Centers for Medicare & Medicaid Services
Webinar: Transitional Coverage of Emerging Technology
Thursday, February 17, 2022
3:00pm-4:30pm

Webinar recording:
https://cms.zoomgov.com/rec/share/kB9RBnfaYelfZv54s4P5PALIXU2zuIECiYgKymtlgSAfeEVuf8GBGHY5cW9WvXyw.doJIU4yN3OAv0aow Passcode: 0sWm&jdk

Jonathan Blanar: Good afternoon, everyone. My name is Jonathan Blanar and I'm the Deputy Group Director in the Partner Relations Group in the Office of Communications at CMS. And I'll be moderating your session today. Today's listening session is an opportunity for CMS to obtain feedback from stakeholders to help inform coverage process improvements including our development of an alternative coverage pathway to provide transitional coverage for emerging technologies.

As such, we are not gathering written comments or taking questions from the Zoom platform. We will also not be responding to the comments made or answering questions asked during the comment portion of this call. If there is a specific topic related to coverage process improvements and transitional coverage for emerging technologies that you would like to include as a discussion point for the March 31 stakeholder meeting, please provide it in the Q&A box. While we can't promise to be able to address all of the suggested topics, we will make every effort to address as many as possible.

The Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease NCD will not be addressed on today's call. The public comment period for that NCD is now closed and the final NCD is due on or before April 11, 2022.

This session is being recorded today and will be transcribed. Please do not speak if you object to the recording. Also, this call is not for press. Like everyone else, the press is welcome to listen to the call, but press questions need to be directed to the Press Office's resource on the cms.hhs.gov website or sent to press@cms.hhs.gov. The list of today's speakers was compiled based on those who indicated through the registration process they wanted to speak on today's listening session. We will do our best to get to as many speakers as possible. Each speaker will have no more than three minutes. We're keeping an eye on the time and will politely ask those speaking to finish remarks at time.

We have been having some Zoom difficulties today at CMS. So, if for some reason we were to get disconnected, we ask that everybody dial back in using the dial in and meeting ID that's found in your appointment. And with that I'd like to now turn it over to Dr. Lee Fleischer, the CMS Chief Medical Officer and Director of the Center for Clinical Standards and Quality. Lee?

Lee Fleisher: Thank you and good afternoon. I'd like to thank all of you for taking the time to join our listening session today. Improving and modernizing the Medicare coverage process

continues to be very important to us and I'd like to reassure you that we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections.

As we noted when we repealed the MCIT/R&N final rule, we currently have initiatives underway that leverage existing coverage mechanisms to modernize Medicare coverage and we're exploring policy options, including rulemaking, to provide for a new expedited coverage pathway that will improve access to innovative and beneficial medical devices when supported by clinical evidence.

We appreciate all the helpful comments and information you've shared with us to date on this topic. One of the key messages we've heard from many of you is that you would like to have more opportunities to engage with CMS as we move forward. To that end, we're hosting today's session and a subsequent one on March 31 for you to share your perspectives, thoughts and ideas on how we can help better achieve timely and improved access for new technologies. As someone who has spent much of his career involved in technology assessments, I'm personally interested in hearing the technology ecosystem's thoughts. Therefore, CMS looks forward to hearing from you today, and again on March 31as well as in the coming weeks and months, as we work to enhance and improve Medicare coverage pathways. And now I'll turn it over to Lori Ashby, Senior Advisor, in the Coverage and Analysis Group. Lori?

Lori Ashby: Thank you Lee, and thank you all for joining us today. As Lee mentioned, this is a very important topic for CMS and we value your feedback. We've developed a series of questions that we would like for you to consider as you offer your comments today. Question one, how can CMS be better at engage stakeholders at all stages of the process? Number two, are there specific synergies at FDA that CMS can leverage to effectuate coverage process improvements? Number three, are there specific coverage process improvements within CMS' existing statutory authorities that you would like for CMS to prioritize? Number four, what are the specific topics related to transitional coverage related to emerging technologies and/or other coverage process improvements that you would like to offer perspective on at the March 31 stakeholder meeting.

As Jonathan mentioned, today is an opportunity for CMS to hear from stakeholders, and we will not be responding to specific comments or questions asked during the comment period of this call. We appreciate your feedback and look forward to hearing from you. Jonathan?

Jonathan Blanar: Thank you, Lori. And now we'll begin the listening session portion of the call. When I call on you, you'll be unmuted to make your comments., You will be held to three minutes, and we really ask that you respect the three minutes, as we have a lot of people who wish to speak today and we want to get to as many people as we can. Let's get started. I'd first like to call on Courtney Yohe, if available. DeVonne, or moderator. if you could unmute.

Courtney Yohe Savage: Yes, hi. Thank you, my name is Courtney Yohe. I am Vice President of Government. Can you all hear me?

Jonathan Blanar: Yes.

Courtney Yohe Savage: Okay. I'm Vice President of Government Relations for the Society of Thoracic Surgeons. Briefly our comments are as follows: in general, STS is supportive of a proposal that would bring innovative technology to Medicare beneficiaries as quickly as possible. However, relative to other FDA approvals, Breakthrough medical device designation sets a relatively low bar for approval in most cases. These devices will need careful monitoring in real-world populations. Collection of real-world evidence is essential to helping to demonstrate the value of a new intervention to different patient groups. New medical devices may need operator or institutional guidelines to ensure patient safety and to optimize patient outcomes. The coverage must allow for this type of bright line to be created, enforced and reimbursed. CMS will need to provide guidance on how coding and payment will work with Breakthrough coverage because application cycles for coding and payment are not aligned with FDA approval and can result in time periods of limited access. A new coverage pathway for Breakthrough technology must not prevent competitive products from entering the marketplace and coverage for Breakthrough technology should not be left to local contractor discretion. Inconsistent and inaccurate coverage policies create access limitations and disparities that impose significant administrative burden on providers and stress on seriously ill patients and exacerbate care and access disparities.

