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CENTER FOR MEDICARE

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
ICD-10-PCS Topics
September 8, 2020

TRANSCRIPT

Transcript of procedure code topics discussed during the September 8th, 2020 ICD-10 Coordination and Maintenance Committee Meeting.

MARILU HUE: Hello, for those of you who are just joining us through the phone and you wanted to participate via the ZOOM link and you've been having the prompt to enter a password, please enter 210372.

We'll give a couple more minutes to allow folks the opportunity to join.

Good morning. We just about have close to 100 participants on the line so we're going to go ahead and get started. I'd like to, again, welcome everyone to the ICD-10 Coordination and Maintenance Committee Meeting.

My name is Mady Hue and our other CMS analysts today include Paula Dupee, Andrea Hazeley, Michelle Joshua and Noel Manlove. Today, CMS will be presenting topics for the procedure code proposals and because we anticipate completing our agenda a little early, we will turn it over to the CDC's National Center for Health Statistics staff so they can begin presenting a few of the diagnosis code topics from their agenda and they'll continue through tomorrow. You can find the link to the diagnosis code topics agenda on the CDC website, which is referenced in the CMS agenda and handout document.

We will adhere to a 10-minute time limit for each clinical presentation and allow the opportunity for participants to ask clinical questions, followed by review of the coding options and questions or comments from participants.

Again, those participating through the ZOOM webinar may ask questions during the Q & A portions of the meeting using the raise your hand feature which can be found at the bottom of your screen.

MARILU HUE: If time does not permit you to comment or ask a question during the live Q&A session, you may still submit comments and questions at any time using the Q&A feature. All comments and questions submitted using that feature, along with any CMS responses to them, will be posted as soon as possible after the meeting in the downloads section of the CMS Web page where you found the meeting materials. Any questions or comments that are not submitted during the actual meeting may still be submitted via the CMS ICD-10 procedure code request mailbox and we'll have that link in the agenda and handouts for you as well.

After the meetings we will also be posting the 508 compliant version of the slides from the clinical presentations as well as a recording and a transcript of the discussion.

Since we always have some folks that are new to this meeting, I'll provide an overview of the process. For those listening in by phone only and following along, we're turning to page 12 of the agenda and handout packet.

And I'll just announced one more time. If you've been having difficulty joining through the ZOOM link and you're prompted for the password, please enter 210372.

The purpose of the ICD-10 Coordination and Maintenance, or C&M, Committee Meeting is to provide a public forum to discuss requested changes or updates to the ICD-10 CM diagnosis codes and the ICD-10 PCS procedure codes. This includes proposals to create new codes, revise existing codes, or to delete existing codes. The committee is co-chaired by both CMS and CDC with CMS having lead responsibility for updates and maintenance to the procedure code classification and CDC having lead responsibility for the diagnosis code of classification.

The proposals that are being discussed today for the procedures are being considered for both implementation on April 1, 2021 and October 1, 2021. We don't make any final decisions at this meeting and we do not discuss MS-DRGs or payment at this meeting. We will go ahead and describe the coding options and provide a recommendation simply to facilitate discussion. And then, after the meeting and during the meeting, the public can submit comments and express support for one of the coding options or not.

Now, with regard to the April 1 implementation date, since some of you may not be familiar with why we have that option, section 503(a) of public law (P.L.) 108-173 included a requirement for updating the diagnosis and procedure codes twice a year, instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to the recognition of new technology under the IPPS. Section 503(a) amended Section 1886(d)(5)(k) of the Act by adding a clause, which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year. The requirement improves the recognition of new technologies under the IPPS by providing information on a new technology at an earlier date and it enables data to be available six months earlier than would be possible with updates occurring only once a year on October 1. If codes are approved for an April 1 implementation, we have to update the DRG software and other systems in order to recognize and accept a new code, similar to what we recently experienced this past year with the new vaping related disorder and a COVID-19 diagnosis codes that were implemented on an

emergency basis. As noted in the timeline in your packet, we would publicize any April 1, 2021 code changes and the need for a mid-year systems update by November 2020.

MARILU HUE: So again, the procedure code requests being considered for April 1 implementation would need to have their comments submitted by October 9th. Any codes being considered for October 1, 2021 would need to have comments submitted by November 9th for consideration. The procedure code comments should be submitted to CMS at the link you see for the mailbox. And the diagnosis codes may have different implementation dates so CDC will announce that tomorrow.

Can you go back to page 12 Andrea, please? Thank you.

If the codes that have been proposed are finalized, you'll find them in the upcoming fiscal year's Notice of Proposed Rulemaking which is usually on display in April. However, this year it was delayed until May. The proposed rule includes the finalized codes up through the March meeting and while the code titles are finalized, the public is provided the opportunity to comment on the MDC and MS-DRG assignments, as well as the severity level assignments for diagnosis codes and the O.R. assignments for procedure codes. So it is through the rulemaking process, and not the ICD-10 C&M meeting process, where MS-DRGs and payment are discussed. The fiscal year 2021 IPPS final rule was put on display last week and includes all the codes finalized from the March C&M meeting, that are to be implemented effective October 1, as well as the 12 new ICD-10-PCS procedure codes to describe the introduction or infusion of therapeutics that became effective August 1st.

So though the final rule is generally not displayed until August each year, you don't have to wait for the final rule to see which codes have been finalized as a result of the C&M Meeting process. CMS and CDC posts what is referred to as the Addendum, which are the files containing the finalized code updates as early as May or June on our respective websites as shown at the bottom of page 12 in your handout.

Turning to page 13, we have provided the opportunity for the public to participate in the C&M meeting code update process via ZOOM webinar or in a listen only mode through phone lines. For those who are either unable to participate today, or for only a portion of the day, we're making available the audio recording, the transcripts and slides on our website in an effort to offer more opportunities for the public to participate and submit comments.

Regardless of how you choose to participate, we ask that you please submit your comments for the procedure code topics being discussed today by October 9, 2020 if it relates to an April 1, 2021 implementation request and by November 9, 2020 if the topic is related to an October 1, 2021 implementation date. And again, you may hear separately from the CDC tomorrow about different implementation dates as shown in their packet for certain diagnosis code topics.

So again, I'd like to emphasize the due dates for public comments that were just presented are for the ICD-10-PCS procedure code requests being discussed today as they relate specifically to an April 1, 2021 or October 1, 2021 implementation date.

MARILU HUE: For those participants interested in submitting a request for code updates to be considered for the March 2021 C&M meeting, the deadline to submit your request is December 4th to the appropriate mailbox, as shown.

Before I turn it over to Noel to present our first topic and speaker, I'd like to first address the requests and proposals for new procedure codes that involve the administration of a drug or therapeutic agent within Section X as it relates to the New Technology Add-on payment policy.

During the past few meetings we have received several comments expressing concern about capacity and urging CMS to explore other options such as using national drug codes or NDCs for reporting these services, instead of a Section X code within the ICD-10-PCS procedure classification. In response to these comments, CMS has expressed appreciation and explained that we are continuing to consider alternative options, including how to best operationalize within our claims processing systems. We can assure you that capacity is not an issue within Section X as each year corresponds to a New Technology Group identifier, for example, a number. We're implementing New Technology, Group 6 codes effective this October.

Therefore, until such time when we have the ability to announce alternative options, we encourage participants to please refrain from making any further comments related to this issue or suggesting the use of NDCs for such proposals during the live C&M meetings, as this time could be afforded to other commenters with specific clinical questions or comments about the drug or the therapeutic agent that is the subject of the code request.

We also wanted to note that as stated in the fiscal year 2016 proposed rule, that CMS created this new component within the ICD-10-PCS codes, labeled Section "X", specifically to identify and describe new technologies and services. The Section X codes identify new medical services and technologies that are not usually captured by coders, or that do not usually have a desired specificity within the current structure required to capture the use of these new services and technologies. We provided examples of these types of services and technologies such as specific drugs, biologicals, and newer medical devices being tested in clinical trials. We stated that the new Section X codes, as you know, would be implemented on October 1, 2015 and they would be used to identify any new technologies and medical services under the new technology add-on payment policy for payment purposes beginning in fiscal year 2016. So again, we appreciate all the thoughtful comments that have been submitted and will provide an update in the future.

And at this time, I'd like to go ahead and turn it over to Noel to present our first topic.

NOEL MANLOVE: Okay. Good morning, everyone. Thank you for joining our call today. I am going to take a second or two to get the slideshow ready.

Our first topic today is regarding an antibiotic-eluting bone void filler. The issue is that there are currently no unique codes available under the ICD-10-PCS code to describe the insertion of an implantable bone void filler that elutes an antibiotic. This topic is being discussed as the requestor will be submitting an application for new technology for approval in fiscal year 2022.

NOEL MANLOVE: CEREMENT® G is an FDA designated breakthrough technology that is classified as a drug device combination product with a device primary mode of action and is currently under review by the FDA for the de novo clearance. So that is the issue.

Let me get the slides up. Sorry about the delay and the first one is always the worst one.

Okay. Can everyone see my screen okay?

MARILU HUE: Yes.

NOEL MANLOVE: Okay, great. And our first presenter is Dr. Douglas Dirschl and he will be discussing this topic for us. So we'll turn it over to Dr. Dirschl. And moderator, can you please unmute Dr. Dirschl's line?

ISAAC FISHER (Moderator): Yes, Dr. Dirschl is unmuted.

DOUGLAS DIRSCHL: Wonderful. Thank you Noel. Thank you all for giving me an opportunity to present briefly today. The next slide please.

CEREMENT® G, the implant we are speaking of today, is a drug device combination as Noel said, which is an implantable bone void filler that consists of hydroxyapatite and calcium sulfate, as well as gentamicin sulfate, which is an antibacterial agent. The CEREMENT® G paste when it's fully mixed in its final form, delivers about 17 and a half milligrams of gentamicin and per milliliter.

And as Noel said, it's been granted breakthrough designation by the FDA and is currently under evaluation for de novo approval. CEREMENT® G is used as, in cases of bone infection or osteomyelitis, as an adjunct to standard treatment and that standard treatment currently consists of systemic antibiotic therapy, surgical debridement of the infected area and any and all dead or infected bone, and then later, many weeks later, reconstruction of that bone defect. CEREMENT® G is an adjunct to this where there's a need for the filling a void within the bone. CEREMENT® G is intended to fill bone gaps and voids created after this surgical debridement, or removal of bone, and it induces bone formation and then resorbs at the same rate at which new bone forms, all the while preventing colonization from gentamicin sensitive microorganisms in order to help protect that bone healing. Next slide please.

CEREMENT® G has two modes of action. The primary mode (the implant mode, the Device Mode) is it serves as a resorbable, osteoconductive, ceramic bone void filler intended to fill gaps and voids to the skeleton created when bone is removed. The secondary mode of action is to prevent the colonization of those gentamicin-sensitive microorganisms in order to protect this bone healing. This is the first combination bone void filler that also elutes an antibiotic. And it will provide the first on label solution for a one stage surgical approach to managing these bone infections. It will eliminate the need for that secondary surgery to reconstruct the bone, thereby improving outcomes as well as preventing colonization of that newly forming bone while it forms.

DOUGLAS DIRSCHL: CEREMENT® G has been tested and then used in Europe for quite a number of years and exhibits a reliable local antibiotic elution rate and works well there. It has an optimal chemical composition and ratio of calcium sulfate and hydroxyapatite. And this is important, not only for the poorest structure that allows bone to grow in, but also because the rate of resorption of the implant matches the body's natural bone remodeling rate.
Next please.

CEREMENT® G is provided in a cardboard container that has two sections. One small one seen on your left here and one larger one. The small section contains the gentamicin, the drug components, Gentamicin powder and saline to be mixed together to present it to prepare a gentamicin liquid. The larger section contains the powder components of the CEREMENT itself. The combine and mixing injection syringe, that large syringe you see there, and then a smaller syringe for delivering the CEREMENT paste if you're injecting it. Next, please.

During the procedure. CEREMENT® G, of course, is used during surgery and during the surgical treatment of bone infection and once the site has been prepared and any dead bone or infected bone has been removed, the CEREMENT is prepared by either the surgeon or a surgical tech on the surgical field and is made ready to go. First, the gentamicin powder is mixed with the saline to make a gentamicin liquid. And then this liquid is added to the powder in the CMI syringe that you see in the middle there and the two are mixed. And then finally, the resulting CEREMENT® G paste, the final form, is transferred to the delivery syringe. Next.

About four minutes after the start of mixing the paste has set appropriately that is ready to be used. And it can be injected using one of the tip extenders that you see on the right here, or by attaching a needle to the syringe. Or, it can be placed into molds to form beads that can be packed into defects that can be used in a variety of ways. But 15 minutes after the start of mixing, CEREMENT® G, having been inserted, will be hard enough that it can be drilled into if internal fixation with screws or other devices is necessary and at 20 minutes, it's fully set in which time the surgical incision can be closed. The use of CEREMENT® G and all the steps I just discussed are dictated into the procedure section of the operative note into the medical record that the surgeon or provider would dictate. And complete remodeling of the bone and resorption of the CEREMENT® G implant is seen usually within 6 to 12 months. And the bottom shows a couple of examples of CEREMENT® G, which has, which is a little bit radio dense within bones. Next, please.

CEREMENT® G comes in two sizes. The number of product units used in a surgical case depends on the size of the bone for your use as much implants as you need to fill the void. It can be used both in inpatient and outpatient operating room settings and it's a permanent implant. It's not necessary to define the range of sites that CEREMENT® G can be used. It is a bone void filler eluting gentamicin that can be used to fill a gap or a void in any bone. Next please.

CEREMENT® G, as I said, it's been on the market and used in Europe and first launched in 2013 and over that period of time, nearly 14,000 units have shipped with 57 total complaints being registered. That's a lifetime complaint rate of around 0.4% and you'll note looking below, that the vast majority of those complaints have been technical issues related to mixing or handling or

inserting the product and only 16 of those were medical complaints, all with very, very minor type complaints. Next please.

DOUGLAS DIRSCHL: CEREMENT® G is not known by any other names. That's the only name of this product but bone infection is referred in medical records and charts variably sometimes also its osteitis, osteomyelitis, and the other names you see listed here including implant related infection. The existing ICD-10 procedure codes relate only to devices or the manual mixing of products, not to a combination device drug product. Which means there are currently no codes to capture the use of a combination device drug bone void filler such as CEREMENT® G. Next, please.

To summarize, there is no other combination bone void filler and antibiotic product that is cleared or approved for use in the United States. CEREMENT® G, which has received breakthrough designation, is currently being evaluated by the FDA, is a device drug combination product. It offers the possibility of a single stage surgery in the cases of bone infection because the bone void fillers resorbed at the same rate as which the body creates new bone, while eluting antibiotic in order to protect that new bone from bacterial colonization. A single stage procedure eliminates the need for the second operation I spoke of earlier and it is in your handout, avoids donor site morbidity from that bone graft harvest, lowers total costs and treatment time, and improves quality of life for patients. CEREMENT® G will be used in conjunction with other procedure codes for the other components of the surgical procedure performed, but these codes cannot presently or appropriately identify the use of a combination device drug product like CEREMENT® G. Thank you very much for your time and your attention.

NOEL MANLOVE: Thank you, Dr. Dirschl. At this time, we're going to open it up for any questions regarding the clinical presentation of CEREMENT® G. If you have a clinical question, please use the raise your hand feature and our moderator will open up your line.

ISAAC FISHER (Moderator): We have one question here. You can ask your question.

LINDA HOLTZMAN: Hi. This is Linda Holtzman from Clarity Coding. Thank you very much. Very interesting presentation doctor. I have a question about the approach that's being used. I might have missed it, but I see that it's injected with a tip extender or by attaching a needle to the delivery syringe. My question is, it's a one stage procedure, so the dead bone has been removed. I'm assuming that that's done via an open approach. So is the site open and then you're just injecting into something that you can you can see directly in front of you or is the site closed and then you're injecting through other tissue? Yeah.

DOUGLAS DIRSCHL: The bone debridement occurs through a surgical incision and open approach, but the bone debridement because of the architecture and nature of bones, it's not always wide open. And what I mean by that is we use fluoroscopy and other tools to help guide us as to what bone is dead, what bone is devitalized or infected and removed. And, in addition, even when we have completed that, even if we can see visually the opening in the bone we've created for the debridement, we can't see the depths of the inside of the bone. All of the interstices that flow in the metastases portions of the bone and such.

DOUGLAS DIRSCHL: And so having a product that can be injected is helpful to fill all of those small dead spaces and gaps that we can't see directly with our eyes at the time of surgery. At the same time, this is a place that is hardening and setting over time. And so during that working period, you also have the time to manually, if you choose, to pack it into open portions of bone that you can see. So it's not solely injectable. That gives you the option to inject which is really important to fill interstices and small voids that you can't see except perhaps on X ray. But the fact that it hardens as it does allow you to also openly pack it into areas that you can see directly.

NOEL MANLOVE: Thank you, moderator. Are there any other raise your hand questions that we can address at the time?

ISAAC FISHER (Moderator): No, that was actually.

ISAAC FISHER (Moderator): One just came up. You may ask your question.

MOHAMMAD ASHRAFUL HOQUE: [Inaudible]Yeah.

ISAAC FISHER (Moderator): Yes, sir. Now can ask your question.

MOHAMMAD ASHRAFUL HOQUE: Again, [inaudible] diabetic foot infection. Can you explain it?

DOUGLAS DIRSCHL: Well, I think that, as you well know as a clinician, diabetic foot infections come in a wide variety of types, sorts, and levels of severity. And so the way I will answer your question is to go back to what the basic use and need for this product is. And it is when there are areas of bone infection, where there is dead bone that needs to be surgically removed, in order to best facilitate treatment or management or cure. Once that bone has been removed surgically, then the product, the implant, can be inserted and can do its work protecting the new bone with the antibiotic helping sterilize the site, or at least prevent colonization and then to promote new bone formation. So this could be used in a diabetic infection, for example, of the calcaneus or any case in which there would be a need to debride bone from the calcaneus is that would result in a bone defect that would then be appropriate for this bone void filler.

NOEL MANLOVE: Okay, thank you very much. At this time, we're going to proceed to the coding options. If you had a question that has not had a chance to be answered, all questions submitted through the Q&A and chat box will be answered and posted after the meeting. So you can continue to submit questions through those vehicles as we go along with our presentation.

So the coding options. Currently, as we said earlier, there is no unique code to address the drug-eluting bone void filler. Facilities can report CEREMENT® G at this time using table 3E0V3GC, which is Introduction of other therapeutic substance into bones, percutaneous approach. So the coding options we're presenting at this meeting today for purposes of new technology application is Option 1, not to create a code, and Option 2 is to create an X code in table XW0. And you can see the chart here.

NOEL MANLOVE: V for bones. We can do open, percutaneous or percutaneous endoscopic. Adding the antibiotic-eluding bone void filler. New Technology Group 7. So CMS' recommendation is to select Option 2 to assign the X code. In the meantime, you may continue to use the current coding as addressed up in the current coding listed above.

So at this time we'll open it up to any questions relating to the coding aspect of this presentation. So moderator. If there are any further questions. Can you please open up the line for a couple of questions?

ISAAC FISHER (Moderator): Yes, we have another question from Linda Holtzman.

ISAAC FISHER (Moderator): There you go Linda. You may speak now.

LINDA HOLTZMAN: Thank you very much, moderator. It's Linda, I'm back for round two. I certainly think that it's appropriate to have a new code for this and I like the structure that is set up. My question has to do with the approach. Both for the current coding and for coding under a new code. It's not clear to me whether or not we would use percutaneous or open here. I do understand that it's being injected and I understand that it's getting into the quote "nooks and crannies" of the bone that can't be visualized nonetheless the bone itself is apparently exposed. So the site of the procedure is exposed here and I can see confusion on whether or not a percutaneous approach should be used or an open approach should be used. So, I'd ask CMS to to clarify that. Thanks.

NOEL MANLOVE: Thank you, Linda and we will note that, and as always, you know, please submit your questions in writing, so that we can address them appropriately.

NOEL MANLOVE: Are there any other questions at this time?

ISAAC FISHER (Moderator): Yes, we have one more question. Sir, you may ask your question.

ISAAC FISHER (Moderator): I'm sorry.

NELLY LEON-CHISEN: Okay, sorry. Okay, so question, I realize that you're inserting antibiotic but in other instances where we've had bone void fillers, it's been to address a dead space or an empty space and in prior Coding Clinic questions, that were related to bone void fillers, we've used the root operation supplement because it was taking up the space that used to be with the bone. Are we proposing here "Introduction" because it's in the primary function is to introduce the therapeutic substance, rather than filling in the dead space that was left once the bone was removed?

MARILU HUE: Hi, Nelly. This is Mady. I think what we would encourage is to have the discussion about what is more relevant for capturing in the data in this instance. So you bring up a good point. Thank you. And I don't know if the clinical speaker has any thoughts on that aspect.

