

Unknown Speaker 58:21
That's correct.

Unknown Speaker 58:25
Any other questions or clarification from the panel and thank you Dr. Messinger, for being called it's that's very helpful.

Unknown Speaker 58:37
Any other question from the panel or from CMS or other options to consider for the vote?

Unknown Speaker 58:50
Hearing none, then I asked the panel members to please cast your vote.

Unknown Speaker 59:05
The next code is all four to six you think also from Rady Children's?

Unknown Speaker 59:14
I think this is presented by Heather Chapelle. Yes, this is another genome sequencing code. This is for ultra rapid sequence analysis.

Unknown Speaker 59:27
The subcommittee recommends gap fill. There is no clear crosswalk. For this code and GAP Phil was also recommended by the lab.

Unknown Speaker 59:42
Any other new options on the panel to consider?

Unknown Speaker 59:50
Hearing none, any comments or questions from the panel or from CMS?

Unknown Speaker 59:58
If not, panel

Unknown Speaker 1:00:00
Members please cast your vote.

Unknown Speaker 1:00:06
Thank you.

Unknown Speaker 1:00:08
Next code is all for four nine you which is also genomic sequencing procedure in this case a carrier screening for severe inherited condition you see the included conditions attached here and there was a complex set of crosswalk recommendations provided here.

Unknown Speaker 1:00:32
Based on the comparison to the other existing tests and the most accurate reflection on the comments, we heard

Unknown Speaker 1:00:40
the sum of seven codes is the recommended recommendation which is here portrayed as option three and that was of course a discussion because the reporting and the information that was available to the panel suggested that that is an adequate reflection there are however two additional

Unknown Speaker 1:01:01
coats that that might be considered for you know, similar diseases etc. But the subcommittee recommended the crosswalk to the some of the seven

Unknown Speaker 1:01:13
individual codes here any new options from the panel to consider?

Unknown Speaker 1:01:26
Hearing none, are there any questions or comments from the panel or from CMS?

Unknown Speaker 1:01:33
Also Hearing none if there are no comments then I asked the panel to please cast your vote now.

Unknown Speaker 1:01:59
I think that meant that we have all votes the next code is x x four nine you

Unknown Speaker 1:02:05
presented by EPA Chapelle.

Unknown Speaker 1:02:11

This is a rare diseases whole genome sequence analysis for chromosomal abnormalities copy number variants, dupes, inversions, translocations etc.

Unknown Speaker 1:02:26
This code was crosswalk to three codes.

Unknown Speaker 1:02:35
The three codes are 81349 plus 81265 plus 88235. These codes together represent similar methodology and resources as the new code or the new code is described. So we have reviewed the labs recommendation for this crosswalk and we've agreed with their recommendation.

Unknown Speaker 1:03:05
Thank you for any new options from the panel for consideration.

Unknown Speaker 1:03:11
Any questions or comments from the panel or from CMS?

Unknown Speaker 1:03:17
Hearing none, then panel please cast your vote.

Unknown Speaker 1:03:37
Thank you.

Unknown Speaker 1:03:39
All right. The next is a reconsideration code or 417. You and I handed over to Heather Chapelle. But Dr. Zhang might also chime in for this code.

Unknown Speaker 1:03:53
Heather.

Unknown Speaker 1:03:55
Sure. So this is a rare diseases, whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis. Also, the nuclear encoded mitochondrial genes,

Unknown Speaker 1:04:08
R 335 are included in this assay.

Unknown Speaker 1:04:14
And we have looked at the labs recommended crosswalk and there were panel members who agree with the labs recommended crosswalk of 81460 plus 81465 plus 81440.

Unknown Speaker 1:04:37
And then, there there was a proposal

Unknown Speaker 1:04:44
also by a committee member, that would reduce the with the modifier, but I think the codes are mixed up in that one. So I would actually ask that that one be removed. I think the committee landed on the cross

Unknown Speaker 1:05:00
swapped, that's an agreement with the lab.

Unknown Speaker 1:05:03
And we removed the first option. It has an error a 1460. Is Is there twice?

Unknown Speaker 1:05:13
Heather, you mean the number three? The choice on number three? Oh, I'm sorry. I'm looking at the option where we can vote. Yeah, that's the option where we can vote is now correct. And the panel recommends the crosswalk of 81460 plus a 1465 plus 81440.

Unknown Speaker 1:05:32
Thank you. And yeah, I don't have anything to add. Thanks. Thanks to both of you any new option from the panel to consider

Unknown Speaker 1:05:43
any questions or comments from the panel or from CMS

Unknown Speaker 1:05:49
hearing on

Unknown Speaker 1:05:51
panel, please cast your vote now.

Unknown Speaker 1:06:05
Think

Unknown Speaker 1:06:07
the next code is 0x 00 N and I hand it over to Dr. Zhang. Thank you Joe. So, this code is for CNS oncology studies and basically they are they use the

Unknown Speaker 1:06:24
methylation array to utilize the DNA extracted from the FFP specimen and the report in a algorism format. So we agree should be crosswalk to the code 0016 M, and with a similar methodology, similar specimen resource as with as well as a similar our report format. So yes, we recommend a 0016 M to Perfect, thank you. Thank you. Thank you, Jennifer. Any new options from the panel?

Unknown Speaker 1:06:59
Any questions or comments from the panel or from CNS?

Unknown Speaker 1:07:05
Hearing on then pattern numbers Please cast your vote now.

Unknown Speaker 1:07:24
Okay, the next code is x x six seven U, which is a combination NGS procedure for single nucleotide variants deletions and insertions in ID h1, h2 and the TERT promoter for CNS neoplasia. And after review of the provided information, and following the recommendations, the

subcommittee recommends the portrayed combination of three codes eight, eight, sorry 811-208-1121 and 81345, SD

Unknown Speaker 1:08:00
key recommendation any other new options from the panel to consider?

Unknown Speaker 1:08:10
Hearing none, any other comments from the panel or from CMS?

Unknown Speaker 1:08:19
If not, then panel members please cast your vote now.

Unknown Speaker 1:08:50
Okay, we're good. Okay, thank you. Oh, four to one use the next coat and ask Dr. Chandra to present the code.

Unknown Speaker 1:08:59
Thank you, Dr. Leonard's, this is Oh 4210 which is under the indication of colorectal oncology. It is a real time targeted and sync signal amplification based assay. There was a

Unknown Speaker 1:09:18
there were good presentations on this code and the recommended crosswalk of 815 to eight. They are similar in resources and methodology and so we agree with the crosswalk of 81528.

Unknown Speaker 1:09:35
Thank you any new options from the panel?

Unknown Speaker 1:09:40
Any questions or comments from the panel or from CMS?

Unknown Speaker 1:09:46
Hearing none, then please cast your vote on all four to one you

Unknown Speaker 1:10:01
Yeah, that was the Okay, then the next code is x x four for you.

Unknown Speaker 1:10:07
And ask Dr. Zhang to present the code. Thank you, Joe. So, um, code numbers, x x four for you. And it's also a colorectal cancer screening tests and using the quantity, quantitative real time PCR to detected

Unknown Speaker 1:10:26
methylated DNA markers and

Unknown Speaker 1:10:30
weigh

Unknown Speaker 1:10:32
the crossover code is considered as a 215 to eight, now that

Unknown Speaker 1:10:39
the presenter from the company did the recommend, mentioned that because of the increase in methylation, DNA markers, as well as the hemoglobin collection buffer, they recommend justify with the increment of 1.25. That's where the multiply factor right there.

Unknown Speaker 1:10:59
We were not very sure how the cost could is. It's just, it's just white. Therefore, we recommend we have we put the both code 821528 s was a two five to eight times 1.25 on the on the list, appalling. So I will open for the panel to decide. Thank you.

Unknown Speaker 1:11:24
Thank you, Jennifer. Was there a question? Or the developer if present, or?

Unknown Speaker 1:11:31
I don't know if I understood that correctly? Oh, sorry. Ashley, I will This is just maybe we can ask. But presented? Well, it up during the public meeting, the

Unknown Speaker 1:11:44
representative from the company did mention the 1.25 to justify the

Unknown Speaker 1:11:52
additional cost for the test. Doesn't make sense. But I kind of disagree. So can we can we just ask if someone is present? From the developer? Yeah, hello, this is my Kevin from exact sciences, and multi qubit by Dr. Olson, who can provide some some deeper explanation. You were correct that in June, we commented on two important enhancements, which increased internal resources and cost. And that was the expansion and enhancement of M DMS, as well as the enhancement of our buffer formulation to increase hemoglobin stability and decrease sample exploration.

Unknown Speaker 1:12:31
Dr. Olson, if you're on would you like to provide some additional details on the resources question?

Unknown Speaker 1:12:37
Yeah, thanks, Mike. This is Marilyn Olsen exact sciences.

Unknown Speaker 1:12:42
With the addition of the methylation marker, which is a quantitative assay, this does add some some complexity. For instance, now we're doing a quadruplex reaction which requires

Unknown Speaker 1:12:57
you know, custom dye calibration and maybe and some more time on the part of the lab operators

Unknown Speaker 1:13:05
custom calibration plates for that quadruplex. In addition, we've made some other formulation changes to the methylation assay along with the formulation changes Mike mentioned on the hemoglobin buffer

Unknown Speaker 1:13:21
Perfect thank you for for this that's very helpful. I just opened it up for the panel if that explanation was was okay, or whether additional information is needed for

Unknown Speaker 1:13:35
the panel to render a decision

Unknown Speaker 1:13:39
uh, you know, questions or the questions or comments from the panel or from CMS

Unknown Speaker 1:13:47
Hearing none, then I asked the panel to castable please

Unknown Speaker 1:13:58
you

Unknown Speaker 1:14:04
expect next code is x x five one you and I asked them to Zhang again to present this code please. Thank you, Joe. So the code x x five one u is the qualitative real time PCR for basically to try to care care Kara's as well as an N RAS genes from the form FFP specimen. So I'm and the company recommend cross over to three coats press together from 82127581276 S was 81311. And we totally agree with a recommendation because it does cover all the genes being detected. Therefore, our panel recommendation agree with the company it is should be the eight to one to seven five plus

Unknown Speaker 1:15:00
821276 plus 81311

Unknown Speaker 1:15:05
Perfect. Thank you, Jennifer for any new options from the panel to consider

Unknown Speaker 1:15:12
any questions or comments from the panel or from CMS

Unknown Speaker 1:15:18
hearing on then I kindly ask the panel members to cast their vote

Unknown Speaker 1:15:33
Thank you. Thanks a lot x x six, eight, you will be presented by Dr. Chandra Bruyneel Can I hand it over to you? Thank you Dr. lenaerts. XX six AU is under the indication of colorectal cancer. The next generation sequencing assay on blood as well as FFP II as well as methylation pattern analysis. rather complex assay looked for a crosswalk code but wasn't able to find an apples to apples comparison. There was no public presentation and as a result we recommend gap fill.

Unknown Speaker 1:16:15
Thank you. Any other options from the panel to consider here

Unknown Speaker 1:16:21
are any other questions or comments from the panel or from CMS

Unknown Speaker 1:16:27
hearing on and I asked the panel to castable please

Unknown Speaker 1:16:46
Okay, thank you staying with Dr. Chandra on xx eight six you

Unknown Speaker 1:16:53
thank you Dr. lenaerts. XX eight six U is oncology based sequencing in the setting of colorectal and lung neoplasia on FFPE tissue of eight oncogenic genes, we recommend the crosswalk recommendation of we agree with the crosswalk recommendation of 81445 which has similar methodology and resources

Unknown Speaker 1:17:25
any other new options from the panel to consider

Unknown Speaker 1:17:32
any other comments or questions from the panel or from CMS?