In late 2011, FDA approved and CMS proposed to cover the first transcatheter aortic valve replacement device. At that time the medical specialty societies worked with policymakers to ensure the rational dispersion of this new technology largely because of the coronary stenting experience in 2000. What we learned from this example was that when CMS was given the opportunity to work with medical societies to establish important operator institutional guidelines, we were able to minimize patient risk and improve outcomes. Data collection was an essential piece of this coverage decision because it allowed for careful monitoring of the rollout in real world populations. Data collection in the postmarket setting actually expands patient access, because it facilitates evidence development and patient populations not studied in premarket trials. The findings from pre-market randomized clinical trials do not necessarily generalize to the real-world setting. Data collection creates opportunities to fill postmarket evidence gaps and better define patient benefit and risk. Without ongoing data collection to bolster postmarket surveillance and studies, FDA may alter their approach for device approval requiring more robust and time sensitive premarket clinical studies, thereby reducing beneficiary access to innovative technologies. Finally, data collection requirements can and must be balanced with careful input from all stakeholders. CMS can help to both mitigate administrative burden and ensure the scientific validity of data collected through volume requirements and other operational and institutional guidelines. Thank you.

Jonathan Blanar: Great. Thank you, Courtney. And I do see a couple folks in the Q&A chat ask if we could post Lori Ashby's four questions in the chat section. I'm going to ask one of my colleagues at CMS if maybe Gene Freund if you could do that that'd be great. So next up we

have Chandra Branham. Chandra, we should be able to unmute you here so you can be able to speak.

DeVonne Parks: Okay, can you spell them?

Jonathan Blanar: B-R-A-N-H-A-M. And the first name is Chandra, C-H-A-N-D-R-A.

DeVonne Parks: I don't see her.

Jonathan Blanar: Okay, that's fine, we can move on the next person. James Moynahan?

DeVonne Parks: I don't see him.

Jonathan Blanar: Mark Leahey L-E-A-H-E-Y.

DeVonne Parks: I don't see him.

Jonathan Blanar: Lisa Sperling.

DeVonne Parks: I don't see her.

Jonathan Blanar: Lisa Betterson

DeVonne Parks: I don't see her.

Jonathan Blanar: Okay, how about Janelle Dunn? D-U-N-N?

DeVonne Parks: No Janelle is coming up.

Jonathan Blanar: Okay, let's try this. We will work on the fly here. Let's try this a different way. If an attendee would like to provide comments, there should be a raise hand function at the bottom of your Zoom screen. If you click on that we can bring you over to provide comments. I see lots of hands now. Okay, perfect, so let's start with Tamara Rook.

Tamara Rook: I apologize I hit the wrong button. I don't have a comment.

Jonathan Blanar: No worries, Tamara. How about Daniel Waldmann?

Daniel Waldmann: Thank you, Jonathan. Can you hear me fine?

Jonathan Blanar: I can, thanks Daniel.

Daniel Waldmann: Okay. I'm pleased to speak today representing the members of the Medical Device Manufacturers Association. I'm the EVP for Health Policy and Reimbursement for MDMA. For nearly 30 years MDMA has been the voice in Washington for the innovative

sector of the medical device industry and we support policies that promote patient access to life saving and life changing medical technologies. We strongly support the goals of the transitional coverage for emerging technologies initiative which includes shortening the time between introduction of important new medical technologies and the implementation of reimbursement policies that provide access for Medicare beneficiaries as well as supporting the development of additional evidence to inform appropriate clinical practice and Medicare coverage policy.

Significant progress in improving the existing Medicare coverage pathways has been made over the past two decades through collaborative bipartisan efforts with Congress and successive administrations. Still, for a small but meaningful number of innovative new therapies, that coverage gap, the significant amount of time that can elapse between marketing authorization by the Food and Drug Administration and the issuance of coverage policies, providing access for Medicare beneficiaries remains a problem. The adverse impact of the coverage gap on beneficiaries and investment in new medical innovations is also real. The creation of a dedicated coverage pathway for emerging medical technologies, which has been proposed in bipartisan legislation, going back to at least 2016, would represent another important step forward for Medicare beneficiaries whose medical needs are unmet by currently available therapies.

That's why MDMA is pleased to join the overwhelming majority of commenters who expressed support for such a pathway during the previous Medicare Coverage of Innovative Technology rulemaking process. Over the course of the previous rulemaking CMS identified a number of concerns relating to its initial proposed pathway. We are strongly committed to working with the Agency to develop a new proposal that will address those concerns, including refining criteria for determining eligibility for the pathway, ensuring adequate engagement between the manufacturer of an eligible device and CMS prior to FDA market authorization, developing additional evidence relevant to the Medicare population during the transitional coverage period, providing for public notice and comment and defining criteria and procedures for CMS to withdraw coverage prior to the expiration of the transitional period, if necessary, to protect beneficiaries.

We appreciate the opportunity to work with the Agency and other stakeholders on those issues. More importantly, we're confident based upon a long history of constructive and productive engagement with CMS, that collectively we will be successful in further improving access and health outcomes for Medicare beneficiaries. Thank you for the opportunity to speak today.

Jonathan Blanar: Great, thank you, Daniel. And to those who let CMS know that they did want to speak, if you could kindly raise your hand. Like I said in the beginning of the call, we're having some Zoom issues. I It seems like, for whatever reason, our search function isn't working so just raise your hand, please. Next, I'm going to go to Peter Thomas.

Peter Thomas: Thanks so much. Can you hear me?

Jonathan Blanar: Yes.