MARILU HUE: What you would consider to be most useful?

DOUGLAS DIRSCHL: Yeah, I think, thank you for turning it back to me. So the, the primary mode of action for this device is filling the bone void and stimulating the resorption, or the, I'm sorry, stimulating the formation of bone to fill the defect, while the implant itself resorbs over six to 12 months. The secondary mode of action is to elute the gentamicin to then protect that newly forming bone from colonization from microorganisms during that time. So it's a combination device, though, that has clearly two separate and distinct modes of action, but both are present.

MARILU HUE: Thank you. So I don't know if that helps you Nelly at all, but it sounds like we may need to explore if perhaps two codes might be reported for this. Again, please submit your comments.

NOEL MANLOVE: Thank you. Mady

NOEL MANLOVE: Any other questions regarding the coding options?

ISAAC FISHER (Moderator): There are no…Actually, one just popped up, one second.

ISAAC FISHER (Moderator): This one is from Mohammed.

MOHAMMAD ASHRAFUL HOQUE: Can you hear me?

ISAAC FISHER (Moderator): Yes. We hear you, sir. Go ahead.

MOHAMMAD ASHRAFUL HOQUE: Is the indication for using this technology or whatever it is, and I don't understand that. How this will work against what specifically the word is used diabetes or diabetic foot infection, if it is related to bone regeneration or something like that, then how is this related to diabetic foot infection? I don't get it. And that's all. Thank you.

DOUGLAS DIRSCHL: As this is a similar to the question, I answered a few moments ago. So let me try to approach it may be somewhat differently. The implant CEREMENT® G is used as an adjunct to standard treatment for all types of bone infection. It can be used in any type of bone infection that standard treatment involves the systemic administration of antibiotics and debridement or removal of infected and dead bone. In the case of a diabetic foot infection, where there is dead bone to be removed, not every diabetic foot infection requires the removal of dead bone, but in cases where there is dead bone to be removed, the CEREMENT® G would be an appropriate adjunct, appropriate implant to consider using at the time of surgical debridement or removal of that dead or infected bone.

NOEL MANLOVE: Thank you very much, Dr. Dirschl. At this time, we'll conclude this topic. If there are any further questions concerning the coding options or the clinical aspect of this proposal, you can submit them through the Q&A feature and we'll answer them and post our responses as soon as possible over the next few days. So with that said, we'll conclude this topic and again, thank you, Dr. Dirschl.

NOEL MANLOVE: At this time, we'll be moving on to Topic number two. And Topic number two, with regards to Restriction of Coronary Sinus.

As with the first topic, there is not a unique code to describe the insertion of a restriction device in the coronary sinus for refractory angina. This proposal that's requested is being submitted with regards to a New Technology Add-on payment for approval for fiscal year 2022. FDA approval for the Reducer System is anticipated sometime this fiscal year, so hopefully by the end of September. I'm not sure if it's been approved, since this paper was written. This Reducer was granted breakthrough medical device status by the FDA in October of 2018. Presenting the presentation for this topic is Dr. Banai. I will get the slides up as soon as I can. Just a second. And Dr. Banai can begin his presentation.

SHMUEL BANAI: Thank you very much. Yes.

NOEL MANLOVE: Sorry about the delay,

SHMUEL BANAI: It's okay. Thank you very much. My name is Shmuel Banai and I am professor of cardiology of the Tel Aviv University and I'm the medical director of Neovasc. Next slide please.

We're going to talk about the Reducer System which is a therapy for patients with disabling refractory angina. So the problem is refractory angina, which is a disabling medical condition refractory to medical and interventional therapies and it's defined as at least three months of angina pectoris due to obstructive or non-obstructed coronary artery disease, and it persists. The angina persists, despite optimal medical therapy which is not amenable or not suitable for percutaneous or surgical revascularization. Not enough blood is getting into the heart muscle, therefore, the patient cannot perform any physical activity without chest pain without chest discomfort and shortness of breath. Next slide please.

It is estimated that about 1.8 million patients in the US have refractory angina which means 50,000 to 100,000 new cases per year. It's also known that following percutaneous coronary intervention, and despite adequate anti-ischemic therapy, about 20% to 30% of patients again, despite successful revascularization by an angioplasty or by bypass surgery, 20 % to 30% of the patients continue to suffer from disabling angina. These patients today have limited treatment options and now that's referred to, no option patient, because we actually do not have any further treatment to offer them. Next slide please.

Other, theoretically at least, treatment option beyond medical therapy include enhanced external counterpulsation, neuromodulation by Spinal Cord Stimulation, transcutaneous Electrical Neural Stimulation and Transmyocardial Laser Revascularization. Actually, none of this therapies are available and readily available and widely used in the US. Only two are even recognized in the US for the patient. So actually, there is no other alternative available therapy for this patient. Next slide please.

SHMUEL BANAI: The Reducer is intended for patients suffering from refractory angina, refractory despite guided and directed medical therapy, who are unsuitable for revascularization by coronary artery bypass surgery or by percutaneous coronary intervention. Clinical evidence so far, show a very high safety profile with a 70% to 80% improvement in symptom and quality of life of this patient. Very high percentage of patients can go back to work and can go back to the normal daily activity with this therapy, which has, as I said, a very high safety profile. Next slide, please.

The Reducer System comprises of a reducer which is a metal mesh mounted on a special delivery balloon, as you can see in the black box, and this hour-glass shaped device is placed in the coronary sinus. The coronary sinus is the major vein draining the heart muscle. It creates a permanent and controlled narrowing of the coronary sinus of the vein which intends to improve perfusion of blood, oxygenated blood to ischemic portions of the myocardial and by that relieve symptoms of refractory angina. On the bottom right, you can see 3D reconstruction of a heart of a patient 12 years after implementation of the coronary sinus reducer. And you can see on the back of the heart the reducer with the hour-glass shape, causing narrowing at the coronary sinus right before it drains into the right atrium. By the way, 12 years follow up using CT angiography, show no obstruction, no migration or no deformation. No problem at all with the Reducer after very long term follow up. Next slide please

The procedure itself is an interventional, relatively very simple procedure. The access is through the vein in the neck, the jugular vein of where this access is obtained under ultrasound guidance. A catheter, diagnostic catheter, is advanced and inserted into the right atrium and into the ostium of the coronary sinus like you see in the illustration below. The guide wire is advanced into the coronary sinus and over the guide wire the Reducer catheter system is advanced into the landing zone, which is in the post proximal portion of the vein of the coronary sinus. After the Reducing System reaches the target of the landing zone, the balloon is expanded and the Reducer is implanted inside the coronary sinus. After inflation of the balloon and implementation of the Reducer, the balloon is deflated and all the system is withdrawn backwards and out of the body through the vein in the neck. And the reducer is implanted and starting to work. Next slide please.

Regarding medical documentation, we can suggest Reducer device implanted into the coronary sinus for treatment of refractory angina, reduction of the coronary sinus diameter with device implant, coronary sinus reduction implant, or simply Reducer or Neovasc Reducer System. Next slide please.

Having a unique ICD code for implementation of a reduction device into the coronary sinus for refractory angina will allow identification of this procedure, tracking and quantifying office utilization, and outcome analysis. Thank you very much for your attention.

NOEL MANLOVE: Thank you, Dr. Banai. At this time, are there any clinical questions?

ISAAC FISHER (Moderator): There are no raised hands at this time.

NOEL MANLOVE: Thank you. Moderator. We'll go and present the coding options.

NOEL MANLOVE: As we stated before, currently, there were no unique ICD-10-PCS code to capture this technology. Currently facilities can report the procedure with the following code 02843DZ. Insertion of intraluminal device into coronary vein, percutaneous approach.

Our coding options, because it's a request for new technology code, we're only presenting two. One is to not create a code and the second option is to create an X code in Table X2: Operation: ADD V-Restriction; Body Part: ADD 7-Coronary Sinus; Approach: percutaneous; Device/Substance/Technology: ADD Q-Reduction Device; Qualifier: New Technology Group 7. CMS recommends Option 2, creating the X code for this device. In the interim, you can continue using the current coding as listed above. So with that said, we'll open it up for any coding questions.

ISAAC FISHER (Moderator): No questions at this time.

NOEL MANLOVE: Thank you, Dr. Banai for your presentation.

SHMUEL BANAI: Thank you.

MARILU HUE: Okay. Do we have Dr. Daniel Hoernschemeyer on the line?

MARILU HUE: The next topic is Vertebral Body tethering I want to confirm that the speaker is available on the line.

ISAAC FISHER (Moderator): I'm looking for him now. No, he isn't on the line currently.

ISAAC FISHER (Moderator): He is. He hasn't joined the meeting yet. Let me one second here.

ISAAC FISHER (Moderator): Okay, I have him and everything.

MARILU HUE: Here, yes. Thank you. Okay, we're on the topic for vertebral body tethering. The issue is that currently there is not a unique ICD- 10- PCS code to describe vertebral body tethering in the treatment of progressive idiopathic scoliosis. This is not related to a new technology application and this device does have FDA approval. And I will go ahead and turn it over to you Dr. Dan. Noel if you could pull up his slide please.

DANIEL HOERNSCHEMEYER: Thank you guys. Can you hear me okay?

MARILU HUE: Yes, we can.

DANIEL HOERNSCHEMEYER: Good. So vertebral body tethering is really a new treatment for scoliosis. The procedure has been around really since 2011 and I have personally been involved with this procedure since 2013. Next slide.

In here, my disclosures really related to medical education and training and a few grants from Zimmer Biomet. Next slide.

DANIEL HOERNSCHEMEYER: So scoliosis is really a 10-degree description of coronal curvature of the spine. But really this is a three dimensional deformity. Most common form is idiopathic scoliosis. When we think about scoliosis everybody wants to know whether this is something that's going to progress over time. And that's really related to the curve magnitude when we think about the symptoms. Really, there's a lot of symptoms related to scoliosis. However, in severe forms with bigger curves, we then see a reduction in total lung capacity.

Current treatments that are out there really observation for curves under 25 degrees. There is some physical therapy called Shroff method directed at treatment of an adolescence curve. There's bracing, and that was well supported by the brace trial in 2013. For curves that progress over 25 degrees and then there's really surgical management for curves reaching about 45 to 50 degrees because we know those curves are going to continue to progress, even after skeletal maturity. Next slide.

So we consider the diagnosis of juvenile or adolescent idiopathic scoliosis. In 2018 there were 8,117 inpatient discharges related to these diagnoses. 97% were operative admissions for surgery and these kids had a four-day length of stay and that continues to drop as post-op protocols continue to improve. Most of these patients are females. And when we consider vertebral body tethering, really it's not indicated for all types of scoliosis. Really the child has to be a kind of a select indication, they have to be skeletally immature with growth. We'd like to see a flexible curve here you see in the IDE study kids average about 12 years of age and then Cobb angles usually are of operative range. So here you see 30 to 65 personally 45 to about 70 degrees have been my indications for this surgery. And then the final comment there is that the severe rigid curves are really not treatment for VBT. Next slide.

So when we compare posterior spinal fusion to vertebral body tethering really posterior spinal fusion has been around for decades. This goes back to Harrington rods. Here you see a form of what was described in the 80s posterior non-segmental fixation, whether we're using hooks or screws, pedicle screws and then fusing the child’s spine. With tethering, this got HDE approval in August of 2019. This is more of an anterior approach, the fusion is a posterior approach, and the tethering is done a bit more minimally invasive. Next slide.

So here you see the implants use the anchor and that prevents really toggling of the screw in the vertebral body and helps with placement, then the vertebral body screw itself. This is an H A coated screw that anchors well into the spine and then we have the polyethylene cord and this is how we tension and correct the scoliosis. Next slide.

So this procedure is done in a minimally invasive fashion. Patient is in a lateral decubitus position, usually the right side is up. Here we use single long ventilation, where we collapse the right lung and then using 15 millimeter ports for the procedure and maybe a five millimeter port for the camera. This allows again to keep this minimally invasive. Sometimes a mini thoracotomy is used by surgeons that are just starting to learn the procedure. Thoracoscopic instruments are then outside the spine as depicted in this picture on the right. Next slide.

DANIEL HOERNSCHEMEYER: And once the screws are all placed. Then we work to tension that the tether thus correcting the deformity. Next slide.

So what we're after here really is, you know, correction of this deformity with a tether. So here you see a patient with a 46-degree curve surgically. They were corrected down to 18 degrees. I would label this the active correction of surgery and then over time, growth, the continued growth of that patient through the Volkmann principle allows for further correction of that scoliosis. So, and say this is more of the passive correction. Next slide.

And so the slides here just really demonstrate the IDE study. This was done in 2016 through the Philadelphia shrine. Really with two year follow up of Lenke 1A curves. What that really describes or what you need to understand is the major curve to be treated was really the thoracic curve. And so this was all done thorascopically. So there was no tethering of the lumbar curves, these kids had continued growth and they've defined success is anything under 40 degrees and they found that an 85 greater than 85% of the subjects. Next slide.

And so here, when you look at the success visited 24 months 97% success most recent follow up 92% success with this procedure. When kids were treated with preoperative Cobbs less than 45 degrees versus more than 45 degrees, you can see long term at their last follow up the percentages here for percent of successful patients at less than 30 degrees 35 and 40 degrees. So again, a very high success rate, not everybody is successful, but a great majority if patient's selection is done appropriately. Next slide.

So, and again, some concluding results of the IDE study, rib prominence improved and this patient population patient related quality of life in outcome measures was at 90% and physical function at 92%. Some of the concerns are over correction that can occur. And so that's why we don't want to tether in too skeletally immature of a patient. Some nausea, vomiting positional things with pain and numbness related to the arms and legs. I think that much of that improves the need for additional surgery really speaks to revision type surgery and that can be performed. Really, if there's a broken tether or if there's over correction and the tether needs to be removed. And say, here you see court breakage development of another curvature of the spine and development of spondylitis thesis seen in this in this ID. Next slide.

And so I can personally tell you that we've recently published on this procedure and seeing a 74% success rate in patients and keeping their curves under 30 degrees so 74% of the population with 21% requiring revisions, but the most impressive statistic is that 93% to date of the patients I've treated have avoided a posterior spinal fusion. That's it. Questions?

MARILU HUE: Thank you, Dr. Moderator, can we open the lines to see if there's anybody raising their hand and might have a question, a clinical question?

ISAAC FISHER (Moderator): Yes, we have one question.

ISAAC FISHER (Moderator): What is your question?

LYNN KUEHN: Hi, Lynn Kuehn from Kuehn Consulting.

LYNN KUEHN: Thank you for the nice of photos of this when I see this, it is done exactly the way your picture has shown, um, is there any, um, any clinical use of this that would touch the posterior elements of the spine?

DANIEL HOERNSCHEMEYER: I have. Yes, there is the possibility, as I've seen a few colleagues around the country use this as a posterior device. Personally, I have not used it as a posterior device, but yes.

LYNN KUEHN: Thank you. That helps a lot.

MARILU HUE: Thanks Lynn.

MARILU HUE: Are there any other clinical questions.?

ISAAC FISHER (Moderator): No other questions at this time.

MARILU HUE: Okay, we'll go ahead and move on to the coding options, for those following along as page 19 of the handout packet for current coding, you would code the use of vertebral body tether would be applicable ICD-10-PCS code from tables 0PS and 0QS which is reposition of Upper and Lower bones using the device value 4 internal fixation device.

Coding Option 1 is do not create new codes for vertebral body tethering. You would continue to code as listed in current coding. Option 2 is for tables 0PS and 0QS reposition of Upper and Lower bones, we would create device value three, spinal stabilization device, for table body tether and create qualifier value 3 anterior column and 4 posterior column, which could be applied to the appropriate body part value and you can see the tables on the screen.

At this time, CMS is recommending Option 2. And I'd like to open it up for any comments or questions.

ISAAC FISHER (Moderator): We have one question that's from Linda Holtzman.

LINDA HOLTZMAN: Hello, I'm forgive me. I think this is more of a clinical question, although it has coding implications, of course I may have missed this, but I just wanted to confirm that the implants are permanent and I know that the proposal mentions instrumentation for removal of the implants, but I assume that that's removal for during the procedure of perhaps their misplaced or whatever, just placed, but I, but otherwise that I assume that the implants are permanently placed, is that correct?

DANIEL HOERNSCHEMEYER: Correct, correct. I think there's been some anecdotal experience early of removal and re-establishment of the deformity. And so currently the practice is to permanently leave those devices.

LINDA HOLTZMAN: Thank you very much.

ISAAC FISHER (Moderator): We have one more question. Lynn Kuehn again.

LYNN KUEHN: I asked my clinical question before about the posterior column, because I'm concerned about the qualifier. Spinal procedures cause coders a lot of challenges and I'm concerned about the device name of that device value that includes vertebral body tether. But yet, we're providing a qualifier option for posterior column and I'm suspecting that we will have some coders who attempt to use this in the way that the physician described, but will assign posterior column, because they don't understand there are no “bodies” on the posterior column.

I don't know how to fix this because the physician said that this is used in some ways in the posterior column, but I'm concerned about the possibility of problems because we've got “body” in the name of the device and posterior column available as a qualifier. I don't know. I don't know whether to recommend that the posterior column qualifier option goes away. Is there any discussion about why this was suggested was this put in by the manufacturer?

MARILU HUE: Thanks. Lynn. So when we reviewed this proposal, the question was asked about if that was helpful to identify the column and the response was, yes. But, you know, if you are recommending that we don't have any qualifier to identify the columns then you can certainly submit that in your comments as well. And we can consider just removing that if it is felt that it's not helpful and it may cause more confusion.

LYNN KUEHN: Saying, tell me to think about that, but I may just recommend that.

MARILU HUE: Okay. Doctor, did you have any comments on that.

DANIEL HOERNSCHEMEYER: No. Um, can you, I mean. Can you restate the question? I mean, I don't really have any additional comments but maybe I didn't quite understand.

LYNN KUEHN: It's confusing to know what qualifier to assign if you don't really understand the anatomy of the spine, and it appears in all of the pediatric work I've ever seen this is applied of course to the side of the vertebral body and we're trying to decide if there really is a value to having a qualifier there at all that says anything about the column, because it's built to go on anterior. And so why would we need posterior column, and then Mady’s question is correct, why would we need a qualifier at all?

DANIEL HOERNSCHEMEYER: Right. I think that can be confusing really to any coder and I, I would say 98/99% of the cases and at least the way the training is being done with surgeons is on the anterior side. But again, I've seen it applied in a few limited cases posted early and I haven't really subscribed to that because I don't really know where that that thought in that approaches you know going to result if we're going to be happy with that. So, would say that like again 98/99% of time this is going to be an anterior vertebral body device.

MARILU HUE: Okay, thank you. So it sounds like we're leaning towards getting rid of that those qualifiers to avoid any potential confusion, but Lynn, submit your comments in writing.

LYNN KUEHN: Yes, I will.

MARILU HUE: Thank you.

MARILU HUE: Are there any other comments or questions for the coding options?

ISAAC FISHER (Moderator): There are no other questions at this time.

MARILU HUE: Okay, well I guess that concludes this topic and in the interim, continue to code as listed above under current coding. Thank you.

DANIEL HOERNSCHEMEYER: Thank you.

ANDREA HAZELEY: Okay. Good morning, this is Andrea Hazeley for those following along with the handout. We're now on page 20 Chimeric Antigen Receptor T-cell Immunotherapies.

Okay, just as background, CAR T-cell immunotherapy is a cell-based gene therapy in which immune cells are removed from a patient, genetically modified with new proteins that allow them to recognize cancer, and then given back to the patient in large numbers. These cells persist in the body, becoming living drugs. The issue we're discussing today is that effective October 1, 2020 ICD- 10- PCS code for the intravenous administration of CAR T-cell therapies can be identified in two different tables in the classification.

Also, the two existing ICD-10-PCS codes for the intravenous administration of autologous CAR T-cell therapies are not product-specific, while the two codes that will be effective October 1, 2020 are product specific. In response to the creation of new table XW2 which will be effective, October 1, a number of comments have been received.

Some comments stated that all four codes should be in the same table to foster correct coding and transparency. Other comments stated that the new ICD-10-PCS codes should be created for KYMRIAH and Yescarta, so they are also named specifically as part of the code description to be distinguishable for data collection. At this time, we like to clarify for the audience that the applicant for Yescarta did not request a specific code.

Okay, we also received comments based on creation of new table XW2 that the FDA regulates CAR T-cell products as biologics, and although they are derived from T-cells, they are not considered to be blood products. Others stated, that CAR T-cells are engineered and manmade and therefore considerably different from blood products such as platelets or whole red blood cells. Another comment stated that innovations in chimeric antigen receptor constructs may produce different products that are not a good fit for the XW2 table.