Unknown Speaker 1:17:40
Hearing none, then panel please cast your vote

Unknown Speaker 1:17:54
Thank you. Next chord is x x nine o u and that's also looked at Chandra.

Unknown Speaker 1:18:06
Sorry, I was I was on mute.

Unknown Speaker 1:18:10
So xx nine o u is also a genomic sequencing procedure and the context of Barrett's esophagus that looks at DNA methylation analysis of numerous genes to give an algorithmic report of likelihood of Barrett's we do

Unknown Speaker 1:18:34
agree with the with the crosswalk 2011. For you. There was a very nice presentation with the rationale and due to similar methodologies and resources. We agree with the crosswalk rep recommendation here.

Unknown Speaker 1:18:54
Thank you, Dr. Shandra. Any new options from the panel?

Unknown Speaker 1:18:59
Or any questions or comments from the panel or CMS?

Unknown Speaker 1:19:05
Hearing none, then I asked the panel to castable please.

Unknown Speaker 1:19:32
Waiting on one more answer if you could check that your vote got was cast. There we are. Thank you very much. Perfect. Thank you. Next coat meeting item 101x x five four. You

Unknown Speaker 1:19:46
ask Heather Chapelle to present this please.

Unknown Speaker 1:19:50
Yes. So I actually have the next five codes that are all similar. They're all hereditary.

Unknown Speaker 1:20:00
oncology testing of multiple genes sequence analysis panel.

Unknown Speaker 1:20:07
That also includes deletions and duplications by next generation sequencing. So, there are

Unknown Speaker 1:20:19
a, sorry to give the explanation for this crosswalk, I have to refer to some other codes. Those other codes are 814-328-1435, and 81437. These are codes that were sent to the panel as revised codes of previously existing hereditary cancer related codes. In the past,

Unknown Speaker 1:20:45
there was a single code for the sequencing of the genes related to that hereditary cancer disorder, and a separate code for the deletions and duplications related to that hereditary cancer disorder. These revisions to the codes have added the sequencing and Dell due to the same definition or description. And so, there's been a recommendation to crosswalk these codes to the previously existing hereditary cancer codes as these are all similar methodologies and resources. And specifically amp recommended crosswalk

Unknown Speaker 1:21:28
of 81435 plus 81436 times 0.25. And they made that recommendation, they said based on the fact that to get to deletion and duplication and next generation sequencing of the genes included in the assay, the the initial methods and resources are similar, and then the actual sequencing and del doop can be performed. So using their logic on 814-328-1435 and 81437. The subcommittee has recommended a crosswalk of 81435 plus 81436 times 0.25

Unknown Speaker 1:22:22
For this assay,

Unknown Speaker 1:22:25
and I don't, there was a recommendation by the lab for crosswalk to 0101. You are 0103. You

Unknown Speaker 1:22:39
so that is also an option. And I don't know if the lab is here and wants to comment, that they're certainly welcome to do that,

Unknown Speaker 1:22:48

too. Thank you. So the so we can choose in either of four. Is that right? Yeah, absolutely. Do you mind introducing yourself? Oh, yes. Sorry that Yeah. Jim Lu, Matador Attersee, CEO of the coop has diagnostics.

Unknown Speaker 1:23:05
Yeah. And so we can choose any of them. Right.

Unknown Speaker 1:23:11
I just want to confirm.

Unknown Speaker 1:23:13
So I think the question that I have a Chapelle asked you is what the reasoning is, for your suggestion to crosswalk to another coat? I think Heather just explained the reasoning of the Subcommittee, but there are other codes, he presented the 0101 u 0103. You think if I weren't the question differently, what is the reasoning behind those proposed crosswalks? Yeah, and we identified these codes and the, we find that the the you look at the description, they are very similar to what we do. And

Unknown Speaker 1:24:00
you know, we are mutations, duplication, deletions. And that's why we choose to do this to no in the it's just different with the code that we choose in the colon cancer and ovarian cancer, we're doing the prostate cancer. So, we certainly like to you know, look into the recommended code 814-358-1436 and the description to us look similar, but I personally I have not we have not studied a 14358143 Since we picked the two that we you know, we listed here the question here that if they recommended the code is a one for three fi can we using the one that we used, you know, I really don't see the you know, I just take a look at the screen I really don't see significant difference between recommended one the one we choose

Unknown Speaker 1:25:00
And as I

Unknown Speaker 1:25:06
so maybe I can ask one other question what you evaluate the 23 genes?

Unknown Speaker 1:25:14
We evaluated 22 genes. So for the UK, and are those separately reported?

Unknown Speaker 1:25:22
Know that they're reported correctly as one report.

Unknown Speaker 1:25:26
Okay. Yeah, that depends on what my irritation, we find it. I think that that was, if I recall correctly, what the subcommittee discussed that that might be different when that is reported in aggregate versus as individual,

Unknown Speaker 1:25:41
you know, sequencing results of individual genes for a certain number of genes. But let me open it up, again to the subcommittee. And okay, I'm Heather, if there are other questions or comments, also from CMS.

Unknown Speaker 1:26:00
I looking at why this is Heather 101 and 103. I think that they are also reasonable crosswalks

Unknown Speaker 1:26:12
because they do include the sequencing and the Dell dupe of multiple genes for hereditary cancer. So it looks like it's a similar with next generation sequencing looks like a similar methodology and resources.

Unknown Speaker 1:26:32
So I think they're acceptable crosswalks to have on the list as well.

Unknown Speaker 1:26:43
Thank you. Other comments or questions?

Unknown Speaker 1:26:51
Hearing none, then I asked the panel to cast their vote, please.

Unknown Speaker 1:26:58
And thank you, Dr. Lu, for for being here and answering our questions. Thank you. Thank you, thank you for your panel.

Unknown Speaker 1:27:35
Just waiting for one more response.

Unknown Speaker 1:27:42
There it is. Thank you. Wonderful. Next code heathered. It's yours again, x x five, five you. Yes. So similarly, this is, as I said, another hereditary cancer test with next generation sequencing analysis, sequence changes and deletion duplication.

Unknown Speaker 1:28:08
And, again, we went with the recommendation consistent with the other hereditary cancer codes by amp of 81435 plus 81436 times 0.25.

Unknown Speaker 1:28:26
And I believe there were no recommendations by the lab. I'm not sure if the lab is here or has anything to say. Yeah, it's me again

Unknown Speaker 1:28:36
go past diagnostics. Yeah. And this is the actually this test with the previous one is very similar one and during the

Unknown Speaker 1:28:48
submission process, somehow the way these these PL code is a missed from the for for for the presentation that I did last time. So so the the test everything you know, methodology everything and reporting is very similar, but it's more in the margins at ages. So we will like to see that if we can still crosswalk to the one that that we recommended same as the previous one if possible.

Unknown Speaker 1:29:34

However, I leave that up to you if you want to

Unknown Speaker 1:29:39
add this or

Unknown Speaker 1:29:42
was this

Unknown Speaker 1:29:44
explanation sufficient?

Unknown Speaker 1:29:50
I think it's similar to the last one Joe it's reasonable to consider 101 or 103 You okay, so

Unknown Speaker 1:30:00
Sarah, can I ask you to modify our ballot to include a second line option of 0101 U.

Unknown Speaker 1:30:12
And then a third line option 0103. You?

Unknown Speaker 1:30:23
Yes, hi, this is this is also truth. I'm also with gopath. We had we had emailed CMS regarding the recommended crosswalk to 01 u or 0103 U, as per our previous PLA, code 0475. You because this this test that we see here 040047 For you, is equivalent in methodology and approach as to the prostate now, test.

Unknown Speaker 1:30:53
So, just a quick quick note here, thank you for that comment. Dr. Andy 047 for you is the final code number, just for the panel? That is not a crosswalk. That's professional code. So we usually go by the code number at Greg's submission. Just for clarification, because, you know, we look at possibly some panel members look at their own tracking sheets. And, you know, just so that no one gets confused with the different codes. Yes, correct. And that our voting ballot has already changed. So just for confirmation, maybe to Dr. Yang, and Dr. Lu. We have 0103. You, or 0101, you or the previously recommended 81435 plus 81436 times oh point two five, those are currently aside from gap fill and abstain. The current crosswalk recommendation, is that correct?

Unknown Speaker 1:31:55
Yes, that's correct. And we would like to advocate for both tests to be crosswalk to either 0101 u or 0103. You.

Unknown Speaker 1:32:05
Yep. And then. Yeah. Thank you. And now I'm back to Heather, whether that's okay with you as its portrayed now? Yes. Perfect. Thank you. And now, opening it up to the panel, whether there are other options that they would like to have included here.

Unknown Speaker 1:32:29
Real quick, I do want to confirm since the ballots aren't public facing we have added those two options to the ballot that the panel sees. So you won't see it on the screen here. But you do

Unknown Speaker 1:32:42
see it on that. But the panel does see it on this unlike their slides. Glenn, are you able to make those edits in real time to the display just so the public can see those changes? shored?

Unknown Speaker 1:32:54
Yes, sir. Could you repeat them? So we're on? Yep. 047 for you?

Unknown Speaker 1:33:01
is good. What just happened here?

Unknown Speaker 1:33:05
Your automated numbering or just do this? Yep. Yeah, that's fine. Good. So Oh, 101. You? That's correct.

Unknown Speaker 1:33:18
And then all 10103

Unknown Speaker 1:33:28
here.

Unknown Speaker 1:33:32
She called Signs and

Unknown Speaker 1:33:35
that's it. That's it.

Unknown Speaker 1:33:40
Thank you.

Unknown Speaker 1:33:42
Okay. Any other questions or comments?

Unknown Speaker 1:33:47
On the panel from CMS? What? Mini recommendation?

Unknown Speaker 1:33:55
Did that change? I think that's a question for Heather, if you can, yeah, my recommendation would continue to be consistent with the other codes that are going through the process, the 81435 plus 81436 times 0.25.

Unknown Speaker 1:34:15
I think the other crosswalks are or the other codes are reasonable to consider as well.

Unknown Speaker 1:34:24
Thanks.

Unknown Speaker 1:34:26
Thank you. So kinda members, please cast your vote no.

Unknown Speaker 1:34:41
Okay, thank you.

Unknown Speaker 1:34:43
That was fair. Thank you. Okay. I'm staying with you, Heather. There's the code 81432. Yes. So this was one of the revised codes. This was an AMA subcommittee.

Unknown Speaker 1:35:00
He was assigned to look at the existing hereditary cancer related codes and to come up with alternatives that more closely represent what is actually being done in labs today. And so 81432 was the first of these revised codes.

Unknown Speaker 1:35:17
There were recommendations for consideration by amp and the acla. For these codes, amp suggested 81432 plus 81433 times 0.25. The acla recommended 81432 plus 81433.

Unknown Speaker 1:35:39
And both of these are reasonable to consider. The subcommittee is recommending amps recommendation with the modifier 281436 of 0.25.

Unknown Speaker 1:35:58
Perfect, and that's a code of three. But for now, any new options from the panel for this code? 81432? You know, I ask a question. I mean, is there somebody that could potentially justify the difference between a point two five and a, an A times one? multiplier?