Peter Thomas: I'm speaking today on behalf of the Orthotic and Prosthetic Alliance which is a coalition of five of the main provider-based orthotic and prosthetic organizations. This is an area where there has been a fair amount of technological innovation over the last 40-year period. People with missing limbs or limb difference have really advanced in their functional level and their ability to participate in activities and society and employment as a result of orthotic and prosthetic care. We do support, strongly support, CMS moving forward with regulations later this year on emerging technologies and hope that the orthotic and prosthetic innovations that come to the marketplace will be included in that paradigm.

We understand some of the concerns with the MCIT rule, but we were very supportive of that as well, only because we really view technology across it, particularly in this area, durable medical equipment, prosthetics, orthotic supplies as frankly being well behind new technologies that Medicare tends to cover much more routinely and much more timely. So, we view the emerging technologies issue as a subset, really, of the broader set of issues around coding, coverage, payment and benefit category determinations around orthotics, prosthetics, durable medical equipment and similar types of assistive device devices and technologies that people with disabilities and injuries and illnesses use and really require to be as functional and independent as they can possibly be. The biggest equity concern here is that if you are not able to afford out of pocket something that the Medicare program does not cover, but arguably should, you don't get access to that technology to that device and oftentimes it becomes a two-tier healthcare system. We'd like to frame our comments in terms of health equity for using that illustration.

So, as you move forward with addressing access to technologies, but by the Medicare beneficiary population, we do hope that you will look farther than just the emerging technology issue and really focus on coding, coverage, payment, and benefit category determinations for this whole sector. We've been advocating for years with CMS to try to improve its systems. We have multiple examples we could give of some of the shortcomings with the current system. I will admit there have been some improvements. We want to acknowledge that. We look forward to continuing to work with CMS to see what other additional improvements can be made so that these kinds of decisions can be made much more expeditiously, beneficiaries can gain access to the technologies in an affordable and equitable manner. And frankly innovators will know that they will receive some return on their investment if they choose to focus on this area of research and development and innovation. That's one of the most important things to ensure that people continue to go into this field to help people who need these assistive devices and technologies, so I won't be too much more specific.

I would love to see additional improvements in the national coverage determination process as well. There's simply a kind of a black box when it comes to a submission of an NCD and the regulatory process that begins is fairly well laid out but, before you get your NCD opened, it really is a fairly non-transparent and lengthy delay, and we hope that you will also look at that. Thank you for the opportunity to make these comments.

Jonathan Blanar: Okay thank you, Peter for your remarks. Next up, I'd like to invite Katherine Meyer to the floor.

Katherine Meyer: Hello, my name is Katie Meyer and I'm head of Government Affairs for Novocure, a global oncology and medical device company striving to extend survival in some of the most aggressive forms of cancer through our innovative therapy tumor treating fields through Optune, a wearable portable FDA approved medical device designed for at home patient use. Electric fields are delivered to disrupt the cancer cell division and cause cancer cell death. Optune is currently indicated to treat glioblastoma and mesothelioma in combination with chemotherapy and we are studying use of the technology and other cancers, including lung ovarian and pancreatic cancer.

Novocure is highly encouraged by CMS' commitment to reforming and improving the Medicare reimbursement process for patients and ultimately expanding access to innovative medical devices. We thank and applaud you for this commitment, as well as for the opportunity to participate in today's listening session. Novocure strongly believes that Medicare beneficiaries most stand to benefit from changes to the coverage process that will facilitate more equitable and seamless coverage to innovative medical technologies like Optune.

As the Agency contemplates future coverage refinements, Novocure wishes to emphasize the importance of implementing a clear and predictable pathway for Medicare coverage of novel medical technology. A clearly established pathway that offers consistent and expedited Medicare coverage for innovative devices with sound clinical evidence and safety data will best ensure that Medicare beneficiaries are able to receive the treatments they need to improve their health and wellbeing as soon as they're made available.

Thank you again for holding this helpful listening session and for allowing Novocure to participate here today on behalf of the more than 20,000 patients we have served. We are excited to contribute to the future of Medicare coverage for medical technology and look forward to serving as a resource to you going forward, thank you.

Jonathan Blanar: Thank you, Katherine. The four questions were dropped into the chat so if folks were looking for them, you can find them in the chat. Next up is Christine Jackson. Christine? Christine, I think you might still be on mute.

Christine Jackson: There we go. Can you hear me now?

Jonathan Blanar: Yes.

Christine Jackson: Thank you and good afternoon. As was said, my name is Christine Jackson. I'm the Vice President of Global Health Policy at Medtronic and I'm here speaking on behalf of a consortium of five companies that include Boston Scientific, Edwards Lifesciences, Johnson & Johnson, Medtronic and ViewRay. We appreciate CMS' efforts in holding this listening session and the opportunity to speak here today.

Each of our companies have an ongoing commitment to clinical research surrounding our respective device technologies and generating meaningful evidence of improved outcomes for

patients, including Medicare beneficiaries. For technologies that are approved by the FDA, we share CMS' express goal of timely and predictable Medicare coverage while ensuring that the Agency covers items and services based on scientifically sound clinical evidence and with appropriate safeguards for beneficiaries. This type of coverage would go a long way in ensuring that patients have timely access to life-enhancing and life- saving therapies. Specifically, we support the creation of a voluntary, timely and predictable coverage process for emerging technologies that provides for continued high quality evidence development when it's necessary to better understand the benefits that these technologies bring to Medicare beneficiaries.

This coverage process is needed to address the uncertainty about Medicare coverage currently facing many innovative technologies after attaining FDA approval or clearance. And this uncertainty is one that in some cases can hinder investments in new technologies that have great potential for improving patients' lives. As part of the coverage process, we believe that CMS has an important role to play in identifying key Medicare relevant [inaudible] that may remain unanswered, after technologies are approved or cleared by the FDA. CMS should leverage fit for purpose evidence generation strategies so that the necessary evidence can be generated and assessed in a timely manner. The coverage process should also include appropriate beneficiary safeguards [inaudible] the transitional coverage process can start when manufacturers engage with the FDA for market authorization. The regulatory timelines offer a sufficient opportunity for an interested manufacturer to apply for transitional coverage. And the early engagement between the manufacturer and CMS can identify any specific evidentiary needs associated with the use of the device in the Medicare population and also understand any coding, payment or other operational issues that may stand in the way of full beneficiary access to an emerging technology.