Speaking of future innovations, as the biopharmaceutical industry has become more involved in the field, a number of clinical trials testing CAR T-cells and other immune effective cell therapies has expanded dramatically. There are trials for CAR T-cell therapies for other routes of administration, including intra-tumor, intra-cranial, and intra-pleura.

ANDREA HAZELEY: Today you will hear requests for PCS codes for allogeneic CAR T-cell products and a Tumor-Infiltrating Lymphocyte immunotherapy. In the future, CMS may need to create a new table as this class of treatment evolves, but today we are seeking input from the audience on coding options.

As mentioned earlier, effective October 1, 2017, facilities can report the intravenous administration of autologous CAR T-cell therapies with one of the ICD-10-PCS codes from table XW0. Effective October 1, 2020, facilities can report the intravenous administration of Tecartus or lisocabtagene maraleucel with one of the ICD-10-PCS codes shown in XW2. On page 21 shows our options. Option 1, do not create new ICD-10-PCS codes. Continue using codes as listed in current coding. Option 2, create new codes in section X, New Technology, in table XW2 Transfusion to identify intravenous transfusion of CAR T-cell products KYMRIAH and Yescarta. Also add non-product specific codes in table XW2 to identify the transfusion of other engineered autologous CAR T-cell therapies and delete codes in table XW0 that identify the intravenous infusion of autologous CAR T-cell therapies.

Moving on to Option 3, we can create new codes in section X, New Technology, in table XW0 Introduction to specifically identify intravenous infusion of CAR-T products KYMRIAH, Yescarta, Tecartus or lisocabtagene maraleucel. We can revise the device value C to Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous, to identify the infusion of other engineered autologous CAR T-cell therapies. And we can delete table XW2 that identifies the intravenous transfusion of Tecartus or lisocabtagene maraleucel.

At this time, we are seeking input from the audience. In the interim, coding advice is to continue coding as listed under current coding. If anyone has any questions at this time. Please use the raise your hand feature and moderator, can we open for any coding questions.

JUGNA SHAH: Andrea, this is Jugna Shah, can you hear me?

ANDREA HAZELEY: Yes, I can.

JUGNA SHAH: Hi. Thank you. This is Jugna Shah with Nimitt Consulting on behalf of ASTCT today. First of all, I wish to thank CMS on behalf of as ASTCT for introducing this really important topic and thank you for the great explanation about the coding options. ASTCT would recommend that CMS finalize Option 3, which is to keep the XW0 table and you know, add the codes, as you just described into that table so that everything stays together. That makes sense to us from just a coding perspective, ease of use and we absolutely agree that the XW0 table is the appropriate table. XW2 would not be appropriate, again, for the reasons that you stated specifically that these are not blood or blood products in the way that we that we typically think of those and as a CMS knows, we did send in a pretty detailed letter discussing this, and had expressed our concerns. So again, we appreciate you guys talking about this today and we recommend Option 3.

ANDREA HAZELEY: Thank you. Thank you. And again, we encourage for you to put your comments in writing as well.

ISAAC FISHER (Moderator): We have two questions. I'll start with the first one. Susan Armstrong.

ISAAC FISHER (Moderator): Susan, you can ask your question.

SUSAN ARMSTRONG: Good morning. I'm Susan Armstrong. I'm the coding manager at City of Hope in Duarte, California. We do provide CAR T therapy to our patients and we really appreciate you discussing this today. I concur with Jugna's comments about recommending Option 3. I think from a coding perspective or a coders' perspective it's a lot easier to have all of the choices in one table and to not have to go back and forth between tables and also to remember which products are in which table.

In addition, I don't know if there's an option if you were to move forward with Option 3 to consider eliminating the XW2 for this fiscal or this coming year, or if that's even possible, but we are in support of Option 3 and we appreciate the opportunity to comment.

ANDREA HAZELEY: Thank you.

ISAAC FISHER (Moderator): Next question is from Sue Bowman.

ISAAC FISHER (Moderator): Sue, you may ask your question.

SUE BOWMAN: Hi, this is Sue Bowman from the American Health Information Management Association. I also would support Option 3. That seems like the best choice. These don't seem to be, while they may be derived from blood. They're not really blood or blood products in the way we typically think of them. and in the way that I think the transfusion root operation was intended for. And I definitely agree that it be best to keep them all in the same table. Thank you.

ANDREA HAZELEY: Thank you.

ISAAC FISHER (Moderator): Next question, Amit, you may ask a question.

AMIT AGARWAL: Can you hear me?

ISAAC FISHER (Moderator): Yes, you have two audio sources active.

AMIT AGARWAL: Wonderful. My name is Amit Agarwal and I'm from Bristol Myers Squibb. As a company that's planning to bring to two CAR T-cells to the market very soon. I think from our perspective, I also agree with what's been said so far and completely concur with the suggestion of Option 3 as a preferred option. Especially because when we think about sort of the quality measures and quality control processes that are in place for the manufacturing of these products. I think, you know, it's sort of certainly beyond the realm of a blood product and just transfusion. And so we would also be completely supportive of going with the Option 3 where all of these are classified as individual products within the XW0 classification. Thank you.

ISAAC FISHER (Moderator): Thank you. Hey, we have one more question.

ISAAC FISHER (Moderator): Caller, you can ask your question.

ISAAC FISHER (Moderator): Okay, here's another question. This is from Nelly.

NELLY LEON-CHISEN: Hi thank you, Nelly Leon-Chisen, American Hospital Association. I think that I'm hearing support primarily for Option 3. And right now, that's the one that looks best to me, but I have a question. It looks like even if we go with Option 3 you're wanting to revise the device value for the letter C, and it's still remaining as a new technology qualifier, I'm sorry, new technology group three as the qualifier and I'm guessing I'm wondering, since that would still be for historical purposes, why are you changing the device C? It seems to me as I look at it, it's just sort of changing the order of the words because I guess I'm kind of wondering if we're not going to go with having the existing products in that code anymore, once this goes into effect, what's the rationale for changing the existing value?

ANDREA HAZELEY: Okay, the rationale behind that was two parts. The first part would be, it will be able for new products that come to market before they have the opportunity to request a specific PCS code to be tracked using this nonspecific device qualifier. So if they are autologous CAR T-cell immunotherapy that becomes available, they'll be able to use this code.

And the second reason, you'll see as we hear additional presentations today is that we also have allogeneic product requests and to keep the naming consistent, we are suggesting this change, but that will become more evident as the day proceeds for that part of the reason why we suggested this revision.

NELLY LEON-CHISEN: Okay, I think it would be confusing in the data because it says New technology group three, and as I think some of us have started to learn how to use that value, pretty much tells you when then code was created. Would another option be, I mean, there are these codes that say "other" substances. I mean, there's a whole bunch of those going into effect now for "Introduction". Would there be value in using those instead of something that says new technology group three for a new CAR T product that would be coming into the market that doesn't have its own code yet?

ANDREA HAZELEY: We definitely could consider that. So we would suggest putting those comments in writing so that we can review as we make our decisions going forward.

NELLY LEON-CHISEN: All right. Thank you.

ANDREA HAZELEY: Thank you.

JUGNA SHAH: Andrea, this is Jugna Shah again for ASTCT. So I just want to express a little bit more in terms of what Nelly is saying, and that ASTCT had also shared with CMS. I think that I'm getting the table numbering right, I think it's the 3E0 table, which is the administration table. We had also suggested that that table could be used.

JUGNA SHAH: And so, so I appreciate what Nelly is saying about when you have the code and it's not product specific. But, you know, so I think there is a way to have that the autologous one nonspecific possibly in a different table. However, I do, I do think the coding community and hopefully they'll weigh in about whether it's just easier for everything to be in one table when it comes to these new therapies versus having to go, you know, into a 3E0 for nonspecific and then the X table for the specific. Thank you.

FRED LEMAISTRE: Ms. Hazeley, this is Fred LeMaistre from ASTCT and I just want to expand on what Jugna said. The other thing is that by the advantage of Option 3 is it allows us naming of the specific products and this is important for analytics. We currently don't have insight into the side effects, resource utilization, outcomes of these products and because they're, they're all so rapidly developed and they're not phase three trials, this becomes really important for our facilities to be able to understand the utilization, so that we can continue to provide access to patients. Thank you.

ANDREA HAZELEY: Thank you.

KRISHNA KOMANDURI: Yeah, and this is Krishna Komanduri and also a physician scientist at the University of Miami and also with ASTCT. I think all of us in in our transplant programs also believe in in Option 3 for that reason that you know these products. Well, similar in their mechanism have unique characteristics in terms of the way that they signal and the T-cells they expand and as Dr. LeMaistre just indicated their trials were often done against standards of care and their side effect profiles resource utilization. And indeed, things like relapse rates and ultimate success rates can be different. And we think that the granularity and the simplicity of both having individual products be able to be tracked with respect to their outcomes and associated characteristics but the simplicity of having them all together in one table that is best addressed by Option 3. Thank you.

ANDREA HAZELEY: Thank you. At this time, I will close the question and answer period for this topic, if you have anything else you would like to add, you can please add it to the question and answer feature within this webinar and we will move on to the next topic in our agenda, which is Administration of Allogeneic Chimeric Antigen Immunotherapy by Paula Dupee. Thank you, everyone.

PAULA DUPEE: Good morning. Thank you, Andrea for that. Again, my name is Paula Dupee. If you're following along with us, we are on page 23 of the agenda and handout packet. The topic Administration of Allogeneic Chimeric Antigen Receptor T-cell therapy. There's currently no unique ICD- 10-PCS code to describe the administration of allogeneic CAR T-cell therapy. This is not associated with a new technology.

PAULA DUPEE: At this time, I would like to welcome Dr. Fred Lemaistre from the Sarah Cannon Blood Cancer Network for his clinical presentation.

FRED LEMAISTRE: Thank you, Miss Dupee. As for getting the slides up, we really appreciate the introduction Ms. Hazeley gave, it was a great segue into this particular topic and there's also you've heard my colleagues, Dr. Krishna Komanduri from the University of Miami and also

representing American Society of Transplantation and Cellular therapy as well as Jugna Shah whose more expertise either come in during her in the technical aspects of coding.

Really want to thank the agency for this opportunity and for you guys spending so much time thinking about the platform for how we code for these things. These are exciting therapies. We have a number in development. And so being able to develop a flexible platform that can that is able to embrace that. But also the granular information as we just discussed to be able to understand what's happening with the patients is really critical. So on the next slide.

Again, Ms. Hazeley gave a great introduction to Chimeric antigen receptors cell therapy. This is a type of immune effector cell therapy in which these Chimeric antigen T-cells are modified so that they have these CARs on them so that they can successfully destroy the tumor cells. Currently, as mentioned, there's two products that are approved. But within the next few months. There's going to be additional autologous products that we anticipate to be approved by the FDA in as in as a result there, the administration code you're talking about are under discussion. On the next couple of slides which will change.

I'd like to sort of go through a clear pathway of what an autologous CAR T-cell therapy is, and "auto" meaning self. So the T-cells come from the own patient the patient's own blood stream. They are collected by pheresis then shipped and processed so that they're genetically engineered to express these CARs so they can become active. They are then expanded and then sent back to the Center for collection. And so this obviously is a complex system in which the centers need to have a sophisticated ability to be able to coordinate that terrible chain of custody associated in coordination of when the cells get back with in these patients so far, really ill. And so being able to do this in a timely fashion is important and there's a gap of few weeks between collection and therapy. On the next slide, we'll talk about the allogeneic CAR T-cell therapy, allo, meaning come from somebody else.

So these cells are collected from healthy donors and then manufactured and they undergo some additional gene editing besides just putting the CAR in because since they're from somebody else once if we put them back into a patient, there's a risk those cells could also attack the patient so these are gene editing goes on to reduce this risk of what we call Graft Versus Host Disease. They're manufactured, but then stored. So these products have the advantage of being off the shelf and being ready for when the patient needs them.

On the next slide we see these differences between allogeneic again from a donor and a colleague as those that are collected from the patient. Obviously the autologous products engineered from their own T cells are unique to that particular patient but requires the coordination of care of the patient must wait for therapy. And as I said, these are very sick patient and then our hand our centers.

FRED LEMAISTRE: Many of the third of the patients that are referred in don't get CAR T-cell therapies, because of this time delay or the need to use other kinds of treatments. In contrast, the allogeneic or donor CAR T-cells off the shelf, look at the different risk profile. On the next slide.

We see that this dimension there. The settings of care associated with allo CAR T-cell are going to be similar to auto but currently, there are no approved allogeneic therapies their number quite a numbers will see ensuing slide that are in development for B cell malignancies, but also solid tumors and there is the potential these may be useful in autoimmune diseases as well. Next slide.

Just to lift some of the ones, and this is not a comprehensive list of cells, CAR T -cells that are in development. I'd also like to note here, though, that there are other kinds of immune cells we're going to need to consider. There's a type of immune cell called the natural killer cell that will also fall most likely into this allogeneic cell therapy category. And so just for awareness, thinking through how we develop a coding platform for these is important.

On the next slide, routes of administration and dosage of the allo CAR T- cells will be like, similar to auto, but since there's no currently approved products, the dosages and trials vary by product and as I said, the products would likely be administered by similar routes. So on the next slide, we list potential complications.

Known complications for autologous CAR T -cells are really two major ones. One is something called cytokine release syndrome in which the cells, create a super physiologic inflammatory response and why these are required to be delivered in a center that were equipped to support these kinds of patients, but there are also neurologic toxicities that can occur which range from simply some confusion, all the way to loss of consciousness and coma, seizures, and so forth. These, these are not unique to allo CAR T-cells. So all of that we see them with autologous CAR but can see them with allogeneic CAR T-cells as well.

And on the next slide, we see that there are potentially some additional side effects with that could happen with CAR T cells and the reason for the additional gene editing in is that these are active immune cells that once infused into the patient could recognize the patient trends and try to attack the patient, something we call graft versus host disease. Next slide.

So we think that new codes are needed to identify the allo CAR T- cells. The current codes for auto only and we won't be able to accurately describe the administration of these products and they're currently more approved. Elegant products, but a number of ongoing calls are very important and it's important for us to be able to have the codes for the salt products so that we can track them like fly. So a new code would mean the coding professionals can report the inpatient administration of one allogeneic CAR T product over another, rather than being forced report other therapeutic substance new code would also help researchers and others identified patient administration of allo CARs and this would mean that all CAR cases could properly be identified and tracked on claims. So I'll stop there. My colleagues Dr and Jugna Shah may have an additional comment.

KRISHNA KOMANDURI: Hi this is Krishna Komanduri and again, I'm a physician scientist at the University of Miami and I want to thank the, you know, the group for allowing us to present in production Lemaitre first presentation. So I just wanted to highlight a couple of points that were made in his presentation, but I think will hopefully help us help you to understand why we think allogeneic CARs should have unique code.

KRISHNA KOMANDURI: Because of the fact that they come from another individual there are the likelihood of a unique complications and unique issues that impact the episode of care or greater. Again, the hope would be that we have an off the shelf product that can effectively go into a recipient without that lag in manufacturing and will be as effective as current autologous products which have really set a dramatic new standard of care for refractory and relapsed cancer patients. And while that's the hope, it is possible that as the technologies develop complications like graft versus host disease, which we hope that we can avoid through cellular injury engineering may occur and that would actually require new therapies for example immunosuppression of the recipient.

It's possible that a CAR T product that comes from another individual might be more likely to be rejected because they aren't of the patient's own cells and that may increase the likelihood of re administration, the cells may not last as long in the patient as a patient's own cells because, again, of these immunologic reactions and it is possible that the advocacy of these products and the relapse rates might be different. Despite obviously the goal of having equivalent efficiencies. So from a clinical perspective, you can see that there are a number of differences that could lead to either again complications like rejection of the cells or attacking of the recipient or differences in relapse rates and what that really translate to translate health information informatics standpoint is that there could be quite a bit of difference in terms of the resource utilization and outcomes. And so, therefore, we believe that having a new code for these allogeneic products would be valuable, relative to the autologous product.

PAULA DUPEE: Thank you for that, Dr. Komanduri and thank you for that, Dr. Lemaistre. We will now open the floor up for clinical questions moderator. Do we have anyone that has raised their hand with a question.

ISAAC FISHER (Moderator): No, we do not have any questions at this time.

PAULA DUPEE: Okay. Thank you. At this time, we will share the agenda and handout.

For the coding options now on page 24 of the agenda and handout packet. So, current coding facilities can report the intravenous administration allogeneic CAR T cell immunotherapy with one of the following ICD-10-PCS codes: 3E033GC and 3E043GC. The coding options are as follows: Option 1, do not create new ICD-10-PCS code for intravenous administration of allogeneic CAR T- cell immunotherapy continue using current codes is listed. Option 2, create new codes and Section X new technology table XW2 transfusion to identify intravenous administration of allogeneic CAR T-cell immunotherapy or Option 3, create new codes and Section X new technology Table XW0 introduction to identify intravenous administration of allogeneic cell therapy.

PAULA DUPEE: CMS to seeking input from the audience. The interim coding advice is to continue using current codes as listed. So we will now open the floor up for comments and input from the audience.

JUGNA SHAH: And Paula. Paula. This is Jugna, on behalf of ASTCT I think it will come as no surprise that we would support Option 3 the XW0 table that allows consistency with the previous

conversation that we just had. And so I'll leave it at that. Other than just also saying that I appreciate Dr. LeMaistre elevating me to Dr. status but I'm not a clinician, so just for your transcript and record.

PAULA DUPEE: Thank you, Jugna. And again, please, submit also your comments in writing to our ICD-10 procedure code requests mailbox that will be helpful as well.

ISAAC FISHER (Moderator): We have a question from Susan Armstrong.

ISAAC FISHER (Moderator): Susan you may ask your question.

SUSAN ARMSTRONG: Again, as, as mentioned, based on the previous topic we would be also in support of Option 3 in an effort to keep all of these CAR T related procedures in the same table would be helpful from a coding perspective and would make it easier for the coders to not have to flip back and forth between different tables. So the existing codes that we have to use today are very generic and obviously don't identify the product that's being or the therapy that's being done specifically. Thank you.

ISAAC FISHER (Moderator): Nelly is next.

NELLY LEON-CHISEN: Hi, thank you. Nelly Leon-Chisen, American Hospital Association, having heard these two back to back proposals, I think that for this particular one, it makes sense to have Option 3 to create, a new code under the introduction, but I would also add kind of as a revision to my prior question earlier, having heard the need to identify the products distinctly so you can track outcomes and potential problems and so on, rather than re-title value “C”,

So in other words in a previous proposal Option 3, the existing code would look the same to just the naked eye, without knowing what has been changed. I would suggest that you create another code under XW0 where the device value actually indicates that it’s CAR T, autologous, and it becomes very much a distinct separate code for anyone to see and not get it confused with the existing codes that we've had for CAR T for a couple of years now. Thank you.

PAULA DUPEE: Thank you Nelly for your comment which we will take under consideration.

ISAAC FISHER (Moderator): Linda Holtzman is next.

LINDA HOLTZMAN: Just a quick question. How will a coder, be able to tell whether this CAR T–cell therapy is autologous or allogeneic will it strictly by the name of the substance?

PAULA DUPEE: Jugna or Dr. Lemaistre. Do you want to?

FRED LEMAISTRE: Yes. Thank you. Yeah, thanks for later. Yes, it just by the name of it. Won't be a product that has one name that will be both. For example, so it would be by the name of the product.

LINDA HOLTZMAN: Yes, I understand that something would not be both allo and auto. It's strictly a question of making sure that then as each new product coming this and this comment is to CMS as each new product comes out that it's immediately placed in the appendix. So we'll be able to tell the difference. Thanks.

PAULA DUPEE: Thank you, Linda. Mady, do you have any feedback on the whether it will be in the appendix?

MARILU HUE: Yeah, so consistent with our standard process, we have the substance key and various device keys. So we would consider proposing to add the names in there for assistance to the coders.

KRISHNA KOMANDURI: Thanks, Mady.

JUGNA SHAH: Hello this is Jugna from ASTCT and sort of in response to Nelly's point, which I think is a really good one, I don't know if it violates kind of the coding convention of the qualifier and the device. Those fields, right, in ICD-10 is if there's a way not to violate, right, sort of the coding convention rule. I definitely appreciate the notion that the autologous code would mirror the allogeneic code and it would be different from how that code has been used to date for KYMRIAH and YESCARTA, just in terms of the analytics that people are talking about dealing with these new therapies. Thank you.

PAULA DUPEE: Thank you. Jugna. And again, just to reiterate, please submit all comments to our ICD procedure code requests mailbox. At this time, I think we are going to close the floor for questions and comments and move to our next topic, Administration of Lifileucel, Thank you.

There's currently no unique ICD-10-PCS code to describe the administration of Lifileucel, an autologous tumor infiltrating lymphocytes cell based therapy. The requester intends to submit New Technology Add-on Payment application for fiscal year 2022 consideration and the requester is also seeking implementation of the ICD -10- PCS code on April 1 2021.