Unknown Speaker 1:36:19
Is there a sponsor something available? It's unusual that the professional organizations have two different recommendations. It is. Looks like we have two hand raised

Unknown Speaker 1:36:33
from Vicki pret Vicki,

Unknown Speaker 1:36:37
are you able to speak? Yes, can you hear me? Yes, we can hear you. Um, so when it made its recommendations, we felt that

Unknown Speaker 1:36:48
since the doop Dal was now included in the NGS pipeline, there was additional work associated with it. But it wasn't completely equivalent to just doing 81436 by itself. So that's why we recommended a multiplier of 1.25 recognizing there is additional work involved in incorporating doop dials into a sequencing pot, platform and resources with that are needed for controls and other other such things, but not the complete resources needed for a completely separate platform such as an LPA, which is, which was the intent when the 81436 was initially created.

Unknown Speaker 1:37:46
Let's see a second hand here as well from the Edgar Rice, if I pronounced that correctly. Yes. This is John categorize, I represent the American clinical laboratory association. So we did present the recommendations for crosswalk 481432 plus 81433. When the CPT panel made the

decision, they did acknowledge that they were moving the work from the child code a 1433 into the parent code a 1432. serving our members before we made these recommendations, we looked to see if they include the duplication deletion analysis, in the same next generation sequencing analysis, and our members clearly stated that they do not always perform these services in the sequencing analysis, we have survey to our members that does show and demonstrate that there are additional work related to the sequence variants and the copy number variants, which in essence, is the duplication deletion analysis, for example, there's a rare comparative genomic hybridization, and there's multiple ligation probe amplification assay. So these services are now represented effective January 1 2025, into that parent code 81432. And that's really why we disagree with EMP recommendation 1.25

Unknown Speaker 1:39:14
multiplayer for that child code 81433 For those reasons, so I'd be happy to respond to any questions you may have on this.

Unknown Speaker 1:39:22
Thank you. Yes, I think that requires a bit of discussion. I also have a question, but let's first Thank you, Dr. Craig rice, Dr. Mike Ryan.

Unknown Speaker 1:39:32
My grind for McDermott. Speaking on behalf of the Coalition for 21st century medicine.

Unknown Speaker 1:39:38
I actually don't summarize our comments very well. This is an analysis that we understood prior to the introduction of these new codes would have been reported with both 81432181433 Maybe that is a cop or a procedure.

Unknown Speaker 1:39:56
Perfect, thank you. Have a question to Dr.

Unknown Speaker 1:40:00
Perhaps comment just for clarification.

Unknown Speaker 1:40:03
You intended to say it 1433 And times 4.25, meaning only 25% of that code or 1.25 to count for the additional work

Unknown Speaker 1:40:17
0.254 The additional resources needed to analyze do details in the sequencing analysis.

Unknown Speaker 1:40:30
Okay.

Unknown Speaker 1:40:32
I see Sarah Harding has her hand raised. Yeah, just wanted to

Unknown Speaker 1:40:38

communicate a comment that came in through our q&a is and I'll just read it says, aren't CPT codes created technology agnostic, it's about the work being completed. It was not about ml PA or any other platform. It's about doing the work to report as a result on doodles.

Unknown Speaker 1:41:01
Okay.

Unknown Speaker 1:41:06
So I think the complexity that we're just discussing, is not about whether or not the CPT code is correctly described. But I think if I, if I may speak, for whatever I had asked why it is this same code crosswalk with a different modifier attached to it. That was, I think the the question had a correct,

Unknown Speaker 1:41:31
yes.

Unknown Speaker 1:41:39
Correct. And B, I can just read or Dr. Arthur, do you want to say this just so it's also on the record? Yes. We received a comment in the chat from Beverly Donna who I believe

Unknown Speaker 1:41:56
asking about and I'll just read it directly who decides which category applies to the code. Our code category was microbiology, infectious disease and genome sequencing procedures RT PCR, and not in a our code for six weeks new has an algorithmic Analysis Report, which means in a per the AMA does a category, whether correct or incorrect, have a bearing on the price. And so the response is, no, the category does not have any bearing on the code pricing categories are created to better organize, review the codes, they are also subject to change and correction. And so if we noticed a categories need to be changed, we can simply update the agenda. But the categories have absolutely nothing to do with the code of payment determination, recommendation or pricing.

Unknown Speaker 1:42:40
Thank you. So that was little out of order that was for another code presented today. So just to keep the discussion organized, but those categorizations mostly helped a subcommittee to assign codes, just like Dr. Arthur said. So let's go back to the discussion of 81432.

Unknown Speaker 1:43:01
So Heather, and or any other panel member? Do you need additional information about the reason behind those two different, let's say combinations of same CPT codes for your vote on 81432?

Unknown Speaker 1:43:18
This is Heather, I guess my only question would be back to amp.

Unknown Speaker 1:43:25
Based on this discussion, does your recommendation change?

Unknown Speaker 1:43:31
Um, I don't know that our recommendation will is changing.

Unknown Speaker 1:43:39
It really is understanding the the amount of work and resources needed to do the Duke Dells

Unknown Speaker 1:43:48
to do the Duke dials.

Unknown Speaker 1:43:56
So maybe then,

Unknown Speaker 1:43:59
for clarification, the option three and four portrayed on the screen or options One and Two portrayed in the same order in our ballot that's not visible here are distinguishing whether you believe that the code description adequately accounts or does not account for dupe Dells. If I may summarize like that, I will abstain from a recommendation I think those are two options that the panel has other than gap fill, of course.

Unknown Speaker 1:44:30
Any other comments or questions on this code? And this discussion is very helpful because we have probably the next code and the next code similar discussions. Yeah, they're gonna be they're gonna be similar. I mean, the The important thing is, is there any economies of scale by combining these two codes that require a reduced modifier on the second code or not?

Unknown Speaker 1:44:57
Are these two truly different

Unknown Speaker 1:45:00
analysis.

Unknown Speaker 1:45:04
I see that categorise has her hand raised.

Unknown Speaker 1:45:08
Yes, thank you, Dr. Lyrans. So first of all, as far as the duplication deletion analysis question, so the duplication deletion was in that child code, but from discussing with our specialists who perform this testing laboratory, that really the sequence variants and copy number variants, in essence is duplication, deletion analysis, and there are different methods and assays that perform this, depending on the genes that are identified in the initial sequencing analysis. So for breast cancer, if there's a specific gene analyzed, the mom, a laboratory might decide to do the MLP da analysis specifically, because that might be the better analysis for that, to set up for that specific gene or genes. So I just wanted to provide that clarity. And so in when we did the survey for our laboratories, these are definitely separate and distinct analysis and not always in the same next generation sequencing

Unknown Speaker 1:46:08
assay.

Unknown Speaker 1:46:16
Thank you.

Unknown Speaker 1:46:21
Any other? See, Dr. Pratt, has her hand raised, but the prep? Yes. Um, so as I, as we read the descriptor, it says duped out by next generation sequencing. It doesn't indicate a separate analysis by MLP. As Joan indicated, I would think if the laboratory required a separate analysis for a specific gene, they could use some of the gene specific codes

Unknown Speaker 1:46:49
as needed for clarification or further characterization of that sample or that specimen.

Unknown Speaker 1:47:01
And I just talked to print, you're referring to the doop dal in the longest crypto of 81432 or two, which code? were you referring to the child code the original?

Unknown Speaker 1:47:13
So if you look at the it's so the gin. So if you're looking at the 81432, it says genomic sequencing analysis, my genes, including copy number, so

Unknown Speaker 1:47:27
our interpretation is that's being done all by next generation sequencing.

Unknown Speaker 1:47:39
Okay.

Unknown Speaker 1:47:44
But my question was, you mentioned that a code contains the duplication and deletion analysis. And that would be

Unknown Speaker 1:47:54
1433? Correct. Right. So the copy number is copy numbers deletion and duplication analysis.

Unknown Speaker 1:48:04
So I don't understand your question. The question is, I believe if I had to look to categorize mentioned that that might be done by a different technology, for example, MLP. A, I think your point was that you could code that separately.

Unknown Speaker 1:48:18
The question is not whether the crosswalk codes adequately reflect what you're doing. But what we need to decide is whether the 81432 code descriptor and the technology related to that can be portrayed using other crosswalk codes. So I think that's, I think those two

Unknown Speaker 1:48:40
opinions are related to what platforms are being used, but suffer categorize. Legit. Yeah, no, I agree.

Unknown Speaker 1:48:50
Our assumption it's being done by next generation sequencing, as we understood,

Unknown Speaker 1:48:57

stood and we're involved with the AMA special committee

Unknown Speaker 1:49:11
talking to the panel, other questions or comments on this?

Unknown Speaker 1:49:20
Any questions or comments from the panel or from CMS?

Unknown Speaker 1:49:29
If not, then I am the ask the panel to vote on 81432

Unknown Speaker 1:50:00
Okay thank you very much

Unknown Speaker 1:50:03
perfect we move on to eight 1/4

PART FOUR

Dr Lennerz MGH 0:00
But hand it back over to Heather Chapelle.

Unknown Speaker 0:04
Thanks doctor letters. So we have the same options available or similar options available for this code. In terms of a crosswalk, there is the 81435 plus 81436 times 0.25 Crosswalk option, which had originally been amps recommendation. And then the 814370 Sorry, 81435 plus 81436 option as well, which was recommended by acla.

Unknown Speaker 0:44
My questions would be the same for this Yes.

Unknown Speaker 0:49
It really the same issue for this code and the next code. Unless someone disagrees? I think these are the right crosswalk options unless there's another option that someone wants to propose.

Dr Lennerz MGH 1:10
Does anyone want to propose another option? Again, and it's very efficient that we already discussed the reasoning behind these two recommendations. So any other questions or comments from the panel or CMS?

Hearing none, then it asked the panel members to move forward with their vote please.

Unknown Speaker 1:41
Okay, thank you.

Dr Lennerz MGH 1:43
The next code 81437 is also Heather

Unknown Speaker 1:49
is the last hereditary cancer code. This is for neuro endocrine related disorders. Similar description to the other descriptions and there are two crosswalk options proposed here. The first is the amp option 81437 plus 81438 times 0.25. And the alternative crosswalk option by acla is 81437 plus 81438.

Dr Lennerz MGH 2:28
Perfect, thank you, any other options coming from the panel? Hearing none, any other questions or comments from the panel or from CMS? I hear no additional comments or questions. So panel members, please move forward with your vote.

Unknown Speaker 3:02
Okay, thank you very much.

Dr Lennerz MGH 3:04
Thank you for the next code, which is 0448. You I hand it over to Dr. John. Thank

Unknown Speaker 3:13
you a little change of the subject, right? We're gonna have a little really, okay, so for code 044 hgu. It is an oncology test. We're using DNA qualitative at NGS testing. Basically, they are targeting for two genes, EGFR as well as K RAS genes and using the FFP solid tumor samples. So, um, so, there are two options we think could be very reasonable one is code 0111 u, which is to detect both Karis and M RAs, so two genes and using similar resource as worth a methodology. Alternatively, you can always think about using two codes which is 81235 to 10, EGFR plus a 21275, which detected Karis. So I think both a G unreasonable and be more precise. A to 1235 plus a 21275. is favored. Thank you.

Dr Lennerz MGH 4:26
Perfect any new or other options from the panel to consider? Hearing none, any other comments or questions on this quote from the panel or from CMS?

Unknown Speaker 4:42
This is another issue of Oh 448 You doesn't have a price I wasn't in this subgroup. So I don't know I didn't look at this code that closely.

