Centers for Medicare & Medicaid Services
Transitional Coverage for Emerging Technologies
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STEFANIE COSTELLO: Welcome. My name is Stefanie Costello. I am Director of the Partner Relations Group in the Office of Communications here at CMS. I will be your moderator today. Today's education session is an opportunity for CMS to provide an overview for the TCET pathway and address questions that were submitted in advance of the meeting. Before I pass things over to our first speaker, I want to share just a few housekeeping items. The session is being recorded, and we will be posting a transcript in the future. This call is not intended for the press or media. The press or media are welcome to listen. However, press or media questions should be submitted to the CMS press office using our media inquiries form, which may be found at CMS.gov/newsroom/media/recordings. All attendees will be muted for today's call. Closed captioning is available via the link shared in the chat by the Zoom pay moderator.
After some brief initial remarks on the TCET pathway, we will respond to as many questions that were submitted in advance of the meeting as time allows. With that, I will turn it over to Dr. Dora Hughes, CMS' Chief Medical Officer to provide opening remarks. Dr. Hughes?

DORA HUGHES: Thank you. Good afternoon. I am Dr. Dora Hughes, the CMS Chief Medical Officer and Director for the Center for Clinical Standards and Quality. I would like to thank all of you for taking the time to join our TCET education session today. As we have mentioned before, CMS is committed to fostering innovation while making sure that people with Medicare have faster access to technologies that will improve their health outcomes. As part of this commitment, we recently released the final notice for the Transitional Coverage for Emerging Technologies, or TCET, pathway. And we released three final guidance documents. Collectively, these documents represent a substantial transformation to our approach for coverage reviews and evidence development.

The TCET pathway, which is voluntary and applies to certain FDA designated Breakthrough Devices, supports innovation by providing an efficient, predictable, and transparent coverage review process while developing robust safeguards for the Medicare population. The TCET pathway uses national coverage determination and coverage with evidence development processes, or NCD and CED, to expedite Medicare coverage of certain Breakthrough Devices. TCET benefits people with Medicare that need access to the latest medical advances, doctors and other clinicians who want to provide the best care for their patients, and manufacturers who create innovative technologies. Under the TCET coverage pathway, CMS will coordinate with FDA and the creators of devices as those devices move

through the FDA premarket review processes to ensure timely Medicare coverage decisions following any FDA market authorization. CMS' goal is to finalize a national coverage determination, or NCD, for devices accepted into and continuing in the TCET pathway, within six months after FDA market authorization. The new pathway provides manufacturers with opportunities for increased premarket engagement with CMS and a new and unprecedented level of flexibility to address any evidence gaps for coverage.

TCET aims to reduce uncertainty about coverage options through a premarket evaluation of potential harms and benefits of technologies while identifying any important evidence gaps. The pathway allows manufacturers to address any evidence gaps through fit-for-purpose studies. A fit-for-purpose study is one where the study design, analysis plan, and study data are appropriate for the question the study aims to answer. In addition, it will help with coding and payment reviews. We believe that manufacturers will be better positioned for multiple product development stages if they anticipate both FDA and CMS requirements when developing clinical studies. To that end, CMS intends to publish a series of guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas. The final clinical endpoints guidance for knee osteoarthritis is the first example.

Additionally, CMS partnered with AHRQ to develop a comprehensive approach that incorporates greater flexibility into the CED paradigm. Accordingly, we have updated our CMS Evidence Review guidance to more clearly describe our review process and our Coverage with Evidence Development study requirements to more clearly allow fit-for-purpose study designs. When developing the TCET pathway, CMS solicited extensive feedback from patient groups, medical professionals, device manufacturers, innovators, and other federal agencies. This feedback included requests for CMS to develop a more agile, iterative evidence review process that considers fit-for-purpose study designs, including those that make secondary use of real-world data.

We appreciate the helpful feedback we've already received on the TCET pathway. CMS will continue to engage with interested parties to ensure that Medicare promotes access to emerging medical technologies while maintaining appropriate safeguards and rigorous evidence standards essential to the health of Medicare beneficiaries. Thank you again for your participation, and we hope you find today's educational session helpful. I will now turn the webinar over to Dr. Steve Farmer, the Chief Strategy Officer in the Coverage and Analysis Group for a full presentation on the TCET pathway. Dr. Farmer?