At this time, I would like to welcome Dr. Maria Fardis, president and CEO of Iovance Biotherapeutics. Maria, are you on the line?

MARIA FARDIS: I am. Good morning. Can you hear me?

PAULA DUPEE: Yes, we can hear you.

MARIA FARDIS: Thanks.

PAULA DUPEE: Just give us a few seconds.

MARIA FARDIS: Thank you so much Paula.

PAULA DUPEE: We'll get your slide deck up. I believe it's coming up now.

MARIA FARDIS: Yes, that's perfect.

MARIA FARDIS: Thank you. I appreciate the opportunity to present our support for Iovance's request of new ICD-10-PCS code for the inpatient administration of Lifileucel. Next slide please.

Tumor infiltrating lymphocytes or TIL offer a highly personalized new treatment option for patients with solid tumors. We anticipate Lifileucel to be the first FDA approved therapy for patients with metastatic melanoma, who have limited treatment options as their cancer has progressed following use of the current standard of care, including immune checkpoint inhibitors and targeted therapies.

Lifileucel has received orphan drug fast track or (RMAT) designation and we are planning on submitting a BLA in late 2020. We also plan to submit a New Technology Add-on Payment application for year of 2022. My presentation will focus on metastatic melanoma for Lifileucel is also being studied in metastatic cervical cancer which is expected to be the second indication for us. As part of a normal immune response, TIL migrate to the tumor site after circulating in blood and through recognition of chemo cards that are produced at the tumor.

It penetrate tumors stroma and engage into tumor cell killing. Cancer prevails in cases where tumor micro-environment overpowers immune response. The principle being in TIL therapy is to amplify and rejuvenate the cancer cells. The cells that are coming from the patient and these are immune cells and thereby enabling them to kill the cancer cells. After TIL product manufacturing, which I will show in a few slides, the therapeutic TIL are now available in greater numbers and with restored functionality. Next slide please.

There's still significant unmet need for patients with metastatic melanoma. While melanoma has 96,000 patients being diagnosed every year in the US, there's still 7,000 deaths and most patients will not achieve a long lasting remission. To treat them with checkpoint inhibitors our chemotherapy has limited efficacy and the five-year survival rate for metastatic melanoma is still less than 25%. There are no approved agents for patients whose disease has progressed after immune checkpoint inhibitors or (ICIs) or targeted therapy. Next slide please.

Here we are showing patient journey as well as TIL manufacturing process. The top of the graph shows what happens to the patient. In a clinical setting, the patient enters the clinical study. The patient is consented. A surgical resection has taken place where a lesion is taken from the patient approximately one centimeter or so cube of the tumor is selected. That tumor is then shipped to our manufacturing facility at the bottom of the graph. The patient recovers and goes home. On the bottom of the graph, when the product arrives, the tumor arrives, at our manufacturing facility, it is fragmented, it is placed in media and this TIL, as well as other cells that are the tumor start exiting the tumor and they start growing at the same time in the media.

MARIA FARDIS: Over a course of a 22-day manufacturing process, we amplify these cells to mostly generate T-cells and a very large number of cells in the billions. Once the product has been grown to billions of cells we wash the cells you put them in an infusion bag, we cryopreserve the product and Iovance is ready to infuse the patient. Once the patient is ready,

and we are looking at the top of this graph, the patient comes to the hospital. They're lymphodepleted using the course of chemotherapy. It's a seven day lymphodepletion procedure.

Then on step four at top of the graph, they receive their TIL and this is followed by up to six doses of IL-2 administration. And once the patient has recovered from their adverse events that they may be suffering from, they are dismissed from the hospital. This concludes the entire regimen. Next slide please.

In terms of mechanism of action, once the TIL is infused into the patient, the cells are circulating in the blood, until the TIL detects the tumor in the facility due to the chemokines that are produced by the tumor. The TIL then departs the capillaries and migrate to the site of the tumor. Upon arrival at the tumor the TIL recognizes the tumor antigen peptides presented on the MHC molecule at the surface of the tumor cells via their T-cell receptors. Once the tumor recognition has been accomplished, the TIL gets activated and secretes perforin, a core forming protein.

The newly formed cores allow for the delivery of granzyme, a pro-apoptotic protein, which is also released by the activation of the TIL and causes lysis of the target cancer cell. Infused TIL the media age regression of tumors by direct cell killing but also they mean do cytokines mediated tumor as well. This slide demonstrates all of the similarities in process to CAR T to compare the various options that are available in cell therapy landscape and there are some similarities with CAR T that has been discussed earlier today as well.

We know that both CAR Ts as well as TIL are a one-time treatment. They're both autologous therapy, so there patient specific. TIL is highly personalized to target the multiple tumor antigens. There's no off target or off tissue effects to date only cellular therapies have been shown at this moment of from the various cell therapies that are available TIL is the only one that is showing activity in solid tumors. We're showing this study design, they will briefly show you the data for on this slide our phase two study is targeting metastatic melanoma patients who have received one prior systemic therapy, including the p one blocking antibody. If the patient has BRAF mutation. I will briefly talk to you about cohort 2 data that is the middle one that has shown on this slide. Next slide please.

On this slide, I draw your attention to the objective response rate for the patient population that we have treated in this study. I note that the patients have received, as an average, 3.3 number of prior therapy. So they're heavily pretreated patients. Overall response rate for this patient population was 36.4%. This was regardless of the location of the tumor that was resected to generate the TIL. This was across a wide range of patients, including less than 65 or over 65. This was in patients who may have progressed, for, as well as BRAF and it was regardless of BRAF mutational status. In addition, the therapy still works. Regardless of the patients PDL one status, whether it's high or low.

MARIA FARDIS: What is remarkable for us was that the median to follow up and off 18.7 months was recorded and the median DUR or median duration of response was still not reached at this time points that was reported 2020. Next slide please.

Treatment emergent adverse events are shown here, on the left hand side, you can see the adverse events over time and the signature of the one-time treatment. On the right hand side you can see treatment immersion adverse events that are over 30%. The adverse events are expected early and transient and they are resolved typically by day 10 to 14 and I also reiterate that there are no unexpected official effects as this point has been observed. In general, the adverse event profile is very consistent as input depletion instead of IL-2 regimen. Next slide please.

To summarize the data, that the overall response rate that has been seen to date is 36.4% median duration of response has not been reached at 18.7 months of median study follow up. We also have Covert 4 data, which is our pivotal program and early overall response rate was reported at 32.4% at 5.3 months of median study follow up. On the right hand side, I draw your attention to what is available for these patients, typically chemotherapy would be their available option with an overall response rate of four to 10% and these patients typically have an overall survival of 7-8 months per literature. Next one, last slide please.

Thank you. Before I conclude I wanted to show this step, that the patient undergoes in the lifileucel treatment regimen. First of the patients' tumor was resected occurs either as an inpatient or outpatient basis. During the 22-day manufacturing process, the patient returns home. Seven days before the lifileucel infusion, the patient undergoes lymph depletion. This is lymphodepletion with lifileucel regimen likely inpatient. Per centers standards, lifileucel infused through into intravenous infusion administered either peripherally or essentially primarily inpatient setting and following lifileucel infusion the patient receives a short course of IL-2 for up to three days that the patient profile to label to support the migration anti-tumor sites toxicity and persistence of the empty TIL, not force antineoplastic affect the patient remains and patient for treatment and monitoring have any adverse events per provider. In conclusion, ICD- 10-PCS procedure codes are needed to identify the inpatient Administration of lifileucel so as it is not otherwise identified through currently available codes. Thanks for your attention.

PAULA DUPEE: Thank you, Dr. Fardis. And now we ask that you use the raise hand feature. If you have a question and the moderator will open your mic.

ISAAC FISHER (Moderator): Currently, there are no raised hands.

PAULA DUPEE: Thank you. Give it a few more seconds before we move to coding options. Again, if you have any comments or questions, please use the raise hand feature.

Okay. At this time, I would like to direct your attention to page 26 of the agenda and handouts for the coding options. Current coding. There are no unique ICD- 10- PCS codes to describe the administration of lifileucel. Facilities can report the intravenous administration of lifileucel with one of the following ICD-10-PCS codes: 3E033GC and 3E043GC.

PAULA DUPEE: Coding option. Option 1, do not create new ICD-10-PCS code for intravenous administration of lifileucel. Continue using current codes as listed in current coding.
Option 2, create a new code in Section X new technology table XW2 Transfusion, to identify intravenous administration of lifileucel. And Option 3, create new codes in Section X new technology table XW0 introduction, to identify intravenous administration of lifileucel. CMS is

seeking input from the audience. The interim coding advice is to continue using current codes as listed in current coding

And again, we are going to open up the floor for comments using your raise hand feature.

ISAAC FISHER (Moderator): We have one. One question.

ISAAC FISHER (Moderator): Caller, you can ask your question.

JEANNE YODER: Hi, this is Jeanne Yoder contractor to the defense health agency, and I know that that I really like this if as a coder to have everything in one place, because there's so many technicalities now it just makes it easy. The issue is sometimes these products are approved as drugs and sometimes they're approved as biological and so if an analyst is trying to find all of the biologicals and they see this except blood or blood products that's this they're going to say that doesn't belong here.

So I will send in if you could consider putting like in the definition and extend a definition for transfusions putting in blood products not excluding blood derived modified products or something like that so that an analyst is trying to connect all of the, the whole hospitalization together and you can find and understand where the products that are FDA approved is biological would really go down into this introduction and then also change that somehow. Though right now it says, except blood or blood products somehow we have to put in there to include blood derived modified products not to, you know, except straight up blood or blood products. So I'll send something and I have to think about it. Thank you.

PAULA DUPEE: Thank you Jeanne.

PAULA DUPEE: Moderator, do we have any other questions or comments?

ISAAC FISHER (Moderator): Yes, Sue Bowman.

SUE BOWMAN: Yes, this is Sue Bowman from American Health Information Management Association based on our previous discussion of some other therapies. I, I actually for Option 3 even more than in our previous discussions because this seems even less like a conventional blood or blood products, since it's actually tumor derived than the other therapies we were talking about.

My second question though is, in regard to the request for an April 1 implementation, I believe the criteria for that require that a clear and convincing case be made that it can't wait until October to be implemented, and I, I guess I haven't really heard that yet.

SUE BOWMAN: It's especially since it sounds like the NTAP application would be for FY 2022 so it's not clear to me why this code would need to be created on April 1, rather than waiting until October 1. If someone could address that.

PAULA DUPEE: Thank you Sue for your comment. We have many factors to consider regarding the April 1 implementation. I don't know. Mady, want to add more to that?

MARILU HUE: Yes, Sue you are correct that the criteria is that the requestor must make a strong and compelling case as to why the code is needed effective April 1 versus the October 1 implementation. So again, it's encouraged for participants to submit comments again by October 9th expressing support or opposition for the April 1 implementation and then of course by the November 9th date for an October 1 implementation.

PAULA DUPEE: Thank you, Mady.

JUGNA SHAH: Hi, this is Jugna Shah for ASTCT. I just want to address the point about the, you know, calling this a drug or a biologic and I think a lot of people will appreciate that. These things are called lots and lots of things. Cell therapy, immunotherapy, immune effector cell therapy trials, biologic etc. I don't think it's ever called a blood product as we heard the clinicians earlier say. So, I think the definition of XW0 since the introduction says putting in for on a therapeutic right and that goes on substance. I think the word therapeutic there helps us and takes care of the XW0, except for blood or blood products. So again, I think that's who works in this case as well thank. Thank you.

PAULA DUPEE: Thank you, Jugna. At this time, to keep on our time limit. We are going to move to the next topic if you're following along, we are on page 28 of the agenda and handout packet Administration of Idecabtagene vicleucel. There's currently no unique ICD-10-PCS code to describe the administration of Idecabtagene vicleucel a B- cell maturation antigen directed chimeric antigen receptor CAR T- cell therapy. This is, the requestor intends to submit a new technology add on payment application for fiscal year 2022 consideration, and the requestor is seeking implementation of ICD-10-PCS code on April 1, 2021. At this time I would like to introduce Dr. Agarwal, the global disease lead at Bristol Myers Squibb.

Dr. Agarwal, are you on the line? I know he was on the call earlier.

AMIT AGARWAL: Can you hear me?

PAULA DUPEE: Yes, we can hear you toggle on and we have the slide deck up. And when you're ready, we can proceed.

PAULA DUPEE: Dr. Agarwal, are you ready?

ISAAC FISHER (Moderator): He is unmuted.

AMIT AGARWAL: Can you guys hear me? Yes?

ISAAC FISHER (Moderator): Yes, sir. Okay.

AMIT AGARWAL: Sorry about that. Alright, I'll go ahead and start. So good morning everybody. My name is Amit Agarwal and I'm the global disease lead for multiple myeloma at

Bristol Myers Squibb. I would like to thank the community for giving us the opportunity to present a request for new ICD -10 code, for the administration Idecabtagene vicleucel that I will call ide-cel for the rest of the presentation. Next slide please.

Before I start talking about ide-cel I would like to provide a quick introduction on multiple myeloma. This is a cancer of a type of white blood cells called the plasma cells, the cells normally produce antibodies as part of the body's immune system. Annually, there are more than 32,000 new cases of multiple myeloma diagnosed in the US and in 2020 more than 12,500 patients are anticipated to die from multiple myeloma. This is a disease of older individuals with an average age of diagnosis of 69 years. The disease is characterized by a specific set of clinical features that involves the skeletal system, the kidneys and the blood system. Next slide please.

What makes multiple myeloma such a huge medical problem. A hallmark of the disease is a limiting relaxing course in the face of treatment. Patients will typically respond to their initial therapy which leads to remission plateau, which is invariably followed by relapse. Typically, multiple relapses lead to low likelihood of deep responses and overall poor durability. Multiple Myeloma remains incurable and the vast majority of patients succumb to the disease. I'll draw your attention to the highlighted box that shows that only the lines of relapse survival is usually measured in months for these patients. Next slide please.

In this context ide-cel has been studied for the treatment of these patients, the proposal indication for ide-cel is for the treatment of adult patients with multiple myeloma who've received at least three prior therapies including an immunomodulatory agent, a proteasome inhibitor and an anti-CD 38 antibody. These are conventional therapies that are using the treatment of these patients today. Ide-cel was granted orphan drug designation in May of 2016 and break through therapy designation in November of 2017 a BLA application was filed in July of 2020 and FDA approval is anticipated in the first half of 2021. Next slide please.

A little bit of a background on the drug product itself. Ide-cel is an autologous BCMA- directed CAR T-cell product which is manufactured by genetically modifying the patient's T cells. BCMA is an attractive target for CAR T-cell development in myeloma because its expression is largely restricted to plasma cells and mature B cells. The expression is fairly uniform, universal on myelomacells and the illustration on the right shows a typical CAR protein, which will be expressed on the surface of T-cells. It consists of a BCMA directed extracellular domain, while the intracellular portion is made up of 4-1BB costimulatory domain and a CD3 –zeta activation domain. When I said expressing the CAR encounter the cancer cell that is expressing BCMA, activation and proliferation of these T-cells is triggered, which leads to an immune mediated killing of the cancer cell. Next slide please.

AMIT AGARWAL: How is ide-cel administered to these patients? Ide-cel is expected to be administered primarily in the hospital inpatient setting, as a standalone procedure. Ide-cel is given as a single treatment administered through the central or the peripheral line vein when the product is provided in one or more infusion bags, which will be taught at the site, and infused by gravity.

AMIT AGARWAL: After infusion, the patient is closely monitored for adverse events like cytokines release syndrome and neuro toxicity. After discharged from the hospital the patients are required to stay in close proximity to the qualified treatment center for at least four weeks. Next slide please.

I would now like to share a clinical experience on the clinical study referred to as the KarMMa study. The study enrolled 140 patients who had relapsed and refractory multiple myeloma with at least three prior regimens. After enrollment patients who underwent apheresis similar to other CAR T products and had the option of receiving bridging therapy, while the product was being manufactured. Once the product was ready, patients received Elin for depleting regimen of through data been inside toxin, or three days. Following two days of rest, patients tendencies is an infusion. These patients were given target doses of ide-cel ranging from 150 to 450 million CAR T positive cells. This trial had more than a third of patients were older than 65 reflecting a robust representation of that population in this trial. The primary endpoint of the study was overall response rate. Next slide please.

Looking at the efficacy of this treatment, I'm showing the response rates by each of the target those who studied. I will draw your attention to the two columns on the right, the response rate in the 450 million dose cohort was noted that 82% with a 39% CAR rate and across all doses, the overall response rate was noted at 73% within 33% CAR rate. It's important to point out that these kinds of responses are essentially unheard of in this disease setting outside of the CAR T trials. Also important to point out that a clinically meaningful efficacy was noted in patients over the age of 65 in this trial. Next slide please.

Moving to the adverse events seen in the study. As Dr LeMaistre and Komanduri mentioned earlier, a common side effect that we usually see with these kinds of therapies is related to cytokine release syndrome and neuro toxicity. Looking at the CRS events. We know that 84% of patients in the study had any great CRS of which about 5% was grade three or higher. In the 450 million dose cohort CRS was seen in 96% of the patients, but almost all these events were grade one or two with 6% patients experiencing grade three event and no grade four or five events noted. Looking at neurotoxicity, we note that the overall incidence of neuro toxicity is 80% which is lower than other CD 19 director CAR T products. This reflects the unique nature of the product as well as the disease setting where this is being tested. Next slide please.

Just quickly looking at the other adverse events, it appears that a drop in the blood count in the form of neutropenia and thrombocytopenia commonly noted patients required an average of two months to recover from the neutropenia requiring monitoring and support. Infections were noted in two thirds of the patients and included bacterial, viral and fungal infections. Five deaths were reported within eight weeks of itis or infusion, two of which were related to disease progression. Next slide please.

In conclusion, I hope that have demonstrated that multiple myeloma remains a significant unmet medical need.

AMIT AGARWAL: In this context, either sell is a BCMA directed CAR T-cell therapy which can recognize my role ourselves and mountain immune response to the cells. In triple expose

relapse and reflecting multiple myeloma patients. I decided, as demonstrated deep and your responses with a predictable safety profile. There is currently no unique ICD-10 code to describe the administration of ide-cel and BMS requests that a unique code we created for this. With that, I thank you for your attention and happy to take any questions.

PAULA DUPEE: Thank you, Dr Agarwal. if you'd have a clinical question for Dr. Agarwal, please use the raise hand feature. Moderator, can you let us have a question

ISAAC FISHER (Moderator): Yes, we have one question. Sue Bowman.

SUE BOWMAN: Yeah, Sue Bowman from the American Health Information Management Association, similar to my question in the previous proposal, I was just wondering what the rationale is and I thought maybe the presenter could answer this for requesting the code for an April 1 implementation since the NTAP application would be for FY which wouldn't be until October 1, 2021. So, I was wondering why a code would be needed in April.

AMIT AGARWAL: Yeah, I can provide our perspective on that. So as I mentioned in my presentation. We have already submitted the BLA application and with the client timelines. We're expecting to have approval and the first half of 2021. And so with that, we will request. that this be created for the April cycle.

PAULA DUPEE: Thank you, Dr. Agarwal.

PAULA DUPEE: Moderator, are there any other questions?

ISAAC FISHER (Moderator): No one.

ISAAC FISHER (Moderator): No more questions at this point.

PAULA DUPEE: Okay, thank you. You're welcome. So at this time we're going to move to page 29 of the agenda and handout for the coding options. There are no unique ICD-10 codes to describe the administration. Facilities can report the intravenous administration with one of the following ICD-10-PCS coding options as follows. Option 1, do not create new ICD-10-PCS code for intravenous administration of continue using current codes is listed in current coding. Option 2, create new codes in Section X new technology table XW2 transfusion to identify intravenous administration of it to capture and Option 3 create new codes and Section X new technology table XW0 introduction to identify intravenous administration of idecabtagene vicleucel so CMS is seeking input from the audience. Interim coding advice, continue using current codes is listed in current coding and we will open the floor up for questions or comments on the coding options.

AMIT AGARWAL: This is Dr. Agarwal. Again, just, I think, you know, very much consistent with the previous discussion and comments from Bristol Myers Squibb perspective, I think we would we would request this be categorized in the Option 3 category as XW0. And again, this is very consistent with the previous discussions we've had on this topic.

PAULA DUPEE: Thank you Dr. Agarwal for that.

ISAAC FISHER (Moderator): There are no other questions or comments indicated by the raise hand.

PAULA DUPEE: Thank you, moderator. Will give it a few more seconds, and then we will move to the next topic.

PAULA DUPEE: Alrighty and Moderator, you still don't have any?

ISAAC FISHER (Moderator): Still no response.

PAULA DUPEE: Okay, gotcha. Thanks for that. So there's none. Let’s move to the topic administration of Narsoplimab.