Dr Lennerz MGH 4:59
So Oh four four AQ is to coat. No, no, no, no, the other 0111 You

Unknown Speaker 5:11
know, Ron, sorry. Sorry, I was looking at something different. Yes.

Dr Lennerz MGH 5:19
That was good. Double double checking. That's so important. And the other questions or comments from the panel or from CMS.

Unknown Speaker 5:30
Can you repeat what the CMS not CMS what the subcommittee preferences?

Unknown Speaker 5:39
Yes, it is eight to 1235 plus 81275.

Unknown Speaker 5:44
Thank you. Yeah.

Dr Lennerz MGH 5:50
So panel members, please cast your vote

Unknown Speaker 6:02
Okay, thank you.

Dr Lennerz MGH 6:03
Thank you. Next code is x x six one you and I handed over to Heather.

Unknown Speaker 6:11

Thank you. This is an oncology assay for non small cell lung cancer that assesses DNA, RNA, and digital PCR analysis of nine genes in formalin fixed, paraffin embedded tissue. And detectable actionable variants are reported for therapy selection. There was no clear code to crosswalk this code to identified by the subcommittee and there were no lab or stakeholder comments. So our recommendation for this code is gap fill.

Dr Lennerz MGH 6:54
Perfect, thank you, Heather. Any other new options to the panel to consider here. Any other questions or comments from the panel or from CMS? Okay, hearing none then panel members please cast your vote for x x six one you.

Unknown Speaker 7:22
Thank you.

Dr Lennerz MGH 7:24
The next code is x x line one you and I handed over to Dr. Chandra.

Unknown Speaker 7:29
Thank you Dr. lenaerts. XX nine one u is an oncology code for whole genome sequencing in the context of ovarian cancer. There was a public presentation and a recommendation to crosswalk to 0401 you and we agree with that crosswalk recommendation and due to similar methodology very similar methodology and resources.

Dr Lennerz MGH 7:58
Thank you to turn to any new options from the panel for consideration or any questions or comments from the panel or from CMS? Hearing none, then I ask the panel to vote on xx nine when you please.

Unknown Speaker 8:34
You're just waiting for otherness Thank you wonderful.

Dr Lennerz MGH 8:37
Next is x x nine two you also book the tundra please.

Unknown Speaker 8:42
Thank you Dr. lenaerts. XX nine to you is a an oncology assay in the context of pancreatic cancer, algorithmic analysis of 16 genes that were previously sequenced. Our recommendation is in this for gap fill, which is in alignment with the stakeholder recommendations.

Dr Lennerz MGH 9:07
Perfect, thank you very much any new options from the panel? When in question Questions or comments from the panel or from CMS hearing on then I asked the panel members to castable please.

Okay, thank you. Perfect. Um, the next code is 81457. Again, a group of three codes that are related. And these are the new DNA gene probe, gene sequencing procedure codes. And quickly I think there was also a question about this earlier in the chat whether the gap fill will interfere with the pricing of Are these three consideration codes that can be taken into account. And I think many of the panel members have looked at that. But that is not a part of the real

consideration here. Price setting is independent, we tried to do the matching based on technology and the complexity of the test to account for those different methods. So quickly 81457, the panel has reviewed all the different recommendations provided. And our recommendation is a crosswalk to 1.5 times 81445. And that was discussed with the panel and you see that there's already a gradation for the next coat. But I first want to open it up for discussion and or any new options from the panel for 81457. Hear no other options, any new any other questions or comments from the panel or from CMS? Hearing none, then I asked the panel to cast their vote on 81457.

Unknown Speaker 11:42
Waiting on one response,

Unknown Speaker 11:46
you can check that you did select an option

Unknown Speaker 11:54
you will complete

Dr Lennerz MGH 12:00
Yes, sir. Oh, perfect. Sorry, thank you. The next code 81458 same code descriptor except that this code also includes copy number variants. And that is accounted for in the subcommittee recommendation by adding a factor to so 0.5 More than the prior code. And so the subcommittee recommendation, taking all elements into account would be two times 81445 as a crosswalk 481458 Are there any new options from the panel to consider? Hearing none, and any questions or comments from the panel or from CMS? Hearing none, so then I asked the panel to vote on 81458 Please.

Unknown Speaker 13:12
Okay, thank you.

Dr Lennerz MGH 13:16
Thank you, then the next code is 81459.

So here we had a lot of discussion because of divergent recommendations. And first, there was a suggestion by actually quite a few people to crosswalk this to 81455. And that is given the the prior coats not in line with the the values. So I see here this crosswalk then that was suggested is 81445. So that's, of course a slightly different number than the what the panel recommended. So given that there's number one, a reconsideration code number two a prior recommendation, and number three, the ongoing gap fill process, the panel ultimately suggested that it should be gap filled. One alternative that was also discussed was a factor of 2.5 times 8144 or five. However, the panel decided ultimately not to include this as an option but go for the gap fill as the main recommendation for 81459. This This, by the way, just as a quick explanation, since this is on different pages. This contains copy number, microsatellite instability and tumor mutational bore burden. So the idea that this should be adequately reflected is a caused by the additional complexity for the often bioinformatics pipeline or additional effort related to the algorithms running those analyses. I opened it up for the panel for others to comment on this. So we're at 1459. And if there any other options by the panel, we could add that

hearing none, any questions or comments from the panel or from CMS?

Hearing none, then I kindly ask you to vote for 81459.

Unknown Speaker 15:49
Thank you very much.

Dr Lennerz MGH 15:52
Thank you. The next code is 044 for you. The code proposal was by the developer and by many on the panel was to crosswalk this to 81455. And these codes all have very similar numbers. I hope I don't mess this up. And the subcommittee reviewed this and agrees that that is an adequate roof selected code, that code is existing and priced, because you could also potentially crosswalk this to other codes that are not yet priced. The other option here is of course, the just recently discussed 81459. But since that is currently in reconsideration, the panel thought that the or the subcommittee thought that the 81455 is adequately reflecting the complexity. Any other new options from the panel? Hearing none, any questions or comments from the panel or CMS? Not then I asked the panel to cast the vote on 0444. You please.

Unknown Speaker 17:16
Thank you.

Dr Lennerz MGH 17:16
Thank you. The next code is x x five, three you. But if I'm correctly informed, this is a coat. Dr. Jang you, you reviewed this but I believe during the process. The vendor, the lab has removed this code, correct? That's

Unknown Speaker 17:36
correct, because it's approved as advanced diagnostic laboratory tests. So officially removed from our discussion.

Dr Lennerz MGH 17:49
So I believe there's no vote so we can move on correct. So the next code would be x x seven one you can present. This is a cell free, circulating DNA oncology solid tumor essay. And the subcommittee reviewed the complexity as well as the recommendations. And there was a big discussion going on which which code is adequately reflecting number of genes complexity and the various elements in the test and this subcommittee recommendation is a crosswalk to all three to six you and there was also another option, or 405 u times two, and you can see the number of genes in the longest crypto on the right side for comparison. The subcommittee just felt that all three to six years is more adequately reflecting what is included in x x seven one you are there any other suggestions or options from the panel to consider for other crosswalks? Or any other questions or comments from the panel or from CMS? Hearing none, then I ask the panel to cast the vote please.

Unknown Speaker 19:34
Thank you.

Dr Lennerz MGH 19:36
Next code is 042 for you. And I hand it to Dr. Chandra for presentation.

Unknown Speaker 19:44

Thanks Dr. lenaerts 0240 You is an oncology code exome based analysis of small non coding RNAs There was a recommendation to crosswalk to 0343. You. And that's a reasonable recommendation. And we agree with that recommendation.

Dr Lennerz MGH 20:18
Okay, any new options from the panel? Any questions or comments from the panel or from CMS? If not, then I asked the panel to castable please.

Unknown Speaker 20:44
Okay, thank you.

Dr Lennerz MGH 20:47
Thank you. And the next code is Oh 433 You. And this is a DNA based quantitative PCR essay from whole blood, including an algorithm that also includes a prostate specific antigen, and it's reported as likelihood for cancer. And the recommendation was a crosswalk to 0012 M, which is existing and very similar technologies. So the subcommittee agreed with that recommendation. And I would like to move forward and ask whether there are any other options coming from the panel or this code or any questions or comments from the panel or from CMS. If not, then please cannot vote on 0433 You.

Unknown Speaker 21:55
We have everyone

Unknown Speaker 21:57
not quite where we narrative.

Dr Lennerz MGH 22:00
Got it. The next code is x x three, three you and I hand it to Dr. Zhang for presentation. Thank

Unknown Speaker 22:07
you, Joe. So for code x x three three you it is a oncologia test, use modified duplex and methylation PCR test and detecting the free DNA from urine cell free DNA from urine and our report as a likelihood of bladder cancer. This is presented by the company and we will agree with their recommendation to crosswalk to the code 81327 Based on the similarity of the tests as well as the reporting the only difference is the specimen use the specimen use in the code 81327 is a cell free DNA from plasma and this test is from the urine but I think essentially they are saying therefore panel agree with the crosswalk to the code 821327 Thank you.

Dr Lennerz MGH 23:03
Any new options or any questions or comments on the panel or CMS? Hearing none, then I asked the panel to cast the vote on x x three, three you please.

Unknown Speaker 23:35
So it's one little straggler,

Dr Lennerz MGH 23:37
there it is. Thank you. Okay, thank you. We stay with that the journal and the next code is x x four five you.

Unknown Speaker 23:49
Sorry, I'm kind of have a hard time to unmute myself. Okay, so this is a code for another oncology test code. So another quantitative methylation specific PCR for two genes. And let me just double check. Yes. And again, we recommend the company recommended 2821551, if I remember correctly, and we do agree with that crosswalk because of the similar methodology as well as the likelihood report. I'm sorry, the algorithm analysis report sorry about that. And also when stuck consider the possibility crosswalk to the 0012 M. Because it is also your theory or carcinoma testing with a similar genetic testing methodology. The only difference is this is using the RM R na. So either one looks pretty good and I think 821551 with a close similarity because of the the gene testing as well as Gene a target gene, the number of the target gene, as well as the the specimen using usage where they use the paraffin embedded tissue. So,

Dr Lennerz MGH 25:38
perfect. Thank you, Ben, for any new options coming from the panel?

Unknown Speaker 25:45
Just the question between the two, the 8155 and one and a 212. M. R is the specimen prep that is different between those two codes. Yes.

Unknown Speaker 26:02
Because the way you do the, you know, the uterus urine versus using a paraffin block in a paraffin block is different.

Unknown Speaker 26:12
And your recommendation was eight

Unknown Speaker 26:14
to 1551. Okay,

Unknown Speaker 26:16
thank you.

Unknown Speaker 26:17
Thank you.

Dr Lennerz MGH 26:22
Perfect. Any other questions or comments from the panel or CMS? If not, then I ask the panel members to cast the vote please.

Unknown Speaker 27:00
Okay, where's that Thank you.

Dr Lennerz MGH 27:01
Thank you. The next code again, Dr. Zhang x x four seven.

Unknown Speaker 27:06
Thank you. X X, four seven U is another oncology code for the bladder cancer basically use the platform of next generation sequencing detected the DNA in the urine, they do provide algorithms report as minimal residual disease status. So we, our committee do feel 81455

Which is pretty familiar with everybody now, and is the most appropriate code however, on the other hand, a gap fill is also optional, because a 21455 does not provide the algorithm report and does not sufficiently coding for the minimal residual disease status. So I think we're kind of torn either 150 54 option gap field versus eight to 1455.