Implementation of certain aspects of the process can build upon [inaudible] is currently available to the Agency. For example, CMS could model the transitional coverage application process after the process that it currently uses to review and cover technologies in an investigational device exemption clinical trial and mechanisms such as the quarterly systems updates can balance the need for timely implementation of coverage with reducing administrative complexity for healthcare providers, Medicare Administrative Contractors and also CMS. The implementation of a voluntary, timely and predictable coverage process will allow CMS again to achieve its goal of providing medical coverage for emerging technologies while ensuring that the agency covers items and services based on scientifically sound clinical evidence and with appropriate safeguards for beneficiaries. Again, we appreciate the opportunity to speak here today and CMS' efforts in establishing a path for transitional coverage for emerging technologies and we look forward to continuing to constructively work with the Agency to shape the development of such a pathway. Thank you.

Jonathan Blanar: Thank you, Christine. And just a reminder, too, if you did notify CMS that you did want to speak today just again raise your hand, please. I want to make sure that we get to folks. Next up is Chandra Jackson. Chandra, you're the second one on the list so I'm glad we found you.

Chandra Branham: Hi, Chandra Branham. thank you. Can you hear me?

Jonathan Blanar: Yes.

Chandra Branham: Okay, great. Thank you so much. I appreciate the opportunity. My name is Chandra Branham and I'm senior Vice President at the Advanced Medical Technology Association. I'm going to go quickly, because I think you're going to hear some common themes, but I wanted to note that AdvaMed represents medical device manufacturers that includes large companies, smaller to mid-sized companies, manufacturers of in vitro diagnostic tests and many of whom are developing emerging technologies. And we have been advocating for a long time for policy and process improvements that would result in more predictability in the pathway to coverage for Medicare and, on top of that, we really, we believe that CMS has a critical role to play in advancing access to these innovations.

We've met with CMS, we brought forward some of our ideas, so I'm going to just quickly summarize those ideas and our current thinking. We have urged CMS to develop a voluntary transitional coverage program that would allow for early engagement between CMS and the companies that are developing emerging technologies. We think that such a clear, articulated process could enable CMS to learn about the new technologies, allow discussion and evaluation of the existing evidence around those technologies with the manufacturer. And to echo some earlier comments, the process could build off of CMS' process for reviewing and covering technologies in IDE trials. So, for the process that we would envision, I'm going to mention six points very quickly.

The first point, it would be a voluntary opt-in approach for coverage based on some eligibility criteria that we would hope to work with CMS to develop. Number two, a feedback loop between companies and CMS so this would allow companies and CMS to communicate proactively to address any concerns regarding existing evidence or use in the Medicare population or any other concerns. Number three, there should be collaboration between device companies and CMS on ongoing evidence development during that transitional coverage period. Number four, should provide for assurance of beneficiary protections. that's very important. Number five, opportunity for public comment, and number six, there should build in adequate time to ensure system readiness, such as you know, coding, payment identification instruction to contractors, etc. So, I went quickly, thank you so much for the opportunity, and we look forward to working with you on this. Thank you.

Jonathan Blanar: Great, thanks Chandra. Next is Joseph Nahra. Joseph?

Joseph Nahra: Hello. Can you hear me?

Jonathan Blanar: I can, thanks Joseph.

Joseph Nahra: Thank you very much. Appreciate the opportunity to speak. I'm speaking today on behalf of the Independence Through Enhancement of Medicare and Medicaid, or the ITEM Coalition. We are a group of about 95 national nonprofit organizations that are dedicated to enhancing access to assistive devices and technologies, particularly for people with disabilities,

injuries, illnesses and chronic conditions. We appreciate the CMS' commitment to moving forward with new rulemaking to expand access to transitional coverage for emerging technologies. And while we strongly supported the previous MCIT rule, and were disappointed to see it withdrawn, we do recognize that the administration identified some issues with the scope of that rule and we're really committed to working with CMS to improve and revise this proposal in advance of a new rule.

More broadly, the ITEM Coalition has long had concerns with the pace of coding, coverage and payment decisions at CMS. The populations we represent often face significant barriers to accessing items and services in the Medicare program and under other payers, even when they are covered. And too often coverage policies, as well as coding, benefit category and payment determinations, restrict or deny access to medically necessary technologies that are used by people with disabilities to enhance their health, their independent function and their ability to participate in activities of daily living, so we really appreciate that CMS also recognizes the need for additional process improvements beyond an MCIT or TCET rule. And we'd like to note a couple of specific recommendations today and, of course, look forward to working further with the Agency.

One of the primary recommendations I want to mention is around the timeliness and the transparency around the national coverage determination process. While the regulatory language around the NCD process outlines typical timelines for various stages, these are not mandated in regulation and oftentimes the Agency's decision making takes significantly longer than six to nine months, which is stated in the regulation sort of the typical time frame. There is also, as was mentioned earlier, there's no timeline specified for the opening of an NCD once it's deemed complete and we found that NCD requests often end up sort of languishing in this limbo for long periods of time. I'd also note sort of as an example of this, that the NCD waitlist or the dashboard which is intended to provide stakeholders with information on how many NCD requests are being reviewed, what's in the queue for being opened, etc., that hasn't been updated at this point since September 16, 2020 and that really makes it difficult for stakeholders to kind of understand where the agency stands in the process and what's pending.