STEVE FARMER: Thank you, Dora. And thank you to everyone participating in today’s education session. As Dora mentioned, we recently released a final procedural notice establishing the TCET pathway for Breakthrough Devices. I am now going to provide you with an overview to the pathway before we entertain questions that were submitted to us ahead of the session. Next slide. I have nothing to disclose. Next slide.

Evidence-based care underpins the CMS/HHS value mission. Delivery of procedures and services that don't work cannot support the goal of improving value in healthcare delivery. Consequently, CMS invests substantial resources in developing coverage policies that shape and frame how we pay for procedures and services. CMS is uniquely positioned to play this important role given the scope of our coverage and it's close -- and our close relationships with its sister agencies. Under the Social Security Act, CMS may pay for items and services that are reasonable and necessary. The three principal tenets of that assessment are that it is safe and effective, not experimental or investigational, and appropriate for Medicare beneficiaries. The third criteria is crucial because in many instances, pivotal randomized control trials in the premarket period do not include patients and treatment conditions applicable to the intended Medicare recipients. Next slide.

The FDA Breakthrough program has granted more than 930 Breakthrough designations as of the end of last year, but not all of them require an NCD. In fact, only a small subset of them might be appropriate candidates for TCET. Let me walk you through how we reached that conclusion. Firstly, FDA Breakthrough designation is based on a device's potential benefit, and it is often before a pivotal clinical study has even been initiated. Of the more than 930 Breakthrough designated devices since 2015, only 95 have been market authorized to date. Of those in the market, some are substitutes for supplies or equipment already covered under our coverage policies. Some may not be appropriate for Medicare beneficiaries, some lack a benefit category, and some are excluded from coverage through law or regulation. Next slide.

CMS and FDA have different mandates and operate under different legal authorities. FDA's charge is to assess safety and effectiveness, which, while CMS' charge is to determine whether an item or service is reasonable or necessary. The populations participating in studies guiding FDA approvals are generally younger, more often male, and less racially and ethnically diverse, and they typically have fewer comorbid conditions than the CMS beneficiary population does. Study inclusion and exclusion criteria may demonstrate the safety and effectiveness of a product or service under idealized conditions, but may lack applicability to the Medicare beneficiary population in the context in which they receive their care. Next slide.

Emerging technologies often face several challenges in obtaining prompt market access after FDA market authorization. Medicare is a defined benefit program, and many of the benefit categories were conceived decades ago. Emerging technologies may not neatly align with the existing benefit categories. National coverage determinations occur through an open and transparent process. As I noted, the evidence needs to be applicable to Medicare beneficiaries, and the standard of medical care may not be well established, and the ideal conditions of coverage may be unclear. To achieve market access, manufacturers must have coverage, a code, and a payment rate. Codes are governed by multiple parties that are not coordinated with FDA review processes. Even temporary

codes may be problematic if they undermine the ability to conduct real-world data studies. Next slide.

So, the TCET pathway is designed to address many of these challenges and forge a more efficient path to market access for FDA-designated Breakthrough Devices. By engaging with manufacturers in the premarket period, TCET is designed to facilitate early, predictable, and safe beneficiary access to new technologies; reduce innovators' uncertainty about coverage; and third, to encourage evidence development if material evidence gaps exist for coverage. Next slide.

The TCET pathway uses existing CMS authorities to develop national coverage determinations. TCET NCDs occur through an open and transparent process with multiple opportunities for public comment. Most NCDs cover a class of items or services a structure that is agnostic to individual devices and can accommodate iterative device refinements and allows for off-label coverage within an approved study. Next slide.

Some NCDs include a coverage with evidence development requirement. I mentioned earlier that CMS may pay for items and services under the law when they are reasonable and necessary. However, many emerging technologies arrive in the market with critical questions that need to be answered. For example, is the treatment effect durable? Do you get similar results in the Medicare population that you saw in the pivotal trials and outside of academic medical centers? Where the evidence is promising but does not yet satisfy the reasonable and necessary standard for coverage, CMS may use the coverage with evidence development pathway. CMS collaborates with AHRQ in the CED pathway and may cover items and services contingent on completing additional clinical studies. CMS believes that CED is a balanced approach to coverage that supports the rational diffusion of new technologies into the market. It balances early beneficiary access to technologies that often address an important, unmet medical need. It promotes further scientifically rigorous evidence generation, and it establishes beneficiary protections through coverage conditions in the NCD. These together promote provision of high-value care for our beneficiaries. Next slide.