Dr Lennerz MGH 28:12
Okay, any new options from the panel to consider? Any questions or comments from the panel or from CMS?

Hearing none, if there are no additional comments, panel members, please cast your vote.

u xx seven nine U is presented by Dr. Chandra.

Unknown Speaker 28:52
Thanks Dr. Leonard's This is a oncology prostate based analysis of a number of circulating plasma proteins to give a polygenic risk score. There was a nice presentation with actually two recommendations 81539 as well as 0359. You both are reasonable recommendations with similar methodology and resources. I would slightly favor 81539 over to 0359. You.

Dr Lennerz MGH 29:29
Perfect, thank you. Any new options from the panel to consider? Hearing none, then any other comments or questions from the panel or from CMS? Hearing none, then I asked the panel to cast the vote please.

Unknown Speaker 30:04
Okay, thank you very much.

Dr Lennerz MGH 30:05
The next code is x x eight one you also Dr. Chandra, please. Thanks

Unknown Speaker 30:12
Dr. Leonard's xx eight one u is an oncology prostate messenger and messenger RNA gene expression profiling assay by real time PCR. Again, another good presentation, public presentation with reasonable recommendations and analysis. And based on the similarity of methodology and resources, we agree with the crosswalk 20047 You

Dr Lennerz MGH 30:43
Perfect, thank you. Any new options for consideration coming from the panel? Hearing none, any other questions or comments from the panel or from CMS? Okay, then I asked the panel to please cast a vote on x x eight one you.

Unknown Speaker 31:17
Okay, thank you.

Dr Lennerz MGH 31:18
Thank you. And then purple Chandra, I think this is the last code you present today, which is eight 8x x Oh.

Unknown Speaker 31:27

Thank you, Dr. lenaerts. Eight 8x x l is an optical genome mapping based sided genomic genome wide analysis. In hematologic malignancies can pick up structural alterations copy number variation, the crosswalk that was recommended by the stakeholders is an apples to apples crosswalk and a very good crosswalk here and one that we agree with which is the crosswalk to 0331 you

Dr Lennerz MGH 32:00
perfect, thank you any new options coming from the panel? Any questions or comments from the panel or from CMS? Okay, hearing on the panel, please cast your vote on eight 8x x zero

Unknown Speaker 32:33
Thank you.

Dr Lennerz MGH 32:37
Okay, next one is 0413 you and it's Dr. Jones.

Unknown Speaker 32:42
Thank you, Joe. So, code numbers 0413 You is also a oncology code for him at all lymphoid neoplasm they are using the optical genomic mapping for the copy numbers alteration and you deploy it as well as balances slash complex structure rearrangement using DNA from the blood and a bone marrow. As you can see, it's very similar to the 033 when you the same methodologies same report the same specimen and therefore I think it's very good just as Dr. Chandra mentioned is apple to apple comparison also we read we agree with the company's suggestion as therefore 033 When you is a good cross walk code. Thank you.

Dr Lennerz MGH 33:36
Thanks a lot. It's very helpful. Any new options from the panel hearing on any questions or comments from the panel or from CMS also non and these panel members then cast your vote on Oh 413 You

Unknown Speaker 34:05
okay, thank you.

Dr Lennerz MGH 34:07
Okay, next code is from Heather Chapelle x x three five you

Unknown Speaker 34:14
Thanks, Joe. This code is a rare diseases code identification of copy number variants, including insertions and versions etc. By optical genome mapping. The recommendation by the lab and the acla was a crosswalk to code zero to six zero you. The subcommittee reviewed this code and agree that this code has similar methodology and resources and we also recommend a crosswalk to zero to six zero you.

Dr Lennerz MGH 34:52
Perfect, thank you. Any new options from the panel? Or any questions or comments from the panel or from CMS? Hearing none then I kindly asked the panel to cast a vote on x x three five you

Unknown Speaker 35:17

Okay, thank you

Dr Lennerz MGH 35:19
all for two three you also presented by Heather Chapelle

Unknown Speaker 35:25
thanks. This is a psychiatry code pharmaco genomic panel of variants in at least 26 genes including metabolizer status and drug toxicity by condition. This, the subcommittee reviewed many existing pharmacogenetic codes, some of which have similar or seem to be similar descriptors. And we have come to the recommendation of 0349 you as the closest single code. In terms of methodology and resources, there was a recommendation by the lab for a crosswalk to multiple codes and those codes are 0345 u plus 0419 u plus 0411. You so, I think those two options will be available to the committee but from the subcommittee's perspective, 0349 new is the most similar crosswalk.

Dr Lennerz MGH 36:47
Thank you. Any new options from the panel to consider? Any questions or comments from the panel or from CMS? Hearing none, then the panel please cast your vote on oh four to three you.

Okay, okay, thank you. Next coat stays with the theme of drug metabolism oh four three for you. This is a adverse drug reactions and drug response test in the pharmacogenetics category, and providing variant analysis and reporting on 25 genes with reported phenotypes. After and following the recommendations by the developer and the company as well as the available material. The subcommittee agrees for the crosswalk 20348 You and that is portrayed here. Are there any other new options from the panel to consider? Hearing none, any other questions or comments from the panel or from CMS? Also Hearing none, then I asked the panel to castable please.

Unknown Speaker 38:38
We have everyone. Yes, we do.

Dr Lennerz MGH 38:44
The next code is x x three zero u and I asked Dr. Zhang to present that. Thank you,

Unknown Speaker 38:51
Joe. Okay. So, again, this is oncology code Pharmaceut pharmacogenomic analysis with a snip genotyping by real time PCR they use in specimen of whole blood or buccal swab and and reporting is included impacted gene drug interaction, and the reported the phenotype. So I feel my best knowledge I find it the closer code with a similar methodology as well as reporting system and a specimen is the code 0055 mu. However, that code is more specific for the cardiology for car transplant and not for the PHARMAC pharmacogenomic analysis. So my preference is for the gap field and options of course including 0055 you at this point.

Dr Lennerz MGH 39:48
I'm one second I may have made a little error here. Because I see the ballot is standing on all 438 You okay, well sorry that was That was my mistake? Yeah, that we skipped ahead. Let's let's not do that. Go ahead. Sorry. So we're talking on top of the page right now. Oh, now the ballot has switched.

Unknown Speaker 40:16
I can do whatever you want, we can still stick with the discussion and then go back or go back

Unknown Speaker 40:21
now since already discussed. Joe, do you mind I can just ask for Yeah, let's

Dr Lennerz MGH 40:26
let's. Yeah, so we're talking the middle row, either 120 9x x three, zero, you know,

Unknown Speaker 40:34
that's correct. Basically, the options including gap field versus crosswalk to 0055 view, but the panel prefer the gap field at this point.

Dr Lennerz MGH 40:48
Any new options for x x three, zero, you. You bring on any other questions or comments from the panel or from CMS? Hearing none, then I ask everyone to cast their vote please.

Okay, okay, perfect. Now we're keeping it interesting. So we jumped to 128, which we skipped before, oh 438 u, which is a drug metabolism essay, also pharmacogenetics, adverse adverse drug reactions and drug response. It's a variant analysis of 33 genes, including Dell dhoop analysis, as well as on the loop analysis of SIP to D six, and the reporting of the phenotypes and Gene drug interactions. Following the recommendation of the developer in the lab is a crosswalk 20350 you in terms of complexity and methodology that was also agreed by the subcommittee so that is the recommendation for Crosswalk for all four, three AQ? Any new options from the panel? Or any questions or comments from the panel or from CMS? panel, please cast your vote.

Unknown Speaker 42:39
Okay, thank you.

Dr Lennerz MGH 42:41
Thank you. The next code is x x six for you, which is Dr. O Heather. Yes.

Unknown Speaker 42:51
Then the last three codes are all pharmacogenetic codes. They're all Maya. So this first one is drug metabolism for psychiatry from whole blood or buccal swab, 14 genes, including SIP to the six copy number variant analysis and reported phenotypes. We reviewed multiple pharmaco genomic related codes and compared them to this code. The subcommittee's recommendation is a crosswalk to code 81418. We did not receive any materials from whoever submitted these code this code so if they would like to comment, they're welcome to do so. But without that the subcommittee's recommendation is a 1418 Crosswalk

Dr Lennerz MGH 43:46
so let's open it up. Do we have the developer available?

Unknown Speaker 43:53
IX X six for you

Dr Lennerz MGH 44:01

hearing none Heather

Unknown Speaker 44:04
with Dr. Tubbs. Hello Nope.

Dr Lennerz MGH 44:20
Okay, any new options for this crosswalk from the panel? Or any questions or comments from the panel or CMS? Hearing none, then I ask the panel to cast their vote please. And whether we stay with you Yes, thank

Unknown Speaker 44:44
you. Do we have all the votes?

Unknown Speaker 44:48
We do indeed.

Dr Lennerz MGH 44:49
Perfect. I see the poll is locked. Wonderful exec six. Oh you would have

Unknown Speaker 44:58
this is a similar code to the previous code for pharmacogenetic testing focused on psychiatry, a whole blood buccal swab genotyping of 14 genes including CIP 2d Six copy number analysis. And again, the closest code the subcommittee agreed on was 81418 for a crosswalk. And there were no materials submitted to direct us in any other way. So, the the subcommittee recommends crosswalk date 1418 Unless there is additional information by the submitters.

Dr Lennerz MGH 45:44
So let's open it up real quick. So, code x x six zero you welcome meeting order number 131. Do we have a developer or the submitter on record available?

To not hear anything, any new options from the panel for consideration? Or any questions or comments from the panel from CMS? Hearing on then I asked the panel to cast the vote on x x six. Oh, you.

Unknown Speaker 46:33
Okay, we're good.

Dr Lennerz MGH 46:36
Perfect. Thank you. Item 132x 100. You, Heather,

Unknown Speaker 46:43
is another

Unknown Speaker 46:45
pharmacogenetic drug metabolism assay. This one includes 40 genes is not condition specific and includes CIP 2d Six copy number analysis, variant analysis and the subcommittee again, I think without input from any the individuals who submitted this code reviewed the code, compared it to many other drug metabolism codes. And we recommend a crosswalk to 0349. You.

Dr Lennerz MGH 47:25
Perfect, any other options from the panel? Hearing none, any other comments or questions from the panel or from DMS? Also Hearing none, so then I ask the panel to vote on x 100. You please.

Unknown Speaker 47:58
Okay,

Dr Lennerz MGH 48:01
bye think with that, we can hand it back to you Dr. Arthur, right. Yes,

Unknown Speaker 48:09
so we're almost finished with our discussion of review codes. But there were a couple of codes during today's discussion where we wanted to revisit just to make sure that we had the proper ballot options and also just to make sure there was no confusion. And so Sarah Harding, correct me if I'm wrong, but I have a couple listed here 40436 You as one code that we needed to revisit?

Unknown Speaker 48:42
I have the I have the line The line items. Hold on. I'll compare it to the codes

Unknown Speaker 48:48
should be 35.

Unknown Speaker 48:52
Yes, we have 0436. You we also have line 33 of eight 7x x one. And then one last one is line number 108. Is x x 910.

Unknown Speaker 49:14
Okay, I actually wanted to go ahead there sorry. I was just gonna say Um, okay, yeah, we'll go in order so.