Additionally, I'd like to note one other issue. CMS noted in the withdrawal of the MCIT rule that one of the concerns was that data collected during the FDA Breakthrough designation process may not require or include data specific to Medicare beneficiaries and specifically stating the senior population. We'd just like to reiterate and ensure CMS continues to recognize that a significant proportion of the Medicare population is under age 65 including about 9 million beneficiaries with long term disability patients with ESRD dual eligibles, so we encourage you to carefully consider the needs of all Medicare beneficiaries when developing future coverage process reforms and again really look forward to working with you to work on these new rule makings. Thank you very much.

Jonathan Blanar: Great, thank you Joseph. Next up is Alyssa Schatz. Alyssa?

Alyssa Schatz: Can you hear me?

Jonathan Blanar: Yes.

Alyssa Schatz: Great, thank you. Good afternoon, I'm Alyssa Schatz, the Senior Director of Policy and Advocacy at the National Comprehensive Cancer Network. NCCN is an alliance of 31 leading academic cancer centers in the U.S. working to improve and facilitate quality, effective, equitable and accessible cancer care. The NCCN clinical practice guidelines in oncology apply in 97% of cancers and cover the entire cancer care continuum. Our guidelines are used by payers representing over 85% of covered lives in the U.S., including CMS for coverage determinations. They are transparent, continuously updated and available free of charge for non-commercial use.

NCCN supports CMS' efforts to identify coverage mechanisms that ensure timely coverage of appropriate care. We also share CMS' concerns that as previously finalized, the MCIT pathway did not include safeguards to ensure patient safety, clinical appropriateness of the intervention for the Medicare population and transparency. We'd like to discuss successful coverage mechanisms that use clinical practice guidelines to achieve the simultaneous goals of expedited coverage and clinical appropriateness. We believe these models could be applied across current gap areas for Medicare beneficiaries. Nationally recognized compendia already play a critical role in ensuring timely and appropriate access to drugs and biologics in Medicare. The use of compendia by CMS and local MACs for off label anti- cancer and cancer related medications allows for timely patient access to the highest quality and most appropriate care available as the evidence evolves. NCCN is also a provider led entity for the appropriate use criteria program at CMS which uses real time clinical decision support to ensure its imaging is appropriate. These types of models that use continuously updated and transparent guidelines to keep coverage current with the evidence are a critical tool for policy. NCCN guidelines include recommendations on some medical devices for use in oncology and can serve as a useful source of evidence.

In the initial MCIT rule, CMS sought comment on whether a coverage pathway should be developed for diagnostics. As cancer becomes increasingly personalized, and with the proliferation of predictive and diagnostic tests, it's becoming more challenging to ensure patients have access to testing that's informed by evidence and that offers clinical utility and not just validity. To meet this need, NCCN has developed the Biomarkers Compendium, a tool based directly on the NCCN guidelines that identifies the appropriate use of biomarkers to screen, diagnose, monitor, and provide predictive and prognostic information for the treatment of patients. This tool has been successfully employed by commercial payers and CMS could replicate similar models. NCCN encourages CMS to consider the use of continuously updated nationally recognized guidelines across both medical device coverage processes where available and biomarker testing to ensure patients are accessing testing based on evidence. Thank you for your time.

Jonathan Blanar: Great. Thank you, Alyssa. Next up, we have Sandra Waugh Ruggles. Sandra?

Sandra Waugh Ruggles: Alright. Hello everybody. My name is Sandra Ruggles. I am an innovator in the medtech and biotechnology fields and faculty teaching innovation and taking a role in policy research at the Stanford Byers Center for Biodesign. Stanford Biodesign teaches a needs-driven approach to innovation that centers on addressing unmet needs in the health care system. And it's now in its 21st year and is the foremost institution of its kind, with hundreds of fellows trained in its approach. The technologies developed by those educated in the biodesign process have gone on to impact millions of patients and our goal as educators and innovators is to use new technology to improve care that drives meaningful benefit for patients in the healthcare system.

We recently started an initiative focused on healthcare innovation policy and published our first paper on the impact of an accelerated path to coverage to the healthcare innovation in the journal Health Management Policy & Innovation. It's a survey of 253 innovators and investors n health tech screened for experience in reimbursement. I want to just quickly summarize some of the key points from that survey and investigation and highlight some of the evidence that is directly applicable to CMS and your rulemaking around the TCET program. So, innovators and investors first off responded that the existing parallel review process and CED pathways were not sufficient to provide timely patient access to novel medical technologies. Investors felt that the reimbursement pathway was the highest impact external factor to their decision to invest in and support new technology. And last, innovators would be more likely to take on the difficult and risky projects represented by Breakthrough designation with a path to coverage by CMS.

What maybe most relevant to your work with this program is that 87% of innovators responding to our survey indicated that their company collects real world evidence after FDA authorization of a Breakthrough technology most or all of the time. So, it's already well accepted by innovators that post authorization studies are a necessary component of the path to coverage.
So, to conclude, a process for transitional coverage by CMS would narrow the gap for patients to receive efficient and effective care and we encourage you to develop a path to coverage that provides early engagement with CMS and creates transparent and predictable evidence-based milestones for innovators developing these technologies. So, because a transitional coverage setup which gets needed high impact technologies into the hands of patients and physicians quickly after authorization also allows for the collection of useful real-world evidence and it will go on to be a benefit for both CMS, patients and the entire innovation ecosystem. Thank you so much for your time.

Jonathan Blanar: Great. Thank you, Sandra. Next up John Chi.

John Chi: Hi, I'm John Chi. I'm the CEO of Synova Life Sciences. We're a small medical device company in regenerative medicine, so we make a device that processes adipose tissue and stem cells from within that tissue for cosmetics, orthopedics and other chronic degenerative conditions that currently have no effective interventions. And I really want to say I love the initiative here and really appreciative of how quickly, you all are moving to get something in place that's going to work. We have a lot of hope for getting some kind of transitional coverage initiative passed, as it would help small companies like us stay alive and also to get our

technologies out to patients and Medicare beneficiaries. I understand that there's a lot of thought and consideration going into what exactly will be considered an emerging technology. And so this is just for your consideration, if it's not already in the mix, is around RMAT designation from the FDA, the Regenerative Medicine Advanced Technology designation and a lot of that has a lot of overlap with the Medicare population just because it's dealing with chronic degenerative conditions and so just wanted to put that onto your radar and just really thank you all for everything that you're doing and everything that's going on, thank you.