While most coverage determinations are made at the local Medicare Administrative Contractor level, many of the most challenging ones, especially those for emerging technologies, are made through the national coverage determination process. NCDs are not just up or down decisions. They are often created to establish the conditions that are most likely to optimize health outcomes. NCDs are made through an open and transparent process that uses the GRADE methodology to assess the peer-reviewed published English-language literature. I wanted to point out that the public, including specialty societies, play a crucial role in shaping how we cover complex therapies. Next slide.

The TCET pathway is organized in different stages. As Dora mentioned, we have done a lot to try to improve transparency in the premarket stage. In the premarket stage, CMS aims to set clear expectations for CMS coverage so that manufacturers can better anticipate our

requirements as they conceive the total product lifecycle for their devices. We have already published several guidance documents to improve predictability and transparency and are preparing two additional documents for release soon. Our CMS National Coverage Analysis Evidence Review guidance provides greater detail on how CMS reviews bodies of evidence when conducting national coverage determinations. Our Coverage with Evidence Development guidance defines the minimum standards for CED studies. Our Clinical Endpoints Guidance series defines the clinical endpoints that CMS believes are important and their minimally clinically important differences for each of them where there are MCIDs available. We have published the first in that series and expect additional guidance documents soon. We have stated that we expect to publish fit-for-purpose study and real-world data protocol guidance very soon. Next slide.

In the near market stage, which is within that period within a year of FDA market authorization or anticipated FDA market authorization, CMS aims to engage with manufacturers to identify best available coverage options. During this stage, CMS has established enhanced coordination with FDA and AHRQ and after receiving a nomination, we will work with the Center for Medicare to determine the benefit category. For the devices accepted into the TCET pathway, we will conduct a collaborative Evidence Preview which allows for substantive contributions from CMS, AHRQ, and the manufacturer, to establish a shared understanding of the available evidence. Once the Evidence Preview is finalized, CMS will hold a stakeholder meeting with the manufacturer to assess the best available coverage options. Next slide.

In the early post market stage, if there is sufficient evidence to satisfy the reasonable and necessary standard, CMS will build on the Evidence Preview to expedite a national coverage determination. However, if material evidence gaps exist, as we have identified them in the Evidence Preview, CMS will work with the manufacturer and AHRQ to agree on an Evidence Development Plan that may include fit for purpose study designs and allow for time-limited coverage with evidence development requirements. During transitional coverage, the manufacturer will regularly engage with CMS to confirm that the agreed evidence development is on track and there are no FDA warnings or product recalls. Next slide.

In the post market stage, or the late post market stage, CMS aims to reduce the burden of evidence development through timely CED-NCD reconsiderations. CMS will initiate a streamlined process to reconsider the NCD at an appropriate date tied to the Evidence Development Plan. The evidence base will be assessed against objective success criteria specified and justified in the agreed-upon Evidence Development Plan. Next slide.

Some in the public have expressed concern that the proposed TCET procedural notice took over a year to finalize. However, CMS used that time to pressure test the concepts in the TCET pathway to ensure that they would work for manufacturers regardless of size. We also extensively engaged with our sister agencies to identify opportunities to improve coordination. Next slide.

When developing TCET, we heard from industry that it should include opportunities to address evidence gaps through fit-for-purpose studies. A fit-for-purpose study is one where the study design, analysis plan, and data sources are appropriate to address the question at hand. We have incorporated language into the Evidence Review and CED guidance documents that align with this approach and two additional guidance documents are coming soon, as I mentioned. Ultimately, conventional studies in real-world data studies offer complementary perspectives. Conventional studies often require idealized conditions, are smaller, have shorter follow up durations, and sharply restrict inclusion and exclusion criteria. By contrast, real-world data studies reflect real-world conditions. They also allow for larger sample sizes, longer follow up durations, and more diverse patient inclusion. Next slide.

During pilot testing, we learned that many manufacturers need more than four years of transitional coverage to complete real-world data studies, and transitional coverage must allow for that. Real-world data studies may take longer to complete because it takes time for new devices to be adopted, studies need to follow outcomes for sufficient time to demonstrate durability, and claims may take up to two years to mature fully and be available for analysis. Next slide.