Unknown Speaker 49:24
So just as a summary, when we did the eight 7x x one. We did indeed have a mistake in the options and I need to double check what they are. So

Unknown Speaker 49:52
we had a crosswalk of okay, yes. So the lab we're missing the stakeholders. recommendation, which was 87624 plus 87625.

Unknown Speaker 50:11
That's correct. Okay.

Unknown Speaker 50:14
Glen, could you add those items to the ballot? Visible? Thank you.

Unknown Speaker 50:20

The way this is, can I the way this is written? It looks like it's six to four and six to five, both times two. That's not that's,

Unknown Speaker 50:30
that's what I was about to say there's a that's that's also a typo. It

Unknown Speaker 50:33
should have the parentheses is wrong on that. Correct?

Unknown Speaker 50:36
Correct. So the parent on number four, so Glen, I'm sorry, go ahead, if you could write 87624 plus 87625.

Unknown Speaker 50:58
And then in the option above it, remove the parenthetical. Second, one, two, yep. And then rules of again, PEMDAS. We all remember that, that that is correct. So because we were missing an option, we wanted to revisit it and revote. Just to ensure that we, you know, have all of the correct options available. So, Vicki, do you want to just real quick, revisit the summary that you gave and your recommendation.

Unknown Speaker 51:43
And make sure I'm on the right spot here. Okay, so no, take your time, take your time. So this is a high risk pooled result for HPV plus six individual high risk types called out. So for the pooled result, they qualitative, ample amplified probe for HPV X seven, six to four applies. And then for the six called out high risk types, 87625, which covers three call outs would be times 246. I hope I just didn't confuse it more. So 87624 for the pooled, and 87625 times two for the six called out high risk types.

Unknown Speaker 52:34
Yeah, this is Brian Currie. I was the presenter at the meeting. And so the recommendation at the meeting was the last one, which is 87624 plus 287625. Just a combined result, not at times to result.

Unknown Speaker 52:53
So yeah, so what we have here is a subcommittee added an option, which is totally allowable. So thank you. Yeah, we have we have all the options up here. I guess I'll I'll pull up. So your question are there? Yeah. There you go. Dr. Leonard's please

Dr Lennerz MGH 53:14
make Can I make one recommendation? I know that this is going back to arithmetic here. But the eights option for currently portrayed on screen means 87624 times one plus 87625 times two.

Unknown Speaker 53:32
Correct? Correct. So that

Dr Lennerz MGH 53:37
a maybe at the times one there. I know that that's not mathematically correct. But the 87624 times one is, is? I think that might be

Unknown Speaker 53:51
perfect. Yeah. Yep. Good job one.

Dr Lennerz MGH 53:54
Even better. Less, less, less science needed. That's always good. No, I think this is this is clear now. And Vicki, just to double check. The recommendation of the subcommittee is in this iteration the option for correct, right. Perfect.

Unknown Speaker 54:22
And this is again, Brian Currie. I'm not sure if the American Society of microbiology is also on. And I think they had wanted to make sure that their recommendation was made clear because there was some confusion at the public meeting about what their recommendation was.

Dr Lennerz MGH 54:40
Do we have a member of the ASM here? Because I think they recommended 876 to four times to correct. Correct.

Unknown Speaker 54:52
They have subsequently I believe, clarified their recommendation to be number five, which would be the 87624 Plus It's six to five, they may be on the the muted line, so they're not able to speak.

Unknown Speaker 55:09
Did CMS receive a revision from ASM? That

Unknown Speaker 55:13
is under my understanding, I don't want to speak for them but I believe they are on the call and didn't did reach out directly to CMS.

Unknown Speaker 55:21
Okay, but I'm asking CMS did did you receive a modified recommendation from ASM?

Unknown Speaker 55:32
We can double check to see receive that. But are there any members from ASM on the line, there doesn't appear to be anyone raising their hands or requesting to speak from either pool the panelists or the attendee pool?

Unknown Speaker 55:53
Dr. Linares I think we can proceed with voting.

Dr Lennerz MGH 56:00
Then let me just double check something real quick, because I want to make sure that this is I believe this was a kin. I don't know if Chris wants to do this don't want to overstep territories here.

Unknown Speaker 56:17
The fact that Joe is perfectly okay. I mean, so breaking his recommendation is option number four in what the public is seeing. Correct?

Unknown Speaker 56:33
That's correct. And Michelle, I believe also verified that that was our subcommittee recommendation.

Dr Lennerz MGH 56:44
And just for the panel members, that's Option three in our voting ballot. Book, the authors should be aligned that or that okay.

Unknown Speaker 57:03
Align the numbering.

Dr Lennerz MGH 57:05
You had to be it? I don't think it matters, right. Because, yeah,

Unknown Speaker 57:10
I think

Dr Lennerz MGH 57:12
I think the pedal should be good with with these options.

Unknown Speaker 57:15
I think it was we agreed on 87624 times one and eight 716. Five times two, which is option three on what I'm seeing on my screen. That's

Unknown Speaker 57:26
correct. Great. Oh, I

Unknown Speaker 57:28
see. Sarah, could you confirm that the order that you have in your ballot is the same order that's presented on screen? Or it could? Glenn Could I just want to reconcile that to ensure that same order?

Unknown Speaker 57:41
Yep, one quick second.

Dr Lennerz MGH 57:50
Just because this is a revote, right?

Unknown Speaker 57:52
Yeah.

Unknown Speaker 57:54
Yep. Want to get right, there we go.

Unknown Speaker 57:56
How's that for fast? Wow. That's great.

Unknown Speaker 58:04

Just to confirm we did get we did get correspondence from ASM regarding their recommendation across what to 87624 plus 876250.

Dr Lennerz MGH 58:17
So then, to be 100%. Correct, we would need to remove the 87624 times two. Because I believe that was the prior ASM recommendation. That is that was neither supported by the subcommittee. I don't know, Chris, you, you might know this better.

Unknown Speaker 58:37
Now, will you hear and clarify? Again, this is Brian Kerry, on behalf of the stakeholders, I think at the public meeting, all stakeholders commented in favor of what would be number five here 876-248-7625.

Unknown Speaker 58:57
Okay, so Glen, let's go ahead and remove that number three. Since that was not put forth by the public ultimately, number four, that is listed there

Unknown Speaker 59:09
before before you before you remove that. Vicki, do you have any other comments because I think the rationale was clear was that it was like one poll result but then six report outs or something like that. I mean, that's why we had the times to

Unknown Speaker 59:29
now that's why that's why the subcommittee recommended times two but I believe removing 87624 times two, if ASM changed, their recommendation is appropriate. Okay. I just wanted to make that doesn't that doesn't change our subcommittee recommendation. It just takes one of the options out okay.

Unknown Speaker 59:51
Just want to make sure

Unknown Speaker 1:00:17
Okay, so I believe what you're seeing on your ballot is correct. It matches what is on the screen. So if you could go ahead and vote.

Unknown Speaker 1:00:30
I'm seeing four options. Did you take away one? No,

Unknown Speaker 1:00:34
I did. I took away the one that was just 87624 times two.

Unknown Speaker 1:00:40
Oh, okay.

Unknown Speaker 1:00:57
Can the panel vote on it now?

Unknown Speaker 1:01:00
Yes, please.

Unknown Speaker 1:01:05
Okay, panel members, please vote on this code.

Unknown Speaker 1:01:13
Okay, perfect.

Unknown Speaker 1:01:17
Now, I will ask we, we just received one other clarification. So we're up to three more codes that we need to revisit. And obviously, it does take a little extra time to catch everybody up. So we were supposed to end today at four. You know, we want to definitely be respectful of the time planned for this. But I guess I would ask the panel, do you want to try to get through these last three codes? Or should we plan to meet, you know, for, hopefully, under an hour in the morning, revisit these, the last thing we want to do is rush through anything, you know, for the sake of of getting it done. So either we can go till 430. Or we can, you know, pause, read, take a breath. It's been a long day, and come back in the morning.

Unknown Speaker 1:02:18
Um, Sarah, can I ask, um, in the beginning of the meeting, we had made recommendations for gap filling certain codes, because they weren't priced on the 2020 fours fee schedule, when we were looking at the analysis back in June, and they may have been priced since then. Because that kind of evolved during the meeting. And I don't know whether we should go back and look at recommendations because there was recommendations to codes that were gap filled. And we said no, can't do it, because it was on it was price to zero. Right? Yeah. Should we look at those two, or I don't we have,

Unknown Speaker 1:03:05
we have some of that we have at least one of those noted, if if there's more, that will take a little bit of time for us to review and ensure we have. So that to me, would push to agreeing to meet it. You know, in the morning, we just had a comment from one of the panelists has a hard stop in eight minutes. So it may be worthwhile. This will give us our team we can review tonight. And you know, have the full list. But again, 130 codes is is is no small feat to have gotten through. And so but of course there are going to be a couple of little glitches that we want to move over. So no, I

Unknown Speaker 1:03:52
appreciate that. But I think two of them are mine, I just want to make sure that I did the best that I could for the labs. Sure. So whatever the group decides to do, we could go back and just make sure that they're either priced or not priced. I mean, some of them might have been reconsidered and then not priced in, they're still zero even in the even in the q3. But we definitely going forward have to address this issue because we're we're making decisions in June and then next iteration comes out in Dubai, we have to we have to get to close that gap.

Unknown Speaker 1:04:41
Okay, well.

Unknown Speaker 1:04:44
I think our team is is this kind of the you know, talking about talking offline, and I think we're all starting to agree. I know it'd be great to be done and have the whole day tomorrow. But I think

the the responsible thing to do was to stop. It will certainly not be all day tomorrow for the for the whole agenda, but this, you know, will allow us to make sure we we get it all right. So I'm Dr. Shoemaker if you want to just shoot me an email or and received an email of the codes that you want to double check, but we'll go back through everything that the committee voted to gap fill, and just ensure that none of the options, you know, fell through the cracks. Yeah, it's legit

Unknown Speaker 1:05:35
just the early chimp codes. Okay.

Unknown Speaker 1:05:38
Maybe

Unknown Speaker 1:05:41
it wasn't just mine. So, so

Unknown Speaker 1:05:43
sorry. Yeah. Understood.

Dr Lennerz MGH 1:05:45
Just a quick note, on the emoji codes, we took the most recent iteration of the clinical lab fee schedule into account. And we only crosswalk the codes that were priced, minus those case, those codes that are reconsideration codes, because they might be in gap fill. But just just for clarification, so I don't think that applies for the emoji codes.

Unknown Speaker 1:06:11
Okay. Perfect.

Unknown Speaker 1:06:12
We did the same thing. But we did ours in June.

Unknown Speaker 1:06:17
Right. Yeah. Before

Unknown Speaker 1:06:18
the third quarter came out. So

Dr Lennerz MGH 1:06:22
yes, so the I think it was June 26. That we downloaded the q3 one. And that's the clap three to five believe. Yeah, I don't know exactly what date it was. But I think we double checked on June 26, if I'm not mistaken.

Unknown Speaker 1:06:44
Okay, we did that apparently, in July, things changed a little bit. And there were some codes that were priced.

Dr Lennerz MGH 1:06:53
I can also double check. I mean, just to be mindful of time, maybe we can do one hour tomorrow and go over these three coats. I mean, this one, I believe, at least on my screen, it says that the

poll is locked. So then we would have two codes to revisit that we know that today plus the gap fill question that Michelle asked Correct?