Jonathan Blanar: Great. Thanks, John for those remarks. Next up is William Welch. William? William, I think you are still muted.

William Welch: Hi, everyone. I'm Dr. William Welch, speaking in my current position as chair of the American Association of Neurological Surgeons and Congress of Neurological Surgeons Drugs and Devices Committee. I want to just have just a few brief statements on behalf of the AANS and the CNS. I want to point out that neurosurgeons have been at the cutting edge of advances in treating diseases and disorders of the brain, spine and peripheral nerves, including stroke, back brain pain, traumatic brain injury, epilepsy, Parkinson's disease and tumors. We are all very aware of the need for innovation, safe and effective medical devices.

Interestingly, neuro is the most common device category that's received the Breakthrough Device designation. AANS and the CNS supported the Medical Medicare Coverage for Innovative Technology regulation and we opposed the repeal. We support pending legislation that would codify MCIT into law. We urge the CMS to act following the repeal of the MCIT regulation to find ways to bring innovative devices to patients. We support the use of specialty society registries. We've partnered with these registries in the past and we've provided this information to the FDA and to payers. While we support an expedited pathway to coverage for innovative devices, we continue to support data collection to develop the clinical evidence base needed to ensure patient safety and efficacy. We're eager to assist the CMS and the FDA to provide neurosurgical expertise and we value our long-time collegial relationship with the Agencies. That's all I had, and I thank you for your time.

Jonathan Blanar: Great, thank you, William. Next up is Jugna Shah.

Jugna Shah: Hi there. Can you hear me?

Jonathan Blanar: Yes.

Jugna Shah: Hi, thank you for the opportunity. I didn't request the opportunity early, so I haven't prepared full remarks, but I'll do my best. I'm here representing the American Society for Transplantation and Cellular Therapy, the ASTCT, thy are a professional membership association of more than 3,000 physician scientists and other healthcare professionals and have worked heavily and very deeply in the cell therapy space specifically chimeric antigen receptor T cell therapy or CAR T. And that is one of the most recent experiences outside of the device space that we have where coverage issues became a real a real problem. And what we are

concerned about is more novel therapies are upon us and the pipeline is quite large. We imagine that there will be additional requests for a coverage analysis, NCAs that will lead to either NCDs or CEDs due to the Medicare Advantage and significant cost issue. And that's a very specific issue and our concern is that there should be a pathway or a new way for Medicare Advantage to be able to deal with the issue of significant cost without having to request an NCA that then launches off a huge process for the Agency, certainly, but also for groups that then want to weigh in and, most importantly, for patients as during that entire process there's questions about coverage, there's questions about access and specifically, with these therapies, given some of the price tags associated with them, hospitals are less and less likely in that coverage period to proceed so that's one significant issue we really hope that there is a way to handle this particular space of therapies without seeing NCA after NCA.

The second issue, and several people mentioned benefit category. For the cell therapy space, we have a very specific benefit category concern and hope that CMS will work to address it. Today hospitals are not paid for the collection of cells and the Agency has indicated there's a benefit category issue. We haven't seen a detailed analysis from the Agency about what the specific benefit category issue is, but the net result is that hospitals engage in cell collection and cell processing and they are not reimbursed at all for that. The Agency pays for the product and the administration but does not pay for these services. The manufacturers also do not pay the hospitals for these services. So far, the issue hasn't bubbled up as much as we believe it will simply because of the number of therapies and the number of treatment centers that are approved, but we anticipate that this will become a growing problem and urge the Agency to work together with us and other stakeholders to determine how these patient specific services that hospitals render can be appropriately covered and then reimbursed. If there is a benefit category issue, we would greatly appreciate working with the Agency on that. Thank you so much.

Jonathan Blanar: Great, thank you. Next up is Brian Carey.

Brian Carey: Thank you very much for the opportunity to present today on behalf of the Coalition for 21st Century Medicine, which is a collection of leading diagnostic providers of precision medicine clinical laboratory tests and we really want to thank the Agency for the listening session today, but also all the work over the past several years to come up with a transitional pathway to expedite coverage of innovative technologies following FDA approval. We strongly supported the MCIT pathway and look forward to working with the Agency on the TCET pathway. We want to just make a few comments based on the comments we've submitted in the past about the need to have a transitional pathway to eliminate the coverage gap following FDA approval. And then we hope that, based on all the work done over the past several years and all the public comments that had been submitted today, the Agency will be able to expedite the rulemaking so we'll be able to have a transitional pathway for these new innovative technologies.

To repeat some of the points that have been made earlier, we think it's really important that for the pathway, the Agency establish clear and transparent criteria for what qualifies as an eligible technology. And as part of those criteria, we would like to make clear that clinical laboratory

tests, such as genomic and genetic tests would be qualifying technologies for the pathway, and in particular that the pathway would be open to screening technologies that fall within a benefit category. The other main point that we would like to emphasize is that this should be a voluntary pathway and that in response to the questions in the chat, that there really is an opportunity to leverage the work that's going on with the FDA with companies and with CMS to collaborate and agree on developing real world evidence that's going to include the type of evidence relevant to the Medicare population and that could be done by at the time, companies are working with the FDA so once there's market authorization those technologies would be able to be covered, through the transitional pathway. So again, thank you for all your efforts and we look forward to working with you on this throughout the year.

Jonathan Blanar: Thank you, Brian. Nicole Deuber, you're up next. Nicole, you still may be muted.

Nicole Deuber: I'm sorry, I must have hit the raise hand button. I don't have a statement.