MICHELLE JOSHUA: Good morning. Can everyone hear me?

MICHELLE JOSHUA: Yes, wonderful. Good morning, my name is Michelle Joshua, if you're following along in the agenda and handout. We are now on page 30, Administration of narsoplimab. The issue is currently there are no unique ICD-10-PCS codes to describe the administration of narsoplimab. This is a new technology add on payment application or will be for the fiscal year 2022. At this time. Dr. Lawrence Kovalick will be presenting the topic.

MICHELLE JOSHUA: We have Dr. Kovalick on?

LAWRENCE KOVALICK: Good morning.

MICHELLE JOSHUA: Good morning.

LAWRENCE KOVALICK: Can you hear me?

MICHELLE JOSHUA: Yes, we can hear you.

LAWRENCE KOVALICK: Now, great. And I'm Dr. Lawrence Kovalick from Omeros thank you for your time today. We'd like to discuss a unique and specific procedural code request for narsoplimab. Next slide please.

Narsoplimab is a fully human monoclonal antibody with a unique mechanism of action that targets MASP-2 effector enzyme of the lectin pathway of the complement system.

LAWRENCE KOVALICK: It's important to note that MASP-2 inhibition does not interfere with the antibody antigen depending classical compliment activation pathway, which is a critical component of the acquired immune response to infection. Narsoplimab prevents complicated mediated inflammation and endothelial damage while leaving intact innate immunity. The FDA

has granted in our supplement breakthrough therapy designation and orphan drug designation. Next slide.

What you see on the right hand panel is a diagram of a compliment system, a key component of the body's immune response. There's the classical pathway. The antigen antibody mediated immune response. The alternative pathway responsible for signal amplification and the lectin pathway, which is inhibited by narsoplimab. Narsoplimab also demonstrates and effect on prothrombin and the coagulation cascade while leaving the classical pathway of compliment mediated immune function fully intact and narsoplimab does not directly affect alternative pathway mediated immune function. Next slide please.

Hematopoietic stem cell transplant from thrombotic microangiography or HSCT TMA is a serious life threatening complication of HSCT, where studies suggest that up to 39% of patients who undergo allogeneic transplant will develop TMA. The Center for International Blood and Marrow Transplant Research (CIBMTR) estimates that there were over 9000 allogeneic transplants in 2018 in the United States 36% were in patients greater than 61 years of age. You can see the data on the bottom of the slide where approximately 90% of severe cases can be deadly. It's important to note that HSCT TMA has no approved treatments. Next slide please.

Then narsoplimab phase two pivotal registration data were presented in June at the European Hematology Society Annual Congress. As listed on the slide, the primary efficacy endpoints are laboratory marker improvement and clinical status improvements. The intent to treat analysis of all treated patients demonstrated a 54% complete response rate. Patients treated per protocol receive greater than equal to four weeks of dosing showed a 65% complete response rate. Next slide please.

The secondary endpoint was 100-day survival following HSCT TMA diagnosis. 68% of all treated patients demonstrated a 100-day survival. Patients treated per protocol showed an 83% 100-day survival and 93% of patients were treatment responders. Next slide please.

The most common adverse events are listed in the table. As you can see on the right hand panel, I'd like to direct your attention to the third bullet where adverse events were consistent with those seen in this population. Narsoplimab was very well tolerated in this very sick patient population with multiple comorbidities. The observed adverse events are comparable to those typically seen in the post-transplant population. Six patients died during the trial, all due to causes common of HSCT and complications of malignancy, and not due to narsoplimab. Next slide please.

Preparation and administration of narsoplimab is dosed at four milligrams per kilogram its diluted by healthcare professional in an infusion bag administered over 30 minutes. There are no anti-microbial preservatives and the infusion should be kept at room temperature. Next slide please.

LAWRENCE KOVALICK: Documentation of administration. Narsoplimab administration should be documented consistent with other intravenous infusions in the physicians' orders, medication administration record, or the progress notes. Next slide please.

As we discussed HSCT TMA is a serious complication that can be fatal. There are no currently approved treatments for HSCT- TMA and narsoplimab is currently pursuing an indication for treatment of HSCT-TMA. Currently, there are no ICD-10 codes appropriately describing the administration of narsoplimab. Without unique ICD-10 codes administration of narsoplimab to HSCT TMA patients cannot be identified and tracked nor can the disease be fully characterized. An ICD-10 code allows for tracking of direct efficacy and side effect profile. This is especially important where everything transplant related is documented by CIBMTR for these critically ill patients. We're requesting that CMS provide a unique and specific procedural code for narsoplimab. Thank you for your time. Are there any questions?

MICHELLE JOSHUA: Moderator, do you see any questions for Dr. Kovalick?

ISAAC FISHER (Moderator): Currently, there are no questions.

MICHELLE JOSHUA: Thank you. We'll move on to the coding options.

Current coding options include codes 3E033GC Introduction of other therapeutic substance into peripheral vein and code 3E043GC Introduction of other therapeutic substance into central vein. Coding options include Option 1, do not create new codes for narsoplimab. The intravenous administration of Narsoplimab may continue coding as listed in the current coding on page 30. Option 2 create new codes in Section X new technology to identify intravenous infusion of Narsoplimab using table XW0. CMS recommends Option 2 creating new codes in Section X, new technology to identify the administration of narsoplimab. Are there any questions regarding coding options?

ISAAC FISHER (Moderator): There are no questions.

MICHELLE JOSHUA: Okay, thank you very much. Thank you again to Dr. Kovalick.

We will move on to the next topic, which is embolic protection if you're following along in your agenda that topic occurs on page 32. The issue is whether or not we should create new codes, ICD-10-PCS code in Section five for extracorporeal or systematic systemic rather assistance and performance to describe temporary intra operative embolic protection. This is not a new technology application and FDA approval is not applicable to this topic.

To give a bit of a background several embolic protection devices are available to capture and remove debris that may dislodge during interventional procedures with the intent to reduce the incidence of adverse events. Effective October 1, 2017, ICD-10-PCS procedure code X2A5312 Cerebral embolic protection dual filter innominate artery and left common carotid artery, percutaneous approach, new technology group 2 was created to describe cerebral and embolic protection using the sentinel device.

MICHELLE JOSHUA: Effective October 1, 2019 ICD-10-PCS procedure code X2A6325 Cerebral embolic filtration, single deflection filter, in the aortic arch, percutaneous approach,

new technology group 5 was created to describe cerebral embolic protection using the Triguard system.

Current Coding is as described above for those two devices. There's currently no ICD-10-PCS code in Section 5 extracorporeal or systemic assistance and performance to describe temporary intraoperative embolic protection during peripheral vascular system procedures or for procedures that utilize cerebral embolic protection systems other than the two described above; the sentinel device and the Triguard device.

Our current coding options as I just described are just for those two devices. Coding options include not to create any additional codes. Option 1, rather, is to not create any additional code. Option 2 would be to create a new code in table 5A0 as listed on page 32 where we would add for the duration option A intraoperative for function adding zero filtration and no qualifier.

Option 3 would be to create columns in table 5A0 the same table, adding option A for intra operative adding option zero for filtration and for the qualifier. We would add option E for head and neck arteries and option J for extremity arteries. At this time, CMS is seeking input from the audience.

Do we have any input from the audience regarding cerebral embolic protection and the creation of codes?

ISAAC FISHER (Moderator): We have one person.

ISAAC FISHER (Moderator): Lynn, you may speak.

LYNN KUEHN: Thank you. Lynn Kuehn at Kuehn Consulting.

LYNN KUEHN: I am actually happy to see this because I have coders who are very frustrated with me when I tell them that other types of filters cannot be coded, yet these new technology filters can be coded and they think that I must be missing something. And I personally like Option 3 to identify the ones that are head, neck, versus extremity and I think those are the best qualifiers. I see these for carotid and for femoral and again coders are frustrated why some and not the others get coded.

MICHELLE JOSHUA: Lynn, thank you for your comment and again, please be sure to include those comments in writing during the comment period. We appreciate your comments.

ISAAC FISHER (Moderator): We have Linda Holtzman

MICHELLE JOSHUA: Good morning, Linda.

LINDA HOLTZMAN: Good morning, Miss Joshua.

LINDA HOLTZMAN: So if I understand correctly, we're looking to create what you would call for example a generic code for embolic protection, is that correct?

MICHELLE JOSHUA: That is correct. Okay.

LINDA HOLTZMAN: I agree with Lynn. It does get confusing sometimes that you code embolic protection when certain devices are used, then you don't code them but embolic protection for others. So I think it's a good idea to have a generic code. I'm curious though what happens with the existing codes that are currently in Section X. There are two that you mentioned in the proposal. There's a third one going into effect, October 1st and I wish to note in the interest of full disclosure, that I worked on the proposal for the third one going into effect on October 1st.

MICHELLE JOSHUA: Go ahead Mady

MARILU HUE: Yeah, I was just gonna jump in. So later today, we actually have the Section X update and we'll be discussing the one code that Michelle has referenced that's specific to the new technology group 2, but just to provide a little bit more background and context for why this came up. It is exactly for the reasons, both Lynn and you, Linda, have mentioned.

That because we have these existing Section X codes, now when coders see the other filters, they're questioning, you know, should they be coded and how, because the appropriate code may not be currently available. So this issue is brought up, you know, to first determine if the industry felt that it would be helpful to code these because in the past we haven't.

The concept of these filters has been around for many, many years and we did not code these until the New Technology Add-on the policy came up. So it was really, you know, a twofold type of proposal to again first see if, if the need seems to be there, if the industry wants it is that, you know, feels that beneficial to collect the data and then also depending on the information and the qualifier how relevant it would be to specifically identify those body parts. So just, again, to answer your question, Linda we will be talking about the other section X code later this afternoon, after lunch.

LINDA HOLTZMAN: I will await that discussion with great interest. Thank you. But I just want to follow up by saying that it's true, embolic protection has been around for a long time, but it is an important component of these procedures and I would like to see it coded separately.

MICHELLE JOSHUA: Thank you, Linda.

ISAAC FISHER (Moderator): We have Sue Bowman.

SUE BOWMAN: Yes, Sue Bowman from AHIMA to follow up on Linda's question, it's not clear to me, it sounds like we're planning to keep the Section X codes, because they have specific purposes. However, I am not a fan of having two different ways of coding the same procedure in PCS, which if we keep, you know, the Section X codes, then that's the situation we would end up with, which I think is very concerning.

MICHELLE JOSHUA: Sue thank you for your comment please be sure to include those comments in writing and we will take them into consideration.

ISAAC FISHER (Moderator): We have, we have Linda Holtzman

MICHELLE JOSHUA: Ms. Holtzman

LINDA HOLTZMAN: I'm back. Just to follow up on Sue's question that was actually one of the reasons why I asked. Because this will create something in two different places, you know, for the same, for the same product or the same component of the procedure. So it does get frustrating trying to move back and forth. I recall that in the proposal that I worked on last time for the extracorporeal flow reversal circuit that we proposed either Section X or 5A0 and either one of them would have been fine. It went to Section X, which was fine, but I can see all of this moving to 5A0 if we want to describe these specifically and it would be worth describing specifically.

MICHELLE JOSHUA: Thank you.

ISAAC FISHER (Moderator): We have Sue Bowman.

SUE BOWMAN: Yes. And just to respond to Linda's comment, in case it wasn't clear from my earlier comment, that's actually what I would support because otherwise I think there's going to be a lot of confusion and miscoding of these procedures so I recognize the value of capturing this in circumstances beyond what is captured in the existing Section X codes. But in that case I'd rather that all of the embolic protection codes move to 5A0 so it's very clear which code, you assign, for which circumstance, and they're all there together and there's no confusion.

MICHELLE JOSHUA: I understand. Thank you very much.

ISAAC FISHER (Moderator): We have one more. And that would be Lynn.

LYNN KUEHN: Hi Lynn Kuehn, Kuehn Consulting, I agree with all of that, but for the product that Linda's talking about, I think we need a different way to describe that one where the filter is on the outside of the body as extra corporeal versus these other filters that we see, which are actually in-line filters in the artery. While the procedures going on because that feature of that new one makes that a totally different, you know, the one with the long name the flow reversal circuit. I believe things should be moved to 5A0 but with the difference between those two types of filters indicated somehow in the function, I would assume.

MICHELLE JOSHUA: I understand, thank you very much for clarifying and adding to your comment.

ISAAC FISHER (Moderator): There are no more questions or comments at this time.

MICHELLE JOSHUA: Thank you. That concludes the embolic protection topic and we will move on to the next topic.

PAULA DUPEE: Hi. Good morning. Again, this is Paula Dupee again and we are moving to page 34 of the agenda and handout packet for the topic Single Use Duodenoscope during endoscopic retrograde cholangiopancreotography ERCP procedures. There's currently no unique ICD-10-PCS code to describe single use duodenoscope during ERCP procedures. The requestor intends to submit a New Technology Add-on payment application for fiscal year 2022 and at this time I'm going to welcome Dr. Brian Dunkin, the chief medical officer with Boston Scientific Endoscopy. Dr. Dunkin, do we have you on the line?

PAULA DUPEE: I know he was on earlier.

PAULA DUPEE: Moderator, do you see Dr. Dunkin?

ISAAC FISHER (Moderator): Yes, Dr. Dunkin should be available to speak now. Okay.

BRIAN DUNKIN: Good morning, everybody. Can you hear me? It's Brian Dunkin.

PAULA DUPEE: Yes. Good morning, Dr. Dunkin, we can hear you.

BRIAN DUNKIN: Hey. Thank you, Paula. So I'm going to spend a little bit of time describing into this topic and discussing ERCP a bit. As Paula mentioned, I am the Chief Medical Officer for Boston Scientific endoscopy division and I'm a therapeutic endoscopist myself and I've done many ERCP throughout my career. Next slide.

By way of background endoscopic retrograde cholangiopancreatography ERCP is an advanced therapeutic and diagnostic procedure that allows us to access the bile duct or the pancreas duct and to treat diseases there. So on this color graph the bile duct is that green tube. It connects our liver to our intestinal tract and allows the liver to deliver bile to the intestine, which we use to digest food and then that yellow serpentine tube connects the pancreas to the intestine as well and delivers pancreatic enzymes.

Both of those tubes come together via a common channel and then enter into the sidewall of the duodenum, the first part of the small intestine. The stomach is connected to via papilla, a small opening and it's that papilla that allows us access to these ducts and to allow us to treat diseases, there. It's a complex endoscopic procedure but done commonly at least 700,000 of these are done per year in the United States alone and they're done on both an inpatient and outpatient setting. Next slide.

This is a partial laundry list, if you will, of the diseases that are treated with ERCP. That fourth bullet point, choledocholithiasis, those are stones that that come from the gallbladder and enter the bile duct. That's probably the most common indication. But you can see there's a wide variety of diseases from cancer that's either in the biliary tract or in the pancreas different growths in tumors, strictures, leaks and fistulas, as all of these can be managed using ERCP. Next slide.

BRIAN DUNKIN: Now, the way the procedure works is that a patient is taken to a specialized endoscopy suite. So it's typically done away from the O. R. and in the endoscopy unit of a hospital. That unit is special in that it has the ability to both do endoscopy, as well as flouroscopy, so x ray guidance is used during the procedure simultaneously with the endoscope. This specialized endoscope that we use is called a duodenoscope and once the patient is either deeply sedated or under general anesthesia, we pass that scope through the mouth down the esophagus across the stomach and into the first part of the intestine that duodenum and locate the papilla opening of the bile and the pancreas duct.

The duodenoscope has a working channel within about a four millimeters in diameter hollow tube that allows us to pass a whole variety of instruments up through the papilla and into the bile or pancreas duct. And typically, we'll start by passing a catheter down that working channel up into the papilla. We call that cannulating the papilla and then we'll inject contrast die that we can see on X-ray guidance, which gives us an outline of the bile duct or the pancreas duct and identifies any pathology there and then depending on what we're there to treat, we can actually use tools to widen the capillary opening so that we can remove stones or take biopsy samples or deliver a stent up into the duct to relieve obstruction. After the procedure is done, thankfully, this is typically a painless procedure so patients recover quickly and then they can go either back to their hospital room or be discharged from the hospital that same day, if that's where they came from, a home setting. Next slide.

Now ERCP, up until late in 2019, was always done using a duodenoscope that was reprocessed between procedures. So this is a reusable duodenoscope and then it goes through a disinfection process between patients so it's clean and ready for the next patient. Beginning in 2013, FDA became aware of problems with this reprocessing. And in fact, a significant number of patients were getting endoscope acquired infections related to bacteria that was still present on the scopes after they had been reprocessed. The scopes are particularly complex. This scope in particular, the duodenoscope has an elevator at its tip, which is basically a movable ramp, that allows me to move my instruments up and down while I'm trying to cannulate that the papilla and a few things have been learned about this infection problem since the FDA first became aware.

First of all, studies were done by the manufacturers of the different reusable scopes to define the magnitude of the problem. And what's become known is that one in 20 patient ready endoscopes that have been reprocessed really using best practices and company guidance still harbor pathogenic bacteria that can cause disease in patients and typically these bacteria are Klebsiella, Pseudomonas, or E-coli and they can manifest as infections in patients in a variety of ways. Typically, it can be away from the pancreas or bile ducts. So patients showing up with pneumonia or urinary tract infections or infections around the pancreas that are kind of progressive and have led to death. And so the other thing that's been learned about this is that while initial focus was on this elevator mechanism, which is really what differentiates a duodenoscope from others.

This is really a biofilm problem and infects the entire endoscope from stem to stern. Biofilm is a syrupy type substance that bacteria make and use to protect themselves from their environment and really any internal wet surface of an endoscope forms biofilm and makes it difficult to clean these bacteria away. It's for this reason that in August of 2019 the FDA recommended that

endoscopists, like myself, begin a transition away from reusable endoscopes to disposable devices which included the use of a disposable duodenoscope. Next slide.

BRIAN DUNKIN: So for us at Boston Scientific we wanted to deliver a comprehensive solution to this problem. And that led to the development of a single use duodenoscope which we call EXALT model D. So this is a scope that functions exactly like a reusable scope, it looks, feels and functions the same. Boston Scientific is really a leader and making devices used in ERCP, the devices that go down networking channel and so we have an understanding of the nuance of the procedure and didn't want to change the procedure by introducing an endoscope that functions differently. And so this scope is meant to function exactly like a reusable Duodenoscope. This device has received FDA clearance in December of 2019 that was associated with breakthrough designation and it's been commercially available since December of 2019. Next slide.

So we've done a lot of work, including the regulatory work that's required by the FDA to ensure that this device functions the way it's supposed to. But also work that wasn't required by the FDA. In order to be as sure as we could be that this device could be used to perform a whole variety of ERCP of different complexities. This is a study that we supported, it was a clinical trial examining the utility EXALT model D in doing at six major academic medical centers. And what they found was that not only were they able to use the endoscope the way they would use a reusable endoscope and successfully perform these procedures.

But that's the adverse events that they were seeing such as post ERCP pancreatitis or post sphincter automate bleeding are in line with what you would see what the reusable scope in the same patient population. So, and that's helped assure the medical community at this device. Not only has its utility but functions in a safety profile, similar to that the reusable duodenoscopes. Next slide.

So that's really what's leading us to this discussion. There is no existing ICD-10 code that uniquely identifies the use of a single use duodenoscope and allows for accurate reporting and outcomes tracking and so that's why we're having this discussion is presentation today. So thank you again for the opportunity to present and I'm happy to answer any questions.

PAULA DUPEE: Thank you, Dr. Dunkin. Moderator, do we have any questions or comments for Dr. Dunkin's clinical presentation?

ISAAC FISHER (Moderator): There are no questions at this time.

PAULA DUPEE: Thank you give it a few more seconds. If you have a question from Dr. Dunkin's clinical presentation, please use the raise hand feature.

ISAAC FISHER (Moderator): No questions.

PAULA DUPEE: Okay, thank you.

PAULA DUPEE: At this time, we're going to go ahead and proceed to page 35 of the agenda in handout packet for the coding options. Coding Option 1, do not create new codes to identify single use duodenoscope in endoscopic pancreaticobiliary system procedures. That's a mouthful.

I'm sorry. Let's start off with current coding, so we're going to go back a little bit. Current coding. Do not separately report the use of a single use duodenoscope in endoscopic pancreaticobiliary procedures. Report the applicable ICD-10-PCS pancreaticobiliary system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic. Facilities may choose to report the radiologic portion of the ERCP procedure with a code from Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas.

Coding options as follows. Option 1 do not create new code to identify single to identify use of single use duodenoscope and endoscopy. Option 2, create new codes and Section X new technology to identify use of single use duodenoscope in endoscopic pancreaticobiliary system procedures. Separately assign the applicable ICD-10-PCS system approach using approach value eight be a natural or artificial opening endoscopic is listed in current coding. Facilities may choose to report the radiologic portion of the ERCP procedure with a code from imaging section table BF1 fluoroscopy of hepatobiliary system and pancreas.