Unknown Speaker 1:07:19
Yeah. And I think the good news is I'm pretty sure in the notes in the tracker file. You all indicated if if, if there was like a, we would crosswalk it, but we can't. So we'll we'll we'll take all those out. We'll revisit them tomorrow. Yeah. And it's an opportunity to if if if you noticed, you know, a discrepancy or something. Certainly let us know. The connection for tomorrow or she does. Yeah. Yep. Same

Unknown Speaker 1:07:56
connection. Correct. Perfect. Yes. As I'm looking at some of the questions, yes, standby speakers who have their codes voted on upon, need to be available tomorrow. So if you're, if you if the CLT panel has already discussed the codes that you were interested in, there's no need for you to connect if, unless you'd like to just listen in. So that will leave that up to you. Everyone's always welcome to listen in on the conversation.

Unknown Speaker 1:08:25
And again, thank you, CMS, you guys have done such an amazing job making, like everything so easy for us and organizing the whole meeting. And you know, we appreciate you for all your work that that you do.

Dr Lennerz MGH 1:08:44
Thank you. Like I like to say I'd like to second bet. Especially the ad hoc, multiple choice, question change. I like that much better than coming back to the codes at the end. Because that was really live live editing right there. I love it. Great. We

Unknown Speaker 1:09:00
love this feedback. Really appreciate it. So it sounds like well, it's determined that we're going to reconvene tomorrow and so our start time would be 10am. And we'll just make sure everyone's connected and we'll go ahead and revisit some of those codes that we discussed today. So this concludes today's session. And so we'll see everyone or here everyone tomorrow, July 26 To finish the remainder of the meeting. Now everyone has a great evening. Thank you. Take care.

Unknown Speaker 1:09:33
Thanks all.

Unknown Speaker 1:09:34
Thank you.

Unknown Speaker 1:09:35
Thank you

Unknown Speaker 1:09:56
I can ask a S M for a phone call tomorrow. or Monday. If people are available here, then we can put in a joint meeting request with CMS for August period.

Unknown Speaker 1:10:14
Ryan, are you submitting that question to CMS? Or are you? Yes,

Unknown Speaker 1:10:18
I was going to ask if people were available to meet with ASM and but I can follow up with with email. That's easier. Yes, please, please

Unknown Speaker 1:10:30
follow up email. Marveling could you just continue recording?

Unknown Speaker 1:10:37
Can I Can I ask a question? Rashida this? Yes, Simpson. Yeah, I heard you're planning to revisit 0463. You but there was some confusion? And I just, I want to make sure that that?

Unknown Speaker 1:10:52
Yeah, definitely. Yes, we are. We're going to revisit zero. Okay,

Unknown Speaker 1:10:56
I think deserves a visit. I'm glad about that. What can I have ready.

Unknown Speaker 1:11:05
So I think they're just confirming that they have the right ballot options, and that the panel understands the option. So I don't know if they actually will have any follow up questions for you. But it's just to make sure that they voted recording stopped. Yeah. And they, they, they understand all the options that were available. So you can call in and just listen to him. But I don't know if there'll be any questions they'll have for you.

Unknown Speaker 1:11:27
Okay. And I'm, they did ask some things about the test and the intended use and all that sort of stuff. So I'll submit that soon, you know, close the business, my time. And today, and then also, but aren't we checking in? Are we still doing the ninth 30 check in? Yes,

Unknown Speaker 1:11:51
you can still check in at 930. But if you didn't have any issues connecting, you can check in 945. But if you want to and just want to make sure you're connected, you can check in at 930. But the meeting won't start until 10.

Unknown Speaker 1:12:02
Okay, very

Unknown Speaker 1:12:03
good. Thank you. No problem. Thank you.

Unknown Speaker 1:12:08
All right. Thank you so much, everyone. Thank you. Marvelous. And we were a pleasure. Thank you. Well, look forward to talking to you tomorrow morning. Yes,

Unknown Speaker 1:12:19
night. I will have to open up again at 830 tomorrow morning.

Unknown Speaker 1:12:24

Okay.

Unknown Speaker 1:12:27
All right. Thank you. By Mr. Berlin.

Unknown Speaker 1:12:32
Yes,

Unknown Speaker 1:12:33
I'm gonna use this. Do I use the same link that I used this morning? Yes,

Unknown Speaker 1:12:36
ma'am. Let me let me do this. So we excuse me, Sasha.

Unknown Speaker 1:12:41
Thank you.

Unknown Speaker 1:12:44
I'm gonna resend it to you tonight. Okay. Okay. And then if you're having difficulties, just reach out to me again, and we'll make sure we can get that for you. Okay, thank you so much. You're welcome. You all enjoy your evening on purpose. You too. Thank you. Thank you. Bye bye.

PART 5 (MISC 0726)

Speaker 1 0:00
The result being reported as using an algorithm being reported as clinical benefit from immune checkpoint inhibitor therapy. The proposed crosswalk was 20249 U, which I believe did not, when we looked at first at this back last month did not have an A rate associated with it. And so the subcommittee had proposed gap filling this code. Because we can't get we can't crosswalk to a code that doesn't have a rate assigned on the fee schedule. And I'm we'd like to hear from maybe some of the emoji members as to whether they think oh, 249 year would be an appropriate crosswalk now that it has a rate.

Dr Lennerz MGH 1:02
I don't know if I'm the best person to discuss this. But I think the the differences of course, semi quantitative analysis of 32 versus 388. Proteins, you know, one is, you know, abdomen at birth based proteomics, the other one is probably phospho proteomics. I think the analysis is fairly similar, but the amount and complexity of the 388 proteins and what is exactly extracted from that might be helpful to hear from the vendor, but I think that's a definitely a reasonable choice. Thank you.

Speaker 2 1:48
This is Chris Chong. I think the best crosswalk is 001 9am, because that same platform at the mall based technology, but it has no value. And so we I think we should still get food.

Speaker 3 2:06
Hi, this is Dr. Jennifer Jones, I have a common regarding the code the two I can see the difference between the 0249 au versus 0436 You because methodology is a little bit different are also a little bit quite different. For example, for the 0249 they use a laser capture microdissection With that assume they are using the FFP specimen and the 0436. You they are doing the Step Up protein test on the plasmas. So plasma analysis, therefore, I do not believe the code of zero to four nine is appropriate crosswalk at this point.

Speaker 1 2:57
Thank you. I appreciate that input. And I know we had that discussion in our subcommittee meetings as well. And at this point, I think I would agree that the subcommittee recommendation should be grateful for this code.

Speaker 4 3:17
Let me clarify is Dr. Chang recommending 001 9am as well? Yes,

Speaker 2 3:23
but there's no value and so we had to keep? Yeah, so

Speaker 1 3:29
yeah, I just looked that one up. It's still is showing, at least in my database here as Mac priced 100 1am.

Speaker 2 3:44

This question so as the panel co chair, so are there any further comments from the panel or CMS?

Speaker 2 3:59
We do have on Dr. Over Sharon from aka hosts who could address the questions on methodology.

Speaker 5 4:07
Okay, good morning game. Can you all hear me? Yes. Wait, so we actually sent the committee a letter after the previous meeting with a comparison indeed, there is a difference in the number of proteins but we are looking at protein using high throughput technologies. Actually both the zero to nine for you and the zero 46. You can look at cell plasma tissue cell eyes, it's both of them. The choice on which one to use, I guess is based on the clinical development of the tissue and the time it was developed in the design of the clinical trial. But both technologies are capable of covering all sample types. So the difference is indeed between a FFP and plasma but it's not limited to one of those in both technologies we're looking at relative quantification of proteins, high sensitivity ability to detect low by this protein, a, looking at the ability to measure a multiple proteins a in parallel with a wide dynamic range, a wide dynamic range, low volume that is required for both samples. And they're both used for a similar application as biomarker discovery, disease profiling and drug response, we tie up with repeatability and reproducibility. So, and both of them actually, in order to perform or come up with a report required specialized bioinformatics tools. So in that sense, we believe that those two are pretty similar. And this is why we asked for the for the coursework. I'd be happy to answer any specific questions if you have, of course.

Speaker 2 5:55
Thank you. So any more questions from the panel? Or CMS

Unknown Speaker 6:08
if not a panel members please cast your vote.

Unknown Speaker 6:33
All the boats in?

Speaker 6 6:35
Not quite. We're just waiting for probably some. Okay. And Dr. Rumbler is still not here, right. Okay, then yes, we have the full, full committee of votes. Thank you.

Speaker 2 6:50
Thank you. So, back to you, Sarah. Next court.

Unknown Speaker 6:59
Okay,

Speaker 6 6:59
um, so the next one, we wanted to just double check and confirm because we did see a typo. Which happens when you write 1000s of CPT codes over and over and over? Was number 108. This was x x nine one you on the ballot. Let's confirm what we saw on the 108. Okay, so on the ballot, that you see publicly, we're looking at code 410. You actually this one's probably okay, the

the voting the voting software had 401. You. And so I just want to confirm that, you know, we'll we don't need to revote on this as long as everyone on the panel is, is is there. Their vote truly was for 410 you and not for 401. You

Dr Lennerz MGH 8:23
should we just we just redo it? Because then yeah, it's easier than doing a roll call on on the yes or no, because if we have the interface open, that would be great.

Speaker 6 8:35
All right. Well, let me clear this. I appreciate that feedback. Thank you. Okay, so, um, if anybody needs who? I'm not sure who presented this

Dr Lennerz MGH 8:48
Shandra Okay. Nina, do you want me to quickly recap or do you want to do it?

Speaker 7 9:02
Yeah, this is I'm happy to do it. Do we have this CPT code? Up here? Okay, good. So, this was a code for oncology, DNA sequencing based on plasma enrichment using whole blood or or and plasma reported as an algorithm. There was a presentation as well as a recommendation for crosswalk to 0410 you and we agreed with that crosswalk recommendation

Dr Lennerz MGH 9:52
perfect. Any other new suggestions from the panel? And I think the interface reflects this correctly. I hear something here.

Speaker 6 10:05
No, I'm sorry. That was my non mute fault. No problem.

Dr Lennerz MGH 10:12
Okay, any other comments or questions from the panel or from CMS?

Speaker 1 10:16
No, I have zero for 10. You opened up here and see it has an almost identical descript. You're just a different type of cancer.

Unknown Speaker 10:29
Thank you, Michelle.

Dr Lennerz MGH 10:32
So the whole I think is still locked. So should we open that up and then move for voting?

Unknown Speaker 10:43
Yes, it should be open now.

Dr Lennerz MGH 10:46
Perfect. So this is revote for x x nine one you item 108. And the subcommittee recommendation was crosswalk 20410. You had members please cast your vote.

Unknown Speaker 11:02

Perfect.

Speaker 6 11:03
Thank you, everyone. Okay, now the next one. We want to check. Just check this myself real quick.

Speaker 6 11:23
Okay, so I'm Dr. Screen maker. I wanted to I hate to put you on the spot. But I did go through back through any of the codes where comments were made that a crosswalk couldn't be used. I believe we've we, it was really just the one we still needed to talk about the others. I think we caught during the cop during the actual code conversation. And so I think we're okay, but wanted to just confirm with you whether you had found others you wanted to go back and revisit. I

Speaker 1 12:00
think I think we're okay. I mean, I think the one there was one that was a crosswalk to two codes 0012 M and zero. I'm scrolling through my notes here m 356. You potentially and I think it was the 0356 you but I think Dr. Chong had also gone through and there were some that were either reconsidered or were still priced at zero on the on a lab fee schedule and hadn't been priced. Let me see if I can find that line. Just to triple check here.

Unknown Speaker 12:44
Yeah.