Jonathan Blanar: Okay, no worries, thank you. Next is Leslie, Leslie Wise.

Leslie Wise: Hello. How are you?

Jonathan Blanar: Doing well, thank you.

Leslie Wise: Okay, I'm going to try to go down the questions as they were submitted. Okay, so how can CMS do better to engage stakeholders. One of the things that I see, because I do work with the Innovation community quite a bit. These new companies they don't understand the process, because the FDA publishes regulations, they have a very clear understanding of what they need to do for the FDA. While CMS does not have the same type of regulations out there, so I don't know if it's webinars, but I do think the CMS should consider putting together some kind of educational materials to help these innovators, because this is where innovation is really occurring as the lady said from Stanford Biodesign so some kind of education materials to help these companies understand what is going to be required. That a code is not reimbursement, because often that's what they think so that's one thing that I think you guys could do.

And then clearly from an FDA synergy standpoint, you know, Breakthrough was ideal. I mean it's an ideal program and I think that there should be a corresponding policy that says that CMS will provide some benefits for Breakthrough Devices, otherwise it's an empty regulation. Because at the end of the day, if you can't get to revenue having an innovation that sped through the FDA but then you get to Medicare, and Medicare slows you all the way down and you still are in that valley of death, it doesn't really help innovators.

So, one of the things that I think might be a good solution, and this goes to two and three, is that Medicare seems to do, to me, the best when they use existing procedures. You guys already have Category B. Now I know it's established for people that already have some kind of FDA approval, but I think for Breakthrough Devices, that the Category B IDE coverage policy might be a good way to pay for a trial for Breakthrough Devices. If you achieve the primary endpoint,

then you achieve coverage. Medicare may want to see longer term data, then there's an NCD with a CED process or local MAC CED process, but you could absolutely make an alternative pathway, just like you did with TPT and just like you've done with NTAP. I think you should make an alternative pathway to Category B for Breakthrough Devices.

And then the other thing is there should be real engagement, like what Chan said when she was talking about her six points. Just like there's engagement for Breakthrough Devices with the FDA, the same thing needs to be there for CMS and I know because of all the work that I've done with AdvaMed when I worked in industry, is that the argument is that CMS doesn't have the resources, and I know that you guys have said that you don't want a MDUFA-like arrangement with industry, but we have to come up with some process so that companies can engage and understand what they need to get coverage, as well as Medicare does have the ability to create codes for Breakthrough Devices.

I think the coding process should be handled by Medicare rather than going through the AMA because if you have to go through the AMA that still can slow down a Breakthrough Device, and this is an innovation that's addressing an unmet need, so I think that's the other piece Medicare should take over the CPT process so coding, coverage and payment is all handled through Medicare when it's talking about a Breakthrough Device. And now I've kind of sped through that, but I wanted to make sure I didn't go over my three minutes. Thank you for this opportunity and I look forward to seeing what happens with this policy. Bye bye.

Jonathan Blanar: Great, thank you Leslie. I know we have about three hands left and we still do have some time left in the session so if anybody else would like to speak, please go ahead and raise your hand using the raise hand function in your Zoom screen. Lisa Rogan, you're up next.

Lisa Rogan Flaherty: Thank you very much. Can you hear me?

Jonathan Blanar: Yes.

Lisa Rogan Flaherty: Excellent. My name is Lisa Rogan Flaherty. I work for Nuvaira, a medical device startup in the field of interventional pulmonology. We have a device which is a pivotal trial phase for patients with chronic obstructive lung disease or COPD. This is a very expensive and debilitating condition which affects a large proportion of Medicare patients and represents a substantial proportion of the total cost of care. My comment is that I think CMS should exercise a right of approval.

Jonathan Blanar: I believe you're on mute.

Lisa Rogan Flaherty: Okay, I don't know how that happened.

Jonathan Blanar: You're back.

Lisa Rogan Flaherty: Can you hear me now? Okay, great. So, my comment is that CMS should exercise a right of approval of new technologies that are eligible for MCIT based on FDA Breakthrough designation. CMS should establish specific approval criteria for the MCIT program including a minimum participation of Medicare patients in the pivotal trial as well as alignment with industry on relevant clinical and safety outcomes specific to the Medicare population to provide CMS with assurance that the novel therapy will add value and benefit to Medicare patients. Finally, a requirement for approval in the MCIT program should include a commitment by the manufacturer to provide reasonable postmarket data to CMS in exchange for alignment with CMS that national coverage determination criteria will be satisfied at the expiration of the MCIT phase. Thank you very much for the opportunity to comment.

Jonathan Blanar: Great. Thank you, Lisa. Barbara?

Barbara Calvert: Hello everyone, this is Barbara Calvert, Director of Medical Products Reimbursement for Abbott. Abbott provides a broad range of advanced cardiovascular and neuoromodulation medical device technologies, as well as diabetes care and nutritional products and diagnostic tests. Like a number of previous speakers, we would like to work with CMS on development of a new transitional coverage process.

We appreciate the changes that CMS has made over the past years to improve national and local coverage processes. During the session today. We would like to focus on recommending some additional changes to the national coverage process for CMS consideration. Our first recommendation relates to coverage of new indications within existing NCDs. Many NCDs state that no other indications are covered. This means that a new indication typically will not be covered by Medicare for a year or longer following FDA approval, pending a revision of the NCD. To address the situation, we recommend that CMS not include blanket language in NCDs that excludes coverage of new indications. In addition, we recommend that CMS include language in NCDs providing that future FDA approved indications automatically will be covered under the NCD. But in cases where such language is not deemed appropriate, CMS could specify in the NCD that coverage for new indications shall be determined by the MACs on a claim by claim basis pending revisions to the NCD.