CMS recommendation is option 2 as described above. Interim coding advice. Continue to code as above under current coding. Please use the raise hand feature for comments or questions on the coding options.

ISAAC FISHER (Moderator): We have one person, Jeanne.

ISAAC FISHER (Moderator): There you go. You can speak no please.

JEANNE YODER: Hi, Jeannie Yoder, Defense Health Agency. I'm a contractor. Um, I, I missed the part where the coders would find this documented so that they could pick it up and I'm kind of concerned about that because as an analyst, I will have other analysts contact me and say, Hey, you know, we have this question from Congress saying how many people are using doing this and I'll say, and so that I found this code. And, um, and then I'll have to tell them all. The code might be there, but just because it's there, doesn't mean it gets used. And so I'm just wondering where we're coders will find this documented. Thanks.

BRIAN DUNKIN: I'm sorry, Paula should I answer?

PAULA DUPEE: Okay, sure.

BRIAN DUNKIN: Yeah, so in the documentation for our procedures, particularly when we're using electronic documentation, which has really become universal, we're actually required to document what scope was used for that procedure and each has a unique identifier. So I would expect that that's where the, the type of doing duodenoscope would be identified.

PAULA DUPEE: Thank you, Dr. Dunkin.

ISAAC FISHER (Moderator): There are no other questions though here's Jeanne. Jeanne has another question.

JEANNE YODER: Again, and you said it was in your electronic health record and I don't believe that they're, they're all the same. So, are you aware? Because there are a number of electronic health records products out there. And so it is this, when you say that the specific code is listed that would infer that somebody would have to maintain a complete list of all of the different kinds of scopes unique to your facility and I know that, at least in our enterprise, the Defense Health Agency, I know we have 55 different facilities and so trying to maintain those lists would be challenging. So whenever you get a new scope you notify somebody or you just have a list of every possible scope that's out there?

BRIAN DUNKIN: Yeah so virtually every electronic documentation record that that I've used, which is, you know, everything from EPIC to probation to the different manufacturers, have a place where you have to document which endoscope that you use. And you're right, there's quite a there's quite a variety of individual endoscopes. But there are actually kind of suites of scopes that that that can help calm that down, but literally every single endoscope and every single endoscopy center has a unique identifier assigned to it. And that is then listed from a drop down menu in these electronic records.

PAULA DUPEE: Thank you, Dr. Dunkin. Moderator, do we have any other raised hands for comment or question?

ISAAC FISHER (Moderator): There are no more questions at this time.

PAULA DUPEE: Thank you. At this time, we're going to move on to the next topic in the agenda.

MARILU HUE: Hi this is Mady. We actually have a little bit of time before lunch. So I wanted to go ahead and do a little bit of CMS website 101 for those of you that may be interested because we have gotten a lot of emails this morning about not being able to locate the materials for today's meeting. So I've asked Andrea to be my driver and what you're looking at on the screen right now is what we refer to as our C & M meeting materials web page.

So this is the page where we post the agenda and handout packets prior to the meeting. It's where you would find the tentative agenda of the topics that are expected to be discussed. Now along the left hand side of the page, you can see a whole list of links, so earlier when I reference the code files, Andrea if you want to click on the ICD-10-CM files. So this is the web page where you can find all the upcoming diagnosis codes that will be effective this October 1.

So while CDC is responsible for the diagnosis code classification, we also post the files so that users of our website can have access to them as well. And also for our contractors and the public. So you can see in the Downloads section it includes the coding guidelines for the upcoming fiscal year. The list of the POA exempt codes. All the code files, the conversion table. So if you do not have this bookmark or as a favorite in your systems, you may want to consider doing that for ease of finding in the future.

MARILU HUE: Similarly, we have the 2021 ICD-10-PCS link for all the procedure code files. And many of you are aware that, in response to the COVID-19 public health emergency, that CMS implemented 12 new procedure codes. So, in the download section on this page we included those update files as Andrea is hovering over so you can find a list of codes and the information related to implementation of those codes and as it states, these codes were effective August 1, however, we still include them because they will be part of the full code set for fiscal year 2021 and again we have the procedure coding guidelines, all the code files with table and index the conversion tables, the code files that have the long and abbreviated code titles. So bookmark this page too if you don't already have it. It would just make everybody's life a lot easier if you had direct access to them.

Moving down towards the bottom again, we have some more links for the Coordination and Maintenance Committee Meetings specifically and I want to go ahead and draw your attention to our listserv. So Andrea, if you want to go ahead and click on the instructions. So the way that we communicate currently is through a subscriber list and we have the link here. So Andrea is showing it on the screen.

To sign up, you have these directions here and this will make sure that you receive important information related not just to the Coordination and Maintenance Committee Meetings, but also any type of code updates or things related to coding and possibly, the DRGs. I mentioned that we don't really discuss DRGs during this meeting, but sometimes it's just inevitable because of the overlap. So if you have not already, I would encourage you to go ahead and join our subscriber list. For example, prior to this meeting we had sent out a list serve message last Friday announcing that the agenda and handout packet was available on both the CMS website, and then for CDC's diagnosis code topics, on their website, and provided the links. So again, just to hopefully avoid any difficulties in the future, especially on the day of the meeting.

We do try our best to respond as quickly as possible. But again, because we're trying to actually conduct the meeting, it can get a little bit difficult. We do apologize for the technical difficulties that we experienced this morning. We're not quite sure what happened as far as needing the password but we believe because we are doing the audio recording and making everything available after the meeting that everybody will have the opportunity to listen to the entire meetings proceedings afterwards. Okay, Andrea, if you could go to the Classifications and Software page.

So I mentioned how when we do create new codes and specifically in the discussion regarding an April 1 that we need time to update the DRG software. So for those that aren't familiar, this is our web page, where we post the publicly available software, you do not need a license to download or use it. And that is the same for the diagnosis and procedure code files, they are in the public domain.

So we include information for the current version. So for fiscal year 2021 we are now at version 38 and it includes the Definition of the Medicare code edits. Two formats for the ICD-10 and MS-DRG Definitions Manual and then the actual Mainframe and PC software. Now a lot of you know that we issued the final rule last week and it has been brought to our attention that there is

an issue. So you are hearing that we will be issuing a rerelease of the Grouper software and Medicare Code Editor.

MARILU HUE: It is expected sometime later this week that we will go ahead and be re-releasing that. So if you have already downloaded it, you can expect a re-release to be on the way. So, at this time, I just wanted to open it up to see if anybody had any questions or comments, based on what I've reviewed so far.

ISAAC FISHER (Moderator): We have one question or comment from Lynn.

LYNN KUEHN: Um, I just am wondering if there are plans to publish a new 2021 PCS file that incorporates the August 1 codes into it, so everything is complete and together?

MARILU HUE: We can consider that if that would useful to you Lynn.

LYNN KUEHN: Well I think it would be because that is the source file that many people use if they're not concerned about capturing a DRG they use that to code from, or quickly look up codes.

MARILU HUE: You want to include that in your comments?

LYNN KUEHN: Yes, I will.

MARILU HUE: Thank you. Are there any other comments or questions regarding the information that I've given a very quick overview on?

ISAAC FISHER (Moderator): There are no raised hands at this time.

MARILU HUE: Okay. Well, as I mentioned, we are a bit ahead of schedule and in fairness to our presenters, we can't put them on the spot because they aren't available. So, you will get an extra bit of time for lunch today, and we will reconvene and begin promptly at 1:30. Moderator, do you have any instructions regarding hanging up the phone lines, keeping them open? Is there a preference?

ISAAC FISHER (Moderator): It'd probably be best to keep them open.

ISAAC FISHER (Moderator): Just don't leave. Okay.

MARILU HUE: All right.

PAULA DUPEE: One second. Um, quick question. I got a comment on how can a participant find that subscriber page that Andrea put up the first.

MARILU HUE: There's the link.

PAULA DUPEE: The listserv. I think was it the listserv page?

MARILU HUE: That was a download section. On this link on this web page and the link right there.

PAULA DUPEE: So they should be able to see that. Thanks. Mady.

MARILU HUE: Your welcome. Okay. If there are no further questions or comments, thank you everybody for your participation so far today and we will meet you back after lunch. Thank you.

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MARILU HUE: Hello. Welcome back from lunch. I hope everybody was able to use that time and fill their bellies with all the discussion from this morning, we are now getting ready to discuss Spinal Stabilization. So I'd like to confirm that Carter Lonsberry and Dr. Lawrence Rhines are on the line.

ISAAC FISHER (Moderator): Yes, Mady. Carter Lonsberry is here.

MARILU HUE: And Dr. Rhines as well?

CARTER LONSBERRY: I believe he's trying to login to the phone, he is on the computer as we speak.

MARILU HUE: Okay, great. Alright well while he's joining I'll go ahead and discuss the issue. We're on page 36 of the handouts for those following along. And the issue is that there is not a unique ICD-10-PCS procedure code to describe the insertion of a radiolucent carbon PEEK spinal stabilization device for the treatment of early or advanced stage spinal tumors. This is a request associated with the New Technology Add-on application. The requestor does intend to submit this for fiscal year 2022 consideration and the device is FDA approved. So at this time I would like to go ahead and ask Noel if she could pull up the slides for this topic. And want to check, do we have Dr. Rhines?

CARTER LONSBERRY: Not yet, he's still trying to log in, on the phone.

ISAAC FISHER (Moderator): What is the name, what is the name Mady?

MARILU HUE: Dr. Lawrence Rhines

ISAAC FISHER (Moderator): Ok, I will check for

MARILU HUE: Rhines, yes. Thank you.

CARTER LONSBERRY: If it's alright Mady, I can start.

MARILU HUE: Okay.

CARTER LONSBERRY: Perfect. Mady, Thank you. Noel, thank you and Mr. Moderator, thank you as well. My name is Carter Lonsberry I'm the CEO of icotech medical. I plan to move quickly here to provide an overview of icotech's Vader one carbon PEEK pedicle screw system so we can move to the clinical value of Carbon PEEK with Dr. Rhines from MD Anderson momentarily. Noel, if you can move to slide 2 that'd be great.

The standard of care for spinal tumor has long been fixation or stabilization with metallic implants for either open or MIS percutaneous insertion. The challenge with metallic impants is the artifact generated on radiographic imaging, CT, and MRI. This artifact or delineation on CT is the basis of radiation planning for treatment after surgery and prevents the radiation oncologist from seeing the spinal cord and potentially dose in the spinal cord which can have a which can cause myelopathy to the patient, if this happens.

This artifact from metallic implant produces scatter and has an effect on where the radiation lands and can harm healthy local tissue as well as the spinal cord, as we talked about before with myelopathy. Artifact from metallic implants has a direct impact on care after surgery for the Spine tumor patient and the multi-disciplined team, unlike degenerative trauma and deformity spine patients. We can go to the next slide.

Long strand carbon PEEK, or what we at icotech call black armor, is the carbon flow molding manufacturing process and material unique to icotech. Carbon PEEK material is available today and is ideal for tumor fixation and stabilization because it does not create artifact or delineation like metallic implants. The clear difference of the material can be seen on CT. Remember, this is the basis for radiation planning. However, there are significant benefits to the radiation oncologist and the multi -disciplined team post-operative to surgery.

This can directly be seen in the radiographic imaging, the CT and MRI. Comparative images will be seen in later slides with Dr. Rhines. Carbon PEEK benefits include the following: the ability to see to clearly see the spinal cord, planning and dosing radiation to a targeted site, proper dosing without toxicity, early recurrence detection, and the strength characteristics of that of titanium. We can go to the next slide.

Understand, spine tumor patients are very compromised. The intent at the time the surgery is fusion, but several factors like radiation, chemotherapy and patient expiration may prevent the goal of fusion. Bone graft may or may not be placed by the surgeons at the time of surgery, depending upon the technique or the goal of the surgery by the surgeon. Carbon PEEK for pedal screw fixation both MIS percutaneous and open for either stabilization or fusion, directly affects the post-operative care and opens new treatment options for the multi-disciplined team after surgery.

Currently, there is not a unique ICD-10-PCS code to adequately describe the insertion of a radiolucent carbon PEEK spine stabilization device for the treatment of early or advanced stage spinal tumors and why we're making the request of CMS. The next slide.

Here you'll see the current FDA cleared Vader one screw for MIS and open procedures. The screw itself is made of the proprietary black armor. Carbon PEEK material as is the rod.

Markers are in the distal tip for the surgeon, so he'll know where the screw placement is. And if we can go to the next slide.

CARTER LONSBERRY: The FDA approved, icotech's Vader one screw in June 2019 with a tumor only indication. In May of 2020 indication was more reasonably clarified and again only for a tumor indication. At this time, I'd like to introduce Dr. Rhines from MD Anderson to speak about the clinical benefits of carbon PEEK or spine tumors. Mady I might have to call Dr. Rhines since he is having problems calling in, so bear with me one second.

MARILU HUE: Okay, I did get a notification that he was showing as a panelist on the line.

ISAAC FISHER (Moderator): Yes, Dr. Rhines is on the line. I'm asking him to unmute now.

MARILU HUE: Great, thank you.

LAURENCE RHINES: Can you hear me?

ISAAC FISHER (Moderator): Yes, sir. We can hear you. Okay.

CARTER LONSBERRY: Thank you, Doctor.

LAURENCE RHINES: I just couldn't get through. Next slide please.

So spine tumor is not an uncommon problem. As you can see from this slide the incidence of cancer is increasing and as the cancer increases, so does the incidence of metastatic disease, spread of tumors from the primary site to other organs and after the lung in the liver, the skeletal system is the most common sight of cancer metastasis, and within the skeletal system, the spine is the most common site. So as you can see here, spine metastasis may occur and as many as certainly in the majority of patients with cancer and no matter where you practice as a spine surgeon, you're going to see these types of cases. Next slide.

So what is the role of the spine surgeon in metastatic disease or spine tumors? Well, what do we do, well? We're good at getting tumor off the nerves off the spinal cord and therefore relieving pain and neurologic dysfunction. We're also good at stabilizing a spine that's been broken, either by the tumor or by the surgery required to remove it. What we're not very good at is getting rid of all of the microscopic disease after we're done, getting rid of the disease that's likely to grow back. And so spine tumor treatment is very multi-disciplinary.

The majority of spine tumor surgeries need to be followed by radiation to mop up that microscopic disease. And our radiation oncologists have gotten really good in recent years' techniques like spine radio surgery proton beam, allow them to precisely target the tumor, avoid the spinal cord give high doses and do a very good job of preventing the tumor from coming back after we've done all that work. So as a surgeon, I think what we should be thinking about, is there anything we can be doing during the surgery to make things easier for our radiation oncologists and that may be where these carbon fiber PEEK screws come into play. For years we've been using traditional metal implants, titanium or stainless steel for our spinal

stabilizations and those work great for holding the spine together. But if you're anticipating subsequent radiation, they have some limitations.

LAURENCE RHINES: There is significant artifact and shadow around these metal implants on post- operative imaging that can make it difficult to discern the tumor versus the spinal cord and for some types of radiation like heavy particle radiation, protons for example, the middle implants can actually affect where the radiation beam is going. And one thing I can tell you about radiation oncologists is they do not like uncertainty. If they can't see tumor versus cord, if they're unsure where the radiation is going to go, they're going to reduce the dose for safety and the treatment can become less effective. Next slide.

So let's take a look at the difference between the carbon fiber PEEK screws and the traditional metal screws and I'll disclose that you don't really need to be a radiation oncologist to see these differences. On the top panel and the traditional medical metal screws. You can see the shaft with the threads and on the bottom panel the radiolucent carbon PEEK screws, you can hardly see the screw at all. In fact, really only you can see is the little marker in the tip. Next slide please.

This really becomes clear on CT scans, which is one of the two imaging modalities, we use for radiation planning. If you look at the image to the left with the radiolucent carbon PEEK screws you can barely see the screws, the delineation of the bone, the delineation of the spinal canal are crystal clear. But look at the panel on the right, where the left screw is metal and the right screw is carbon fiber. You can see the difference. You can see the beam hardening artifact around the metal screw on the left and you can see how this makes it more difficult to see and to plan your treatment. Next slide.

This becomes even more evidence on the MRI scans shown here, which are also critical to the radiation oncologist treatment planning. If you look at the paddle all the way to the left. On the left side is a metal screw and on the right side is a carbon fiber PEEK screw and you can see the difference. The left screw has an enormous halo around it. That's actually obscuring the spinal canal on that side. Imagine if there was a little nugget of tumor there, you barely be able to see it. And the next panel over that says metal on the bottom is a cervical spine image. Look at the halo the dark shadow around the implants, you can barely see where the spinal cord is. This is in comparison to the two panels on the right, and I'll direct your attention to the panel, all the way over to the far right, which shows an axial view through the spine with Carbon fiber PEEK implants. You can see that the implants are black. There's no difficulty seeing the bone and that circular area in the middle with all the staples. That's actually the nerves sitting in spinal fluid, you can see them perfectly clearly so a big difference between the imaging characteristics of the two different implants. Next slide.

So if you're a radiation oncologist, I'd ask you which type of imaging, would you rather be looking at to plan your treatment. I think that we're good. What we're going to see is that the Carbon fiber PEEK implants with their decreased artifact will make it easier for our radiation oncologist to see early recurrence of tumor to distinguish tumor from spinal cord or esophagus structures that are highly sensitive to radiation.

LAURENCE RHINES: By not obstructing or scattering the radiation. I think the radiation on colors will better be able to predict where the dose is going to go. And by being better able to see what they're treating and better able to predict where the beams are going. I think that's going to allow them to deliver a much higher dose to the tumor. Deliver lower more protective doses to the spinal cord to the esophagus structures that we don't want to radiate that we want to protect and that's ultimately likely to make the radiation safer and more effective and decrease the likelihood of local recurrence. Thank you.

MARILU HUE: Thank you, Dr. Rhines.

MARILU HUE: Your summary.

LAURENCE RHINES: Carter?

CARTER LONSBERRY: The summary. Yes. So we, again, we were asking for new codes to be created, because it is a differentiation from the metal current metal options and more to clearly define this so that we have it as a new technology clearly defined for the coding requests and so that we can differentiate this technology from metal as opposed to this was done with the nano surfaces and the radiolucent porous previously. So we're asking for the same consideration to be made for Carbon PEEK and not to be confused with that in that indication. So that's why we like the X code requests here. Again, significant to us for patient outcomes, data tracking, and clinical differentiation for tumor diagnosis that we can study as well. Thank you.

MARILU HUE: Thank you both very much. Do we have any clinical questions for Dr. Rhines or other questions? Moderator, can you check to see if anybody has selected the raise your hand feature to submit a question.

ISAAC FISHER (Moderator): There are no questions at this time. Okay, give me a minute.

ISAAC FISHER (Moderator): Still no. Go ahead.

MARILU HUE: On to the coding options at this time at the bottom of page 37 for current coding, you would currently code this procedure to place a radiolucent carbon PEEK spinal stabilization device from tables 0RH or 0SH. And that's Insertion of Upper or Lower Joint and then separately if a spinal fusion was performed, you would assign a code from tables 0RG or 0SG.

Our Option 1 is not to create new codes for the spinal stabilization device, you would continue to code as listed in current coding. For Option 2, we're proposing to create new codes in Section X to identify the use of this radiolucent carbon PEEK spinal stabilization device and again separately assign the applicable procedure code from table 0RG or 0SG if a spinal fusion is also performed.

MARILU HUE: So as you can see in the table, we would propose to add H Insertion for the root operation and the various body parts because it can be performed more than one level and we would propose to add R for Spinal Stabilization Device, Pedicle Based, Radiolucent

Carbon/PEEK. CMS is recommending Option 2 and I'll go ahead and open it up for any comments or questions regarding the coding.

ISAAC FISHER (Moderator): We have Jeanne. Jeanne has a question or comment.

JEANNE YODER: Hi this is Jeanne Yoder. I'm a contractor to the Defense Health Agency and um so I'm once again I'm looking at thinking about the, where's the documentation so that the coder will know to pick up these, these items and also will these items be having a unique identifier device identifier, or UDI?

I mean, like, because I think, will the O.R. nurse, take the little piece of paper something off of it and put it into the record? So, I mean, how did we get into the record so that the coder knows that these particular retained devices are the PEEK guys?

CARTER LONSBERRY: As far as the coder getting to know this is going to come from the surgeon and we're gonna have to educate the surgeon on the change, should it be granted, to put this into the documentation. So it would be on the surgeons notes. Thank you.

ISAAC FISHER (Moderator): We have Sue Bowman.

SUE BOWMAN: Yes, Sue Bowman from the American Health Information Management Association. My concern is that this creates duplicative way to code the same procedure unless a modification is made to the current device value in 0RH & 0SH, because right now, there was nothing. And they have code description to suggest that that's only for non-radiolucent carbon devices and I so I think there could be some misquoting and some confusion. Since the description is very similar and doesn't lift any materials to suggest that it would not include these devices.