Speaker 8 12:53
So doctor, school maker Are you referencing code 0420 You line 57 item 57 where the ballot options were obtained get filled zeros or one to m and the fourth option was 0012 m plus 0356. You Yes,

Speaker 1 13:17
that's the one okay. There are threes was it six five or 56560012

Speaker 8 13:24
m plus 0356? You

Speaker 1 13:34
okay, so it looks like 0356 you was priced $1,800 that the code descriptor is oncology, oral pharyngeal or anal evaluation of 17 DNA markers using droplet digital PCR cell free DNA algorithm reported as a prognostic risk score for cancer recurrence when we evaluated this to begin with. This had been gap filled and so we felt like the gap fill was still the option the recommended subcommittee option does the subcommittee feel differently with you know a rate assigned to the zeros 356 You being priced? Does this does the descriptor match the methodology for the new proposed code?

Speaker 1 14:55
Think yesterday if I recall there was some discussion around Cell free DNA versus other DNA detection and whether or not you know, the fact that it's cell free is different.

Speaker 3 15:20

I was the one who asked a question regarding the cell free DNA. But they didn't mention that because you're you they are using the urine specimen. And by default specimen from the urine, it will be considered as cell free, either DNA or RNA. That being said, so I was reading the alarm code descriptor for the code 0420. You they're using, they're detecting the messenger RNA. And the two code Yeah, for the 0356 years. They're using DNA biomarkers a little bit different, but it's pretty tough call Michelle. Yeah, I believe the gap failure is always a option right there. So.

Speaker 2 16:12
So this is Chris Shives. co chair for this section. Since it was a CH I am cold. Have any more comments from the panel or CMS?

Dr Lennerz MGH 16:29
Maybe one quick comment to Jennifer, what you just said you looked at 0420? You correct? Which is mRNA expression, but that code is not priced yet. So I don't think we can crosswalk to that. And the Oh 356 You seems a little bit different in terms of number of genes. And as you outlined, some of the methodology differs. So I think we can, we can recast the vote with the additional options. But as far as I can tell the chimp meeting still recommend spike capital, correct?

Speaker 1 17:13
Yeah, that would be my recommendation. Um, I just want to make sure everybody's on board because it is one of the options is 2001 2am. By itself, or the fourth option is 0012 m plus 0365. U, which is, which was the one that was not priced when we were looking at these back in, in June.

Speaker 8 17:40
Correction, Michelle, I'm sorry, it's 0012 m plus 0356. You did six, five, you,

Speaker 1 17:46
I'm sorry. No problem. And so the 0012 M was oncology urothelial, mRNA, gene expression profiling, real time quantitative PCR, five genes, using your urine algorithm reporting as a risk score for having your little cancer as an as 060356. You adds the the evaluation of 17 markers using droplet digital PCR in addition to the five markers.

Speaker 6 18:37
I just want to confirm does the does the committee want to recast votes for this?

Speaker 2 18:46
I think we should recast votes in view or the addition or the new comments.

Unknown Speaker 18:51
Okay.

Speaker 2 18:58
Are there any more comments from the panel or CMS? Hearing none, panel members please cast your vote

Unknown Speaker 19:24
Perfect, thank you.

Speaker 2 19:27
Sara, do you have any other codes you want to revisit?

Unknown Speaker 19:34
So those were the ones that

Unknown Speaker 19:36
we had

Speaker 6 19:39
sort of identified either again as typos or those about you know, questions of rates on the fee schedule. But I know we've we other there have been a couple others that that you guys have raised. So I I turn the question back to you all if there are specific ones that you'd like to you know discuss more that is that's the panel's prerogative to do that.

Speaker 2 20:05
One or two. There is, so I'd like to visit line 55. And Dr. Landis will co chair this portion.

Dr Lennerz MGH 20:16
Perfect. Thank you, Dr. Chong. So I think this came up yesterday during the presentations, we're talking about item 53, code x x six to zero, which is an immunology coat. And the long descriptor, although it's not very long reads tau comma phosphorylated comma p tau 217. Which upon further review is a single biomarker, meaning this is providing the phosphorylated tau status on the position 217 of the tau protein. At least, that is what we gathered from, you know, reading the additional materials. So if the test developer is present, which is, I think ALC hath if I'm correctly reading this, it would be great if we could clarify that this is, in fact, a single marker. Because for consistency, I would ask that we add a fourth voting option to be consistent with the other essays for example, if you jump two lines down, there's there's times oh point five. We have used that for the 0358 you times oh point five for several of the Alzheimer diagnostics so I move an additional option to be added to those three options protect portrayed on screen and that would be Oh 358 You times oh point five

Unknown Speaker 22:04
three

Speaker 2 22:09
So Glen, can you add that new option? Yep, yep,

Unknown Speaker 22:15
one quick

Unknown Speaker 22:16
seconds. times point five. You said Correct. Sorry.

Dr Lennerz MGH 22:22
I mean, you could leave that just to ensure that everyone has that original option. But I think just adding another line saying Oh 358 You times oh point five Yep. 53 Right. Yes. For meeting or x x six to you

and can I just ask if the developer of the test is present by chance that okay. Yes, that looks good. Yes.

I hear no other comments. So are there other options for code x x six to you? Hearing none other comments from the panel or from CMS on this code? All right, so let's recast the vote on x x six to you with the subcommittee recommendation Oh 358 u times point five

Unknown Speaker 24:01
Okay, thank you very much

Speaker 2 24:09
this is Chris Chung. There are no other codes that I want to revisit. Joe

Dr Lennerz MGH 24:16
I wanted to just ask the emojis subcommittee for one quick double check because one of the category one codes This is fucker meeting ID 11281459.

So, I think the could you scroll up a little so that the items 110 and 111 are visible as well. I don't know if that works easily. So why I wanted to bring this up is because there's, if you scroll, like a little bit down just a little bit it should work. Actually, that was good. That was good. So I just wanted to bring something to the attention of everyone. So if you look at, these are the three codes 457458459. And the codes. The third option is a crosswalk 281455 times 1.5, then times two. And then I think this is because it's a reconsideration code. And because there was some inconsistency, the third option is 81445. But there is no modifier, but the modifier should be to be consistent with the other triplet codes of increasing complexity 2.5x. Or alternatively, gap fill, of course, so this is perfect. So here, you can see that the code would be 1.5 times 1.5, times two. And then on the 81459, which is the code with microsatellite instability, and tumor mutational burden, the modifier was missed. So there was times 2.5, to account for the additional complexity related to let's say, the algorithms or microsatellite instability and tumor mutational burden. So I just wanted to add that for clarification, because, you know, we were jumping across those codes with increasing complexity. And I just wanted to, you know, ask my emoji panel members, whether they would agree that we should revote on that. And of course, gap fill is another option.

Speaker 6 27:15
So Dr. Leonard's let me just make sure I can sum this up. So you would essentially suggest looking specifically at 81459. And amending the number three potential crosswalk to 81445 times 2.5?

Dr Lennerz MGH 27:37
or adding that as another option as

Speaker 6 27:39
another options, but then, but then calling for a recode?

Dr Lennerz MGH 27:44
Yes, please, because the the modifier was missed the code, the live call it, the smallest code has a modifier of 1.5. The second tier has a modifier of two. And that the third, arguably more

complex code has no modifier is a mistake. So that should have point times 2.5. And then, and just for the whole panels information, this code is currently undergoing a gap filling, but it is under reconsideration. And therefore, we get to vote again. And that's of course, important, because you know, ultimately, both independent, let's see sources of truth will probably help with price setting. But the 81445 as a single category one code to crosswalk to, would be internally inconsistent with our own recommendations, because the 81457 and 81458, which are the smaller complexity codes in the same group of the triplet have a lower multiplier. So in a sense, we want to make sure that the fuckup panel recommendations are internally consistent. And therefore, I would argue that we should recast the vote with this additional option. Fully acknowledging that gap fill is a feasible alternative because that is currently undergoing a gap fill price determination. So I see four options now on the voting ballot. And yet any comments from the the other emoji subcommittee members or from the factor panel in general?

You Hearing none, any comments from the panel? Or from CMS or any questions? Alright Dan Pena numbers, please cast your vote

Unknown Speaker 30:16
it's perfect. Thank you very much.

Dr Lennerz MGH 30:20
Thank you The these these codes, the triplets as the next gen sequencing codes, branching up into more sub categories, or I just don't appreciate that that we voted on that again. Thank you.

Speaker 6 30:40
Absolutely. All right, we have had another request Dr. Chapelle pointed out, I'm just want to make sure we confirm this. I'm looking at x x 771, which was number 115. On the back on the ballot. She says it should not have had the option of 405 U times 2.0. So Dr. Chapelle Can you just explain that a little bit more, please?

Speaker 9 31:16
Yeah, so I think maybe when there was some copying going on, that this might have just been copied from another code that was submitted, this is the lab that I work for. So the only reason that I noticed that this was didn't belong there is because I know I know what was recommended for these codes. And I think this was just a copy over from zero from xx seven, seven, you. That's the code where the recommendation was 0405 u times two. And 0405 u times two doesn't look anything like this seven one code, it's just there by mistake. So somehow it got copied.

Speaker 6 32:02
Okay. All right. I appreciate this very much we can certainly revote it copy paste errors, or we are Yeah, as susceptible to them as anyone so I prefer

Unknown Speaker 32:14
I'm surprised there

Unknown Speaker 32:15
aren't many more.

Speaker 6 32:19

So I am going to clear the results. I have taken that option out and feel free if the if there's any more discussion, I'll step back but the vote is is now cleared and open to recast.

Dr Lennerz MGH 32:45
But just to clarify, I think the subcommittee recommendation was all three to six you because of similar complexity, etc. So that still stands. So are there any other suggestions from the FICO panel? Or any other comments from CMS or the panel? Hearing none, thank you Heather for pointing this out. Let's cast the vote please. Panel on x x seven one you

Speaker 6 33:36
Okay, perfect. Thank you very much. Okay, so um, we have have gotten through all of them that were on our list. I guess I would open it to the panel. Were there any others that that y'all wanted to revisit?

Dr Lennerz MGH 33:59
I double checked yesterday. I'm okay. From the emoji site. Chris

Speaker 2 34:04
are the same. I've checked out other CHFM course. There's nothing else to revisit that I'm aware of.

Dr Lennerz MGH 34:14
Anyone else from the panel? Nope, I think we're good.

Speaker 6 34:23
I'm I'm grateful for the added confidence that we now have in all these results. And I'm grateful for everyone's time to revisit. So Rashida, I think this can go back to you, or any last pieces. Yeah.

Speaker 8 34:41
Thank you so much. So Glen, could you progress those so just want to one thank everyone for another successful year and another successful meeting. Special thank you to the CFO. The panel members for all of your service and hard work in ensuring that CMS gets it right. And so we really appreciate your expertise, time and commitment, because this was a very tedious process. And so we really appreciate it. Also just want to submit a special thanks to the CMS team, and all of our virtual attendees and your flexibilities with switching to a virtual platform at the last minute. So we really appreciate that. In terms of next steps CMS going could you progress. I think there's one more slide. We'll post the preliminary payment determinations, typically in the month of September, then the public will have 30 days to provide comment on those Bloomerang determinations. Then we'll post our final payment determinations in the fourth quarter, typically in November. And so after that, you'll have 60 days to request a reconsideration for the codes. We just want to thank everybody again for a wonderful meeting. And so at this time, this concludes our meeting.

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