Our second recommendation relates to NCD requirements for clinical trial coverage. Many NCDs include coverage requirements for clinical trials which may address, for example, a trial design and/or specific endpoints. While such requirements may be appropriate when the NCD is first established, they can become outdated as evidence for a technology evolves and new indications are studied. So, in order to allow more flexibility for an appropriate trial design, we recommend that where possible, CMS not include specific clinical trial coverage requirements in NCDs. Instead, CMS could simply state that the clinical trial must be approved by CMS.

Our third and last recommendation relates to NCD process timelines. To increase predictability in the national coverage process, we recommend that CMS establish a [inaudible] timeline for respond to formal NCA requests and a 90-day timeline for issuing implementation instructions following finalization of an NCD. Those are our three recommendations, and thank you very much for considering them.

Jonathan Blanar: Great. Thank you, Barbara. Next up is Elizabeth Tuckwell. Elizabeth? Elizabeth? I think you're… Thank you, there you go.

Elizabeth Tuckwell: Okay, I just wanted to say that I'm a patient covered by Medicare because I'm 74 years old. I was born with a kidney defect. And I was born in 1947, and in the 50s and I believe in the 60s, there were tremendous advances in the area of kidney possibilities. As a Medicare recipient, what I have found is that there is not a lot of emphasis on kidney patient care until one reaches the stage of dialysis. I would, just speaking as a patient, I mean I don't represent any money source at all, but speaking as a patient covered by Medicare I would be grateful if Medicare could encourage innovations that would provide possibilities for care of chronic kidney disease, which I've had all my life, before the level of dialysis, which I have not yet reached, even though I'm 74. But I mean I give you great credit, because I mean the fact is I'm 74. I was born with a kidney defect, and I have not yet reached the dialysis stage that's wonderful credit to the American medical system, so I give you credit for that, but if you could somehow put a little more emphasis on kidney care.

I know as a Medicare covered person what I have found is that the tendency is to want to refer me to a prostate specialist and I understand that prostate specialists are equipped to deal with kidney patients, I understand that, but I also know that there are kidney specialists and I'm just saying that maybe it would be one possibility to expand the coverage provided by kidney specialists to broaden that and include more than just dialysis like end stage kidney disease. Thank you very much. I appreciate you letting me speak, thank you very much.

Jonathan Blanar: No, thank you Elizabeth for providing those remarks to us. We have two hands left, and we want to invite others who haven't spoken if you'd be interested in providing comments. Next up is Jonathan Romanowsky. Jonathan?

Jonathan Romanowsky: Yes, Hello, hi. Good afternoon. I'm the co-founder and Chief Business Officer of Inflammatix, a northern California-based molecular diagnostics company. I'd like to first thank you for your interest in receiving our input to best implement a rule that will facilitate Medicare beneficiary access to important emerging technologies. Inflammatix is developing tests that measure patterns of a human immune response using advanced informatic techniques, including machine learning. Our first test currently in development is designed to help physicians better diagnose acute infections, including COVID and sepsis. Our test works by combining the expression levels of multiple genes using advanced algorithms. The test will inform on the presence of a bacterial infection, the presence of a viral infection, and the severity of the patient's condition. The test will run on our novel proprietary instrument which is also in development and deliver results to the ordering physician in about 30 minutes. Our tests is intended to aid physicians in their decisions to prescribe antibiotics and antivirals, determine what other downstream diagnostic tests may be needed and inform the level of care needed for patients, including weather hospital admission is warranted.

I'm in agreement with many of the suggestions provided by my industry colleagues so far on today's call. I'd like to highlight the coding and payment for novel technologies which you may

deem eligible for TCET but do not have a current billing code or set payment amount. While we are thrilled that TCET could close the coverage gap, it's imperative that corresponding coding and payments schemas are implemented concurrently. Under current Medicare coding schemas, we would expect that our test and others like it to be categorized as a multianalyte assay with algorithmic analysis test. We encourage that the TCET process includes clear and rational methods for how MAAA tests and other new technologies that require a unique code and corresponding prices would be set.

Accordingly, we would welcome price setting the price setting process to include collaboration between Medicare, health care providers using these technologies, and manufacturers like us. I'll provide some questions for your team to consider regarding setting prices for technologies requiring novel codes. Will CMS accept the manufacturers price? Will it conduct a crosswalk or gapfill analysis? Will it employ alternative methods? We think that there could be multiple approaches to price setting that generate value to the healthcare system, cover healthcare provider costs and generate reasonable returns for innovators making the investment. Thank you again for the opportunity to comment this afternoon and for your dedication to this important initiative.

Jonathan Blanar: Okay, thank you Jonathan. We're up to our last speaker. If anybody else is interested in speaking, please raise your hand. Next up is Gail Daubert. Sorry if I mispronounced that, Gail.

Gail Daubert: Hi, this is Gail Daubert You did a good job on the last name. It's a little tricky.

I did not raise my hand to make a comment, but I've thoroughly enjoyed the discussion. I agree with most commenters on points related to developing and ensuring that a pathway to facilitate coverage for emerging technology is needed and I think the recommendation regarding the Category B IDE process as being used as a model would be very helpful and I will consider other comments to provide for the upcoming March 31st meeting. Thank you.

Jonathan Blanar: Thank you, Gail. It looks like we don't have any other hands raised so with that I am going to turn it t back over to CMS' Chief Medical Officer, Dr. Lee Fleischer. Lee?

Lee Fleisher: Again, I want to thank everybody for joining us today. We will be providing more information as we continue to ideate with our goal of ensuring that technologies that are reasonable and necessary and improve the lives of our beneficiaries have a clear pathway for coverage and, most importantly, to just remind people about the next listening session on March 31 and with that I'll turn it back to you, Jonathan.

Jonathan Blanar: Thanks, Dr. Fleisher. As Lee mentioned, just a reminder again about the March 31 session, and the same link that you connected with should work for the 31st as well. Thank you again for attending and we look forward to speaking with you in a couple weeks, or a few weeks. Take care. Thank you.