MARILU HUE: Thank you.

ISAAC FISHER (Moderator): No other questions.

MARILU HUE: Okay.

MARILU HUE: Well, thank you for your comments. And as more of you thinking over please submit them in writing and in the interim, you would continue to code this as above under current coding. So now brings us…do we have something that would somebody raised their hand or no?

MARILU HUE: Okay.

ISAAC FISHER (Moderator): No, no.

MARILU HUE: We're moving on to page 39 of the hand out for our beloved Section X update. So, as noted on page 39 about two years ago, we announced our plans to analyze the Section X, New Technology Group 1 codes as it had been three years since the codes were implemented.

We stated that we would consider how they related to a new technology add-on payment application or NTAP, and if it was, whether or not it had been approved and then separately, the frequency in which the section X code was reported in the data. We also noted that we would propose one of the three options listed based on our analysis. So, as shown at number 1, that option is to leave the code in Section X. Option 2 would be to reassign the code to the Med/Surg or another section of ICD-10-PCS and delete it from Section X. And Option 3 would be to simply delete the Section X code that would be removed from the classification entirely.

Since that time, we have provided the findings from our analysis of the Section X New Technology Group 1 and Group 2 codes in association with the March 2019 and the March 2020 meetings to try to give time for you, the public, to review in more detail and also, to allow additional time for CMS to consider any comments that may be received after the March meeting involving the codes, and to also determine if any proposed changes should be discussed at the September meeting. As we have now shared data for the Section X New Technology Group 1 and Group 2 codes, we hope that by doing this, it's helped you, the participants, as you've hopefully been able to consider the options just mentioned earlier.

If we turn to page 40 of the handouts. We included the New Technology Group 1 codes according to fiscal year, by the frequency in which they've been reported, and we've indicated whether or not the procedure described by the code was approved as a technology with respect to the NTAP policy. So what I'm going to do is just go over a couple of examples to give you an idea of what we're proposing and how it would then potentially appear in a classification, if there is support for the proposals. For example, if we look at the first four codes describing extirpation of matter from coronary artery we see that the first procedure code showed a steady increase in the frequency of reporting over the years. However, the technology was not approved for an NTAP and it's no longer eligible.

So for those codes we would propose what we're calling option 2, to reassign them to the Med/Surg section of ICD-10-PCS and delete them from Section X. For the next two codes describing the monitoring of the right and left knee joint. We see data fluctuations with regard to the frequency of reporting over the years and that the technology was not approved for NTAP and is no longer eligible. For these we propose what we're calling option 3, to delete them from Section X and the classification.

For the next set of codes describing Introduction of ceftazidime- avibactam anti-infective we would propose option 2, to reassign them to the third section of PCS and delete them from Section X. So overall, we're basically proposing to delete all of the Section X New Technology Group 1 codes.

If you turn to page 41 of the handouts, you will see the proposed index Addenda changes that correspond to the examples that were just discussed. So for ceftazidime-avibactam, we would propose to delete the entry instructing users to look in Section X and add the new entry instructing to use anti-infective. We believe that users should already be aware to find the substance value in Section 3E0. Moving down the page, we would propose to delete the entries at letters E and O for Orbital Atherectomy Technology and at letter O, add the entry to see

Extirpation, Heart and Great Vessels in table 02C. At letters I and M we would propose to delete the two entries for intra operative knee replacement sensor. At letter N under New Technology, we would propose to delete the three entries shown.

MARILU HUE: Moving to the bottom of the page, we have displayed the substance key addenda as shown using that same example ceftazidime-avibactam. So essentially if it is felt that it would be helpful to retain references for a specific substance in the classification, we can use the Substance Key to accomplish that. So I'm going to stop for now, and see if there are any comments or questions regarding what has just been discussed.

ISAAC FISHER (Moderator): We have one from Pam.

ISAAC FISHER (Moderator): Pam, you can speak now.

MARILU HUE: Hello, Pam, are you on?

ISAAC FISHER (Moderator): I'm asking her to unmute her mic.

ISAAC FISHER (Moderator): There's no response.

MARILU HUE: Okay.

ISAAC FISHER (Moderator): That is the only question. The only hand is raised at this time.

ISAAC FISHER (Moderator): And, still no response.

MARILU HUE: I'll let that digest for a little bit. And while people are thinking over that again, the proposal would be to delete all of the Group 1 New Technology codes. Okay. It looks like a couple people have raised their hand.

ISAAC FISHER (Moderator): That'd be Moorman, Abby.

ABBY MOORMAN: Abby Moorman from Avalere Health. For some of the codes that aren't on page 41 like blinatumomab, are you proposing to just delete that for the third group? Or was it just not included on the next page because that wasn't part of the example.

MARILU HUE: Yeah, so we just wanted to include a couple examples for reference, but as I stated the proposal is to delete all of the Group One new technology codes. And as I mentioned, for any codes that involve a substance, such as, you know, the introduction or administration of the drug, yes, if it helps, to be helpful we can still reference that specific agent in what we call the substance key. So that's the example is for blinatumomab on the page that shown on the screen right now. But the proposal, again, it is to delete that code and then what we would ask for comments is because that includes you know both antineoplastic and immunotherapy, in the current code title we would, you know, want to confirm what we had originally included as interim coding advice at the time that this proposal came to the C&M meeting just, you know, for consistency and then, you know, we'd also rely on public comments.

MARILU HUE: You know, you can draw the conclusion that antineoplastic, you could get that information, it's diagnosis code. But again, we would need to go back. But the proposal would be to delete all those group 1 codes so we are, you know, encouraging public comments on these and then what we can do after the public comment period closes is we can bring all of these back to the March meeting and display them in what you know we call our full addenda. And that way, that would give another opportunity in case you know additional considerations come up. We can absolutely do that. But this was more of an informational, informal discussion at this time because this is the first time that we're actually proposing to delete any of these Section X codes. That we're looking to get some feedback.

ABBY MOORMAN: That makes sense. Thank you very much.

MARILU HUE: You're welcome.

ISAAC FISHER (Moderator): We have June.

JUNE BRONNERT: Hello. Hi. This is June Bronnert with IMO and just so hopefully you can hear me okay and I think that proposal is I mean just reviewing the document. Around the process is based upon analysis, there would be one of three options. One would leave codes in Section X alone. The other would be based upon data of the codes being reported, even if they did not qualify for the NTAP the potential to move those. And then the third is the deletion of those codes from Section X all together. My reflection around the deletion… Is there a way to, thinking about this from a data perspective over time, that if somebody would want to be able to, for whatever reason reference the deleted codes, would be able to find a list or some type of key? Just thinking about this from the data perspective.

MARILU HUE: Then yeah, so we do have the conversion table that we make available on an annual basis. So it would reflect you know the date that the code was active as well as the date that that code was deleted, and that would also be in the annual you know addenda files.

JUNE BRONNERT: Thank you.

ISAAC FISHER (Moderator): Pam, you can ask your question you can ask a question if you choose to.

ISAAC FISHER (Moderator): Still no response, Mady. Okay. All right.

MARILU HUE: I'll just continue on to page 42 at this time where we show the Group 2 New Technology Section X codes. So, in looking at the first code cerebral embolic protection, as we discussed a little bit about this topic earlier, there were some concerns regarding what would we do with these codes. So prior to that conversation we were thinking to propose to keep this code to continue the ability to compare outcomes to the other codes in Section X. So, based on the earlier discussion and concerns about confusion we certainly encourage you to submit your comments and writing about that particular proposal.

MARILU HUE: Moving on, for a replacement of aortic valve, we would propose what we're calling option 3 to delete that from Section X without the need to re-index. We believe it's pretty clear that this is an aortic valve replacement.

Moving down for the repositions using the magnetically controlled growth rods. We can explore Option 2 or 3. Again, looking for input and feedback whether or not it is felt that there needs to be some type of reference to these magnetically controlled growth rods or if it's felt by the majority that they know it's going to go to "Reposition". So, option 2 would be the re-indexing and deleting from Section X and option 3 is just deleted from Section X and don't worry about any indexing and the same would be for the fusion codes using nano-textured surface.

We're looking for any feedback regarding option 2, to re- index and delete from Section X or just simply delete these codes for Section X. And there's really no need to re-index it back because we all know that it goes to fusion with the interbody fusion device.

Moving down the page for the remaining codes that are your introduction or route of introduction, and at the bottom of the page, we would again propose to delete these from Section X. For some of these you can see like this over time NTAP has been exhausted, we propose to delete from Section X. The last one is your Uridine Triacetate (Vistoguard). This was an emergency treatment for toxicity again NTAP exhausted so we propose to delete that from Section X. And if no specific class or category of the drug exists, we would consider using other therapeutic substance, just to give you an idea. And again, we can always use the Substance Key. If that is the preference for whatever reason for people. We can do that. I know it's a lot to absorb and again this is intended to be more of a discussion we've, you know, talked about what we were thinking of proposing for these codes. So we are looking for comments regarding what has been discussed as far as the proposals. Pretty much looks like everything except for the cerebral embolic protection one is being proposed to be deleted in some way or another. Any other comments or questions regarding this issue?

ISAAC FISHER (Moderator): Yes, we have Linda Holtzman

ISAAC FISHER (Moderator): You can speak now, Linda.

LINDA HOLTZMAN: Thank you very much, actually. The first thing I want to say is, well done to the moderator really manage this very well. Thank you, sir. Second, I said I was going to look forward with great interest to what was going to happen with the cerebral embolic filtration systems. So here we are and I want to be sure I understand what you're intending to do. So, you are going to retain a code for the cerebral embolic filtration dual filter in the dominant artery and left common carotid artery because there's been significant utilization? It's useful to see this in the data. But is your intention, then to move this to code table 5A0?

MARILU HUE: Yeah, depending on the public comments received based, you know, on this discussion that that is the consideration, you know, again, as I mentioned, prior to that previous discussion for the topic that Michelle Joshua had led. The thinking was that we would propose to retain the code, however, based on the comments, it's, it's not you know, something that we feel, you know, strongly about. It's more of what is felt beneficial for the industry in terms of, as

I mentioned, is it important to still compare clinical outcomes for these different types of filters? And so if somebody makes a strong and convincing case, then we could, you know, consider keeping this code. But otherwise, to answer your question, yes, we would fold it into the 5A0.

LINDA HOLTZMAN: So when you say folded into 5A0 would it just didn't start to use the generic code that's been approved, or would you put it into 5A0 using a subset, excuse me, the device value for a specific device value that says cerebral involved filtration dual filter?

MARILU HUE: Yeah, it would be based on the proposal, the language that was included in the proposal, so it would be more generic.

LINDA HOLTZMAN: Oh, so it would, you would move it by basically eliminating the Section X code that is very specific and then telling people to use the generic code in 5A0, is that correct?

MARILU HUE: Yeah, that would be correct.

LINDA HOLTZMAN: Okay, the other, the other two codes that are in X2A, Section X for Cerebral embolic filtration, one is in New Tech Group 5, one is in New Tech Group 6. So those would stay until their time comes? Correct?

MARILU HUE: Correct.

LINDA HOLTZMAN: Okay. Thank you for clarifying that. I shall give us some more thought.

MARILU HUE: You know where to send the comments.

LINDA HOLTZMAN: Yes, you always seem so happy about that. Thanks.

ISAAC FISHER (Moderator): We have Lynn next.

LYNN KUEHN: Hi, Lynn Kuehn, Kuehn Consulting. Mady, there is one code on here that we did not look at yet. It's just a single liner for the replacement of skin using porcine liver skin substitute and a kind of a low utilization. I'm interested in knowing what you want to do with that. You talking about getting rid of it or re-indexing?

MARILU HUE: Yeah. Okay. On that one.

LYNN KUEHN: You know when, if you want to re index it to go to Med/Surg, we don't have a zooplastic option in the skin tables. So we probably could use some guidance that says that that just goes to the non-autologous or something.

MARILU HUE: Okay.

LYNN KUEHN: Um, that's the only one we didn't talk about. So thanks. You want to go to Med/Surg with that.

MARILU HUE: Yep, thank you. You know where to send your comments to.

MARILU HUE: OK, we have Nelly.

NELLY LEON-CHISEN: Can you hear me now?

ISAAC FISHER (Moderator): Yes. We hear you clearly. Thank you.

NELLY LEON-CHISEN: Nelly Leon-Chisen with the American Hospital Association. Thanks, Mady for giving us advance warning because I think this will require a lot of thinking and probably discussion with other folks for us to kind of know really what our final comments are going to be, but just as preliminary, I would say that if you are deleting or changing these things to your question earlier about indexing. I totally agree that it would be helpful to make those changes in the Index so that people know where to go when they start looking for these either substances or even devices because to the extent that somebody still thinks that there's some value in either collecting this information or looking at historical data and they're trying to find out where was it they can actually see where it would have belonged or where it belongs now so that they don't have to keep trying to find previous years complete list of code to kind of figure out where, where was it and I guess I you know this is more of a process question that I have.

If someone feels that one of the codes that has, for example, a large number of procedure codes reported it just take it as an example from Group 1, the first code, it never really was approved for new technology add-on payment, and yet over the years that that extirpation code was effective there were over 6000 codes. If someone felt that it was important to be able to still distinguish using orbital atherectomy technology.

Suppose someone could still submit a proposal and request a brand new code to be put in the regular extirpation side. Right. I mean, so there would be nothing to prevent someone later on, saying, oh, wait a minute. I didn't notice. And I do want to capture information on this type of technology separately.

MARILU HUE: Yeah. Yes, that's correct. There's nothing that precludes somebody from coming back in the future and requesting that we consider, you know what we call a code for the main section of PCS or, you know, if they're entertaining new technology and other section X code that's similar. So I hope that answers your question that the answer is no, there's nothing that prevents them from doing that.

NELLY LEON-CHISEN: Yes, it does. Thank you.

ISAAC FISHER (Moderator): Next we have Sue Bowman.

SUE BOWMAN: Thank you. Yes, this is stuff. Sue Bowman, and Nelly’s question brings up another question I had. Then I interpreted the difference between the second and third option to be that the second option would result in a code being a unique code, but it would be moved to

the Med/Surg section because it is not a new tech issue. Is that correct? Or because otherwise, it sounded like options two and three sort of blurred together.

MARILU HUE: So the difference between option 2 and 3 is for option 3 when we talk about totally deleting the Section X code, it means that there is going to be no reference to that current code in the Index or the Tables or anything at all. So the example of that is the intra operative knee replacement sensor. So we were recommending what we're calling option 3, to delete those Section X codes and then as we showed the addenda, we would just delete those entries from the Index entirely. So we're getting rid of that whole concept of an intraoperative knee replacement sensor in the classification itself option.

Oh, go ahead. No, go ahead. No, I was gonna say. And so in that case.

SUE BOWMAN: You wouldn't you wouldn't point to some generic category of code at all.

MARILU HUE: Right yeah that's the difference. So for option 2 it's not so much reassigning a unique code, it's really about re-indexing or revising. So the example that we use for ceftazidime-avibactam, right now under C in the index, it's telling you for that particular agent anti-infective go to table, you know, Section XW0 and so the proposal is we would still keep the reference and index, but we're instructing users to go to anti-infective which, like we said, everybody should know that table 3E0.

SUE BOWMAN: Okay, then that that helps clarify for me, I would suggest, in light of Nelly's comments which I completely agree with that you might want to consider a fourth option which is create a unique code elsewhere in PCS. Because my understanding when Section X was created was they were always supposed to be sort of temporary codes. And so one of the outcomes could be not that the frequency was really low, but that it became standard of practice, the frequency was very high. But it really wasn't a new tech issue any longer. And so it belonged as a unique code somewhere else. So I would actually propose that as a legitimate option for some of these scenarios Nelly's extirpation example probably being a good example of that.

MARILU HUE: Okay, want to include that in your comments, Sue?

SUE BOWMAN: Yes, I will, thank. Thank you.

ISAAC FISHER (Moderator): We have Amy. Amy, you can speak now. Hello Amy?

ISAAC FISHER (Moderator): Amy is unmuted…

MARILU HUE: Amy, are you there?

ISAAC FISHER (Moderator): Okay, we have Linda Holtzman.

LINDA HOLTZMAN: Thanks. I just wanted to follow up on Sue's comment. Hi, I'm

ISAAC FISHER (Moderator): Hello Linda. Yeah. Okay.

LINDA HOLTZMAN: I just wanted to follow up on Sue's comment. There does seem to be interest in for some of these really high volume codes, or those that are extremely distinct that there's an interest in putting them in what we would call the regular sections Med/Surg or extracorporeal therapies or whatever. So right now, if you wanted to do that and you wanted to have a specific value for it, as opposed to just going to the generic. It sounds as if you'd have to make you, the requestor, would have to make a specific request to do that. Otherwise, it would just get re-indexed to a generic code and Sue is suggesting another option 4. Sue, correct me if I'm misinterpreting you but the option for would be to automatically create a new value new code using the new value in the regular section. So a request or wouldn't have to come back and ask that something be created. Am I understanding that correctly?

ISAAC FISHER (Moderator): Sue, you can speak when you're ready.

LINDA HOLTZMAN: Well, you

MARILU HUE: Sue, are you there?

SUE BOWMAN: Now I am. I was muted. I couldn't get myself. I couldn't get myself unmuted. Yes, Linda. That's exactly what I was suggesting that based on this analysis of each of these Section X codes each group that it be looked at as does it appear from the data and of course based on also public comments on these recommendations as we're discussing today. Does it make sense to continue to have a unique code for that technology going forward, even though it's outlived its Section X usefulness. Because I always thought that Section X was always going to be temporary. And it wasn't just a matter of it's time to get rid of the code. But now the technology is maybe standard practice or used to significantly enough, high enough volume that there's still interest in capturing it separately and not we're not referencing it to a generic code, but to sort of move the code to one of the regular sections where it would belong. And so, yeah. And so like you suggested, Linda, this wouldn't have to be like, you know, like, like CPT is category 3 codes, where somebody has to go back and you know request that it be maintained or be made a code in another section, but rather that would be based on CMS' analysis, along with public support for going ahead and just doing that.

LINDA HOLTZMAN: Thanks so much. Am I still able to speak?

ISAAC FISHER (Moderator): Yes, thank you.

LINDA HOLTZMAN: Yeah, that's along the lines of what I was thinking too. It occurs to me though. You almost you almost have to go back and at least alert the original requestor that this is happening because otherwise they might be in the dark and just say, Wait, where'd my code go you know it's out of Section X, where to go. So you they wouldn't necessarily have to undertake to have a new request, but they should at least be alerted that it's being moved.

LINDA HOLTZMAN: That, that makes sense to me. Although I do want to add that I thoroughly agree with one of the options. I can't remember which one of just deleting some of the codes which don't seem to have much usage or and or there doesn't seem to be a data driven

reason or clinical reason to keep them as unique codes. So I'm fine with just deleting some and not having a reference. I'm also fine with deleting some from Section X and having a reference to a generic code, but I like the idea of option 4 of deleting from Section X and moving/creating a new value of some kind, to identify certain codes distinctly in the regular sections. Thank you.

MARILU HUE: Thank you, Linda. I think when we receive the request, initially, we do try to take that into consideration thinking in the long term, where would this maybe fit in the main section of PCS when it would be time to sunset, so to speak, the code. So, you know, we can definitely look into this further. And, you know, look forward to your comments and feedback, a little more on this topic and what codes you think might be eligible for this. You know, fourth option that we're talking about.

And just to go back to the example with the extirpation, I just wanted to point out that you know, the description of that code the Orbital Atherectomy Technology that's describing the technique used to perform the procedure. And there's not a specific device left in after utilizing it so I, I just don't know that that would be, you know, a prime example to use. But again, we encourage you to submit comments for that and any others because again we're just talking about Group 1 and Group 2.

And we have every year moving forward to talk about each group number and whether or not we believe you know they should be deleted or re index having the same conversation. So I'd also like to get feedback on the information that's shared regarding these codes, it's if it's helpful. And also the manner that it's displayed and the pattern that we've seen to establish just the fact that we tend to share the data at the March meeting to give time to review it, consider it, and then make the proposal at the September meeting, get comments and then we can always bring it back at the subsequent March meeting and get those final comments prior to making any final decisions for the upcoming fiscal year. So if, you know, people could also comment on that, that would be greatly appreciated.

LINDA HOLTZMAN: Thank you very much.

ISAAC FISHER (Moderator): Still have Amy there.

ISAAC FISHER (Moderator): Amy, are you there?

ISAAC FISHER (Moderator): Okay, let's go to Nelly, Nelly, you say hello. You can speak, you're ready.

NELLY LEON-CHISEN: Yes, thank you. I just thought of another question. When the Section X codes were created some people were comparing them to CPT Category three codes, and I realize that's a whole different system, but those Category three codes within CPT the requesters from the get go, understand that those are temporary codes. And at some point, a belief is five years still will go away. And so they have the ability to request that either they are re-upped for another period of time, or if they have become the standard of care.

I think it is Sue mentioned that they could request a code in the regular section. But I think there was a process for the requesters to be notified or not. So I and I realized that this is the first time they were talking about deleting Section X code. So I wonder how much did the requesters know. I guess I would hate for them to be part of this first group and be entirely surprised and find out. Oh, you know, my code went away. Now, what so any I don't. Yeah. Can you share a little bit about what requesters may have known when they were given codes in Section X?

MARILU HUE: Yeah, so, um, when we first discussed the analysis that was at the September 2018 meeting. So all of those New Technology Group 1 codes were in all, say, the "window" of being eligible are already having received the approval for NTAP you know, add-on. If it was associated with that. We did get a few who contacted us because when we announced that for the Group 1 codes, some of the Group 2 code related requesters touched base to ask about or what's going to happen to my code, as you mentioned, so we corresponded with them when we were you know contacted. So the difficulty, again, we, you know, this is the first time. So we don't have a set process. But if for whatever reason contact information changes, it's maybe a little bit difficult to track down but I appreciate, you raise a good point, we can introduce that as part of our normal process, to make it clear that these Section X codes were not intended to, you know, last for years and years.

MARILU HUE: They, you know, everybody knows the history and the intent from all the discussions that we've had so I appreciate you bringing that up Nelly and, you know, we can definitely work to again make it clearer so that there is continued communication from the point of the initial request. And if it's subsequently finalized and approved and then moving forward, where that code may go.

ISAAC FISHER (Moderator): Okay, we have Amy. Amy is trying. She raised her hand again. So let's see if we can get her Amy.

SUE BOWMAN: Amy, are you able to hear us. Yes, but I cannot speak.

ISAAC FISHER (Moderator): Very, very low.

AMY BLUM: Let me try to get closer…I can't even send a chat. It won't even let me chat.

ISAAC FISHER (Moderator): just sent you a text I was chatting with you, trying to get to let you know that we were trying to get you.

AMY BLUM: Hear me now? Okay?

ISAAC FISHER (Moderator): Mady, are you able to converse with Amy?

MARILU HUE: Yeah. Yes, I can hear you.

AMY BLUM: Wanted to know because I agree that temporary codes, especially in the procedure section to get, you know, aged out at what point will you be reusing the same numbers.

MARILU HUE: They don't get reused.

AMY BLUM: Well, if they're never going to get reused, then is it necessary to delete them?

MARILU HUE: We propose to delete them based on public comments about maintaining Section X codes and everything else that has been discussed in prior meetings about Section X. So that would be a comment to submit in writing if you do not support a proposal to delete a specific code from Section X.

AMY BLUM: I don't have any problem with deleting it. I think it's perfectly fine. They were temporary codes. I was just wondering if you're never going to use the number again. But you're going to create another code in a different section that just seems like a redundant effort if you're going to continue to have those that you're getting competitive completely, that's fine. But the ones you're going to create a new code in a permanent section. I don't know, just seems like something to think about for long term use of temporary codes, especially.

MARILU HUE: Thank you.

ISAAC FISHER (Moderator): One more. Actually two more. Jugna Shah

ISAAC FISHER (Moderator): I don't know if I'm pronouncing that right but Mr. Shah.

JUGNA SHAH: Can speak now. Hi there. Can you hear me?

MARILU HUE: Yes.

JUGNA SHAH: Okay. Question, as we look to the future and in light of the discussion today about the immunocellular therapies and the new codes that are going to get created. Will they sort of follow the same cadence that at some point, CMS will, you know, make the same sort of proposal and moving them into another section such as 3E0? Am I following some of the logic correctly?

MARILU HUE: So the process is obviously we discussed the code request. And if the code is approved. And it happens to be a Section X code, yes, at the three-year timeframe because that is what is associated with the New Technology add-on payment. We would bring it to the meeting and allow the opportunity for the public to comment on whether or not they agree with our proposal, whether it's to delete it or keep it or re- index it somehow in the PCS system. So yes, they will at some point.

JUGNA SHAH: I guess I guess the point that I just want to make, since we're not there yet. It seems to me that, for the reasons that a lot of the presenters today talked about with these new cellular therapies and the importance to be able to track the individual products and to understand outcomes and long term effects. It seems to me that we would want to know, you know, which cell therapy was actually administered and while I don't think we want ICD-10-PCS to become sort of a, like a drug coding table or biologics, you know, table indexing. I guess I haven't thought about it enough, but seems to me like we should spend time now before we get

to that juncture, thinking about how to handle solving therapy so that we don't lose the granularity of the data, especially the time that we're, right, you guys are just making the change to identify the cell therapy in the code descriptor. So we'd have access to that data for a few years and then if that were to disappear. I think, I think that would be a problem. And I don't have a solution right this second. But I guess I wanted to just put forth that we should do some early thinking.

MARILU HUE: Thank you Jugna and I look forward to your comments.

ISAAC FISHER (Moderator): We have Lynn Kuehn.

LYNN KUEHN: Hi Lynn Kuehn, Kuehn Consulting. I, have a question about the qualifier that has the Group number. Since we're on group number 7 that we're looking at now, are we trying to make these decisions so that we are going to be able to reuse that single digit? When we get basically…

MARILU HUE: No

LYNN KUEHN: Okay, just wanted to understand

MARILU HUE: No, so when we get through to New Technology Group 9, we would transition to using letters of the alphabet.

LYNN KUEHN: I see. Perfect. Thank you.

MARILU HUE: You're welcome.

ISAAC FISHER (Moderator): No further questions at this time.

MARILU HUE: Okay, great. I think we're ready to wrap this topic up and I'm going to go ahead and turn it over to Andrea Hazeley to review the standard addenda and key updates. Thank you, everyone.

ANDREA HAZELEY: Okay, can you hear me.

MARILU HUE: Yes.

ANDREA HAZELEY: Okay, great. Okay, thank you. This is Andrea Hazeley again. And for those following along with the handout. We are now reviewing the addenda found on page 43. Okay. So to begin with, in the ICD-10-PCS index, we have a number of entries being proposed to be added. For example, we're adding entries for the ALPPS procedure and staged hepatectomy. There are other entries included here to direct the appropriate body part, devices and substance character values.

ANDREA HAZELEY: Starting on page 44 for the body part key addenda, we have entries for the dorsal root ganglion, fibular sesamoid. Down a little bit, tibial sesamoid, parapharyngeal

space and retropharyngeal space to identify the body parts that should be coded when these terms are documented in the medical record. Okay. In the device key we are proposing to add an index entry for the alfapump system and in the substance key, we are adding terms that may be found in the documentation that should be coded to the substance character Globulin, and adding the trade names Yescarta™ and Tecartus™. Can see here.

Okay, now move into the table addenda. In the medical and surgical section, Table 02V Restriction of heart and great vessels. Want to add body part value L ventricle, left applied to the device value C Extraluminal Device, D Intraluminal Device and Z No Device and all available approaches to identify procedures such as the placement of the Ancora Accucinch device which treats heart failure and functional mitral regurgitation by targeting left ventricle dysfunction and dilation.

Okay, next in Table 07D Extraction of lymphatic and Hemic systems add body part value T, bone marrow, to identify when bone marrow is extracted from other sites such as the femur…see the table here.On page 46, in table 0F8Division of Hepatobiliary System and Pancreas, add body part values 0 Liver, 1 Liver, Right Lobe, and 2 Liver, Left Lobe, to identify the partitioning of the liver, or ALPPS procedure, performed as the first step of a staged hepatectomy.

Next in Table 031 Bypass of Upper arteries add approach value 3 Percutaneous, applied to the body part values 7 Brachial Artery, Right and 8 Brachial Artery, Left and applied to the qualifier value F Lower Arm Vein, to identify procedures such as the creation of an arteriovenous fistula by connecting the brachial artery to a lower arm vein using the Ellipsys® vascular access system. There are also associated index entries associated with this request which can be found on the top of page 47.

Okay, next in table 06L occlusion of lower veins want to add approach values 7 Via Natural or Artificial Opening and 8 Via Natural or Artificial Opening Endoscopic applied to the body part value Y Lower Vein, to identify procedures such as endoscopic banding of the hemorrhoidal plexus. On the top of page 48, Division of Muscles. At table 0K8, Division of muscles, add approach values 7 Via Natural or Artificial Opening and 8 Via Natural or Artificial Opening Endoscopic, applied to the body part value 4 Tongue, Palate, Pharynx Muscle, to identify procedures such as the stapling of Zenker's diverticulum performed via a transorifice or transorifice endoscopic approach.

In table 0NH, Insertion of Head and Facial Bones, add device value 3 Infusion Device, applied to the body part value 0 Skull, to identify procedures such as the implantation of an Ommaya reservoir for the intracranial administration of chemotherapy…You see the index entries here.

ANDREA HAZELEY: Moving to page 49 table 0QB, Excision of Lower Bones, add qualifier value 2 Sesamoid Bones 1st Toe, applied to the body part values N Metatarsal, Right and P Metatarsal, Left, to identify procedures such as the excision of the fibular or tibial sesamoid bone…You see that addition down here.

On the top of page 50, in table 0RP, Removal of Upper Joints and 0RW Revision of Upper Joints, want to add qualifier values 6 Humeral Surface and 7 Glenoid Surface, applied to the

body part values J Shoulder Joint, Right and K Shoulder Joint, Left, to identify the revision or removal of the components of a partial shoulder arthroplasty. Arthroplasty, I'm sorry.

In the Extracorporeal or Systemic Assistance and Performance table 5A1, want to add new qualifier value J Automated, applied to the body system value 2 Cardiac, duration value 2 Continuous, and function value 1 Output to identify the usage of devices such as the Lucas device and Defibtech for medical, I mean mechanical, chest compressions…See the entries here.

And last but not least, on page 51 in the Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas, add qualifier A Guidance, applied to the new body part value 5 Liver to identify when fluoroscopic guidance is used with procedures such as the drainage of liver abscesses.

Okay give everyone a moment to review and then moderator, can you review for any questions on the addenda?

ISAAC FISHER (Moderator): Yes, we have one question or comment from Lynn Kuehn. Lynn, you can speak now if you're ready.

LYNN KUEHN: Hi this is Lynn. I'd like to go back to page 48 if we could at the top of the page for the endoscopic division of pharynx muscle. This, this particular procedure has Coding Clinic opinion that recently came out for this and it's caused quite a bit of trouble. Lots of questions surfacing. The root operation decision here has caused serious trouble because even in the description that was well put about the goal of the surgery creating a common channel.

My problem here is that you are going to continue to confound the problem. This is a problem with a tubular body part. The method used to fix the problem is cutting, but the objective is to create a single channel for the esophagus so that food does not get stuck in the diverticulum and I'd like to request that this situation be looked at again for the root operation of Dilation, specifically, and that this addition not be made because this is not the objective of the procedure and I just don't want to see this problem multiplied any further. Thank you.

ANDREA HAZELEY: Thank you. Lynn if you could please put that comment in writing.

ANDREA HAZELEY: I'm sorry. Go ahead.

ISAAC FISHER (Moderator): No, there are no more questions at this time.

ANDREA HAZELEY: Okay.

ANDREA HAZELEY: As I was saying, Lynn, thank you so much for that comment. And if you could please put that in writing and submit to our email address that would be greatly appreciated. Again, I would give a few moments for everyone to absorb the addenda additions and if there are any other comments.

ISAAC FISHER (Moderator): Still no comments or raised hands.

ANDREA HAZELEY: Hearing none, I guess, I will turn the presentation over to Mady.

MARILU HUE: Thank you Andrea, it looks like we are at our last ICD-10-PCS procedure code topic and I do want to confirm whether or not Dr. Oswald is available on the line.

MARILU HUE: Moderator. I'm not sure if you can check to see if a Dr. Tim Oswald.

ISAAC FISHER (Moderator): Thank you.

ISAAC FISHER (Moderator): I don't see him as an attendee or panelist. Did you say Timothy, or Tim Oswald.

MARILU HUE: Yeah, Tim Oswald. There was a chance that he would still be in surgery so okay, if he's not available right now. We'll go ahead and we'll switch gears to the CDC and NCHS staff and they can go ahead and present a couple of their diagnosis code topics and we'll check back in about 30 minutes or so to see if Dr. Oswald is available at that time. So I am going to go ahead and turn it over to Tracy, are you there from CDC or David?

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NOEL MANLOVE: This is Noel. Andrea is going to be presenting the next topic and I believe that our presenter, Dr. Oswald is on so we can, we are able to present our next topic at this time.

DAVID BERGLUND: Okay, I have stopped sharing the screen and I yield back to you.

NOEL MANLOVE: Thank you.

ANDREA HAZELEY: Okay. Can you hear me now? Okay. So returning to your PCS agenda and the handout packet. We are on page 52. The topic is posterior dynamic distraction. The issue is currently there is not a unique ICD-10-PCS code to identify the utilization of a posterior dynamic distraction device for treating spinal deformities, such as adolescent idiopathic scoliosis. The requestor intends to submit a New Technology Add-on payment application for fiscal year 2022 consideration and is seeking implementation of the ICD-10-PCS code on April 1, 2021. The ApiFix Liiteds Minimally Invasive Deformity Correction MID-C system received FDA approval under a humanitarian device exemption on August 23, 2019 so I would like to turn over for the clinical presentation.

PAUL MRAZ: Thanks, Andrea, you have both Paul Mraz and Dr. Oswald here for the presentation.

ANDREA HAZELEY: Thank you.

PAUL MRAZ: Great. So this is Paul Mraz. I'm the general manager of ApiFix Limited and with us today also is Dr. Timothy Oswald from Pediatric Orthopedic Associates and Children's Healthcare of Atlanta, Georgia. I know you've all had a long day today. And I appreciate you

letting us present last. Dr. Oswald had two cases today and just finished so timing is perfect. Thank you. Next slide please.

So we're here today to request an ICD-10-PCS new procedure code for posterior dynamic distraction device as Andrea mentioned. This is for the placement of posterior segmental instrumentation for correcting spinal deformity, as well as the performance of a one level proximal fusion. The product that we produce at ApiFix is referred to as the minimally invasive deformity correction system or the Mid-C system and this is a viable alternative to traditional spinal fusion, as many of you may be familiar. It incorporates a self-adjusting rod that has novel poly axial joints at both the proximal and distal ends and this rod is a self-adjusting rod that enables us to achieve curve correction of the spinal deformity while preserving spinal mobility in all directions (rotation, flexing, extension, and lateral bending). This was FDA approved in August of 2019 and there's an image here to the right of the implant. Next slide.

The device and the procedure itself. It is a posterior placed device and we are basically placing this from what we call cob to cob or treating the entire curve on the concave side so a periapical concave distraction is performed to straighten the curve. As I mentioned earlier, there's some images of the device here but it incorporates a self-adjusting ratcheting rod that can elongate in only one direction. That is a can get longer, but it cannot get shorter. That's obtained or achieved via one-way ratchet mechanism inside the device and as I mentioned, there's a novel polyaxial joint each and that provides a three dimensional motion. We do enhance the proximal fixation of the device cephalad if you will, with an extender, where we perform a one level fusion. Next slide.

This is a viable alternative to failed bracing, that is kids that are not responding to bracing for either reasons of natural history or compliance and something that can now be considered with its FDA approval before something like a definitive spinal fusion for the treatment of progressive scoliosis. So typically, bracing is up until about 40 degrees and fusion contemplated after 50 degrees and our on-label FDA indications are for treating AIS curves between 35 and 60 degrees. Next slide. And I'll turn it over to Dr. Oswald for the rest of the presentation.

TIM OSWALD: Hopefully you can hear me. So, this is Tim Oswald. I'm going to go through just the procedural steps that are involved with the application of this device. This is a standard midline incision only on one side of the spine. It is with placement of one screw at the very end or caudally and then two screws at the top of the construct or cephalad which is then augmented with bone graft for a one level fusion. This is the implants placed submuscularly and it's with the self-adjusting rod between the pedicle screws with the extender bar placed at the cephalad pedicle screws. Then interpretively we perform a distraction or correction of the deformity by the ratcheting mechanism. Once this is maximally achieved, then there will be the way there's a standard closure multi-level with dissolving stitches. This is in an inpatient setting only and it's for only for the treatment of adolescent idiopathic scoliosis. Next slide please.

TIM OSWALD: Currently, the United States indications are for adolescent idiopathic scoliosis with significant curve classification being designated as Lenke one which are chest wall thoracic base and Lenke five, which are lumbar or low spine base. Curve magnitude is between 35 and 60 degrees. Skeletal maturity is from zero to five, so people who are actively growing or have

completed growth. The sagittal profile which is kyphosis measured from T5 to T12 to be less than 55 degrees for curve flexibility is required to be less than 30 degrees on bending films. Next slide please.

The device is a permanent device. Only one device is routinely inserted. Again the device system equals three pedal screws, one extender bar, and one self-adjusting rod. The procedure involves the placement of the segmental instrumentation and always performing one level fusion, arthrodesis, proximally with the use of bone graft to augment the fusion. The normally expected rate of device, I mean device related and non-device related adverse effects events is can have occurred without sequela which could include infection, screw migration or device failure. Current analysis indicates survival rate of at two and a half years of greater than 90%. Failure rates, are less than 3%. Re-operation rates for any reason whatsoever is approximately 8.5%. Next slide please.

Currently, a description of the procedure performed includes use of the MID-C system is recorded in the physicians' post-operative notes and part of patients' permanent medical record. There are different naming conventions for the device technology or procedure, which include ApiFix procedure, minimally invasive deformity correction MID-C, or posterior distraction device, posterior dynamic deformity correction, posterior dynamic distraction device or posterior dynamic spinal stabilization. Next slide.

Here's an example of what the device application would look like for a lumbar curve or Lenke curve with follow up radiograph showing correction and maintenance of correction while maintaining motion. Next slide please.

This is another example of a curve very similar and similar results at one year follow up. Last slide please. So this is just a submission for a unique code identifier. If there are any questions, Paul and I are happy to help with this process. Thank you.

ANDREA HAZELEY: Thank you so much. Moderator, do we have any raised hands or clinical questions for this topic?

ISAAC FISHER (Moderator): There are no questions at this time.

ANDREA HAZELEY: Okay. Hearing none, I'm going to discuss the coding options for posterior dynamic distraction. For current coding, code the use of a posterior dynamic distraction device with the applicable ICD-10-PCS codes from tables 0PS and 0QS, Reposition of Upper and Lower Bones, using the device value 4 Internal Fixation Device. Option 1, do not create new ICD-10-PCS codes to identify the utilization of a posterior dynamic distraction device. Continue coding as listed in current coding. Option 2, create new codes in section X, New Technology, to identify the utilization of a posterior dynamic distraction device. Separately, assign the applicable ICD-10-PCS codes from table 0RG or 0SG for any spinal fusion performed at the non-instrumented segment of the vertebrae. You can see the table here.

ANDREA HAZELEY: CMS recommendation at this time is Option 2, as described above, and our interim coding advice is to continue to code as listed under current coding. At this time again, I'll open for any coding questions. If you have any, please raise your hand.

ISAAC FISHER (Moderator): Looks like we have one and that's Nelly.

ISAAC FISHER (Moderator): Nelly, you can speak when you're ready.

NELLY LEON-CHISEN: Yes. Nelly Leon-Chisen, American Hospital Association and I have a question similar to what was asked earlier of two proposals that were requesting an April 1st implementation. I wonder if the presenter can speak to the rationale for requesting an April 1st implementation when the request for new technology add-on payment is for fiscal year 2022 consideration, which would be October 1st instead of April. Can you speak to that, sir?

PAUL MRAZ: This is Paul Mraz. The intention is that we will apply for the NTAP during the cycle for 2022 but we'd like to have this in place that we can begin tracking the procedure and the use of the device, both for having that in place for that application, but also now we're, we have a registry in the United States where we are putting all of the CERT data from the surgeries in the United States into the registry from the pediatric spine study group and then having this sort of unique PCS code will allow us to also track the device for future reference as well use of the device.

NELLY LEON-CHISEN: Thank you.

ANDREA HAZELEY: Do we have any additional questions?

ISAAC FISHER (Moderator): No, this. That was the last question.

ANDREA HAZELEY: Okay, so hearing no additional questions, I'll turn the presentation over to Mady for some additional remarks.

PAUL MRAZ: Thanks, Andrea.

ANDREA HAZELEY: Thank you.

MARILU HUE: Hi thank you Andrea, I was having some connection problems, so you were able to pinch hit for me. I appreciate that. Thank you to the presenter. I'd just like to close out the procedure portion of today's meeting. And again, encourage participants to submit comments by October 9th and November 9th for the indicated proposals April 1 and October 1, 2021 and with that I'll turn it over to CDC.