Based on manufacturer feedback, we adjusted the Evidence Preview and the Evidence Development Plans, or concepts, during pilot testing. We heard from manufacturers that they wanted a greater voice in the Evidence Preview, and we have reframed the process to allow for greater collaboration. Our contractor conducts a systematic literature review cross referenced against the manufacturer's proposed bibliography. After CMS and AHRQ develop and edit the draft, the manufacturer can propose technical edits and include detailed commentary in an appendix. If an NCD is opened, CMS will review all of those materials together when conceiving the national coverage analysis. We also heard that manufacturers wanted a focused, time-limited CED process. The Evidence Development Plan allows the manufacturer to present all their intended evidence generation plans so that the CED study can be as focused as possible on the remaining issues that CMS needs to address. It specifies endpoints and clinically meaningful differences and the NCD reconsideration date is tied to the expected completion of the studies. We also found that manufacturers were uncertain about what a real-world data study protocol should look like and include, so we have developed detailed guidance and expect to propose it soon. Lastly, as I mentioned earlier, NCDs coordinate input from a large range of parties, and we are developing a web-based tool that makes it transparent and easier to navigate for all parties. Next slide.

The pilot projects and public comments resulted in changes to the proposed TCET pathway. CMS has clarified eligibility, created a mechanism to predict TCET demand through letters of intent, established an equitable and operational quarterly review process, and developed a real-time platform that streamlines nominations for transitional coverage, tracks multiple inputs, improves forecasting accuracy, and allows timely

problem identification. The public will soon have the opportunity to comment on the proposed guidance for fit-for-purpose studies, real-world data protocols, and TCET prioritization factors. Next slide.

This process map gives a high-level overview to the TCET process. From left to right, the process begins with a device domination. Eligible nominations are considered during quarterly reviews, and CMS initiates an Evidence Preview for devices accepted into the pathway. In a CMS-sponsor meeting, CMS and the manufacturer can review the best available coverage options based on the Evidence Preview conclusions about the state of evidence. If the evidence satisfies the reasonable and necessary standard for coverage, the manufacturer may pursue an expedited NCD once the product is in the market. If the evidence is promising but likely does not yet satisfy reasonable and necessary standard, the manufacturer may draft an Evidence Development Plan and pursue an expedited CED NCD. Lastly, if the manufacturer chooses to withdraw from TCET, the evidence summary will be posted without a CMS assessment, and the device will remain at Medicare Administrative Contractor discretion. Next slide.

CMS believes that it can finalize TCET NCDs as early as six months after FDA market authorization provided sufficient early engagement and timely collaboration with the manufacturer. Also, if the coverage group is adequately resourced. Coverage with evidence requirements would continue only as long as necessary to close material evidence gaps identified in the Evidence Preview. Next slide.

CMS is committed to enhancing access to high-value emergency technologies. Even so, we must ensure that covered devices are appropriate for Medicare beneficiaries. We will soon propose fit-for-purpose study and real-world study protocol guidance, followed by prioritization guidance when possible. Devices must be submitted by October 31st 2024 to be considered in the first quarterly review cycle. I want to thank you for your attention. Now, I will turn the call over to Stefanie, who will be moderating the question and answer portion of this webinar.

STEFANIE COSTELLO: Thank you so much, Steven. Steven mentioned, we are going to be turning it over to go through the questions that were previously submitted. Lori and Steven are going to go through questions. Our first question today is for Lori. The question is, when does the one-year clock start for nominations? Is it August 12th since that is the date the policy was effective? Or after the first quarter review? And then what happens if there are delays in FDA market authorization?

LORI ASHBY: Thanks, Stefanie. Under the TCET pathway, CMS will conduct extensive work in the premarket period to shorten coverage review time frames after devices are FDA market authorized. We believe that 12 months before the anticipated FDA market authorization is the appropriate time frame for TCET procedural steps to be completed and for better coordination of coding and payment. CMS may be unable to reach a final NCD within the expedited time frames for TCET nominations submitted or accepted less than 12

months before anticipated FDA market authorization. This timeframe is not tied to the quarterly review cycle or the date the final notice was released. The final notice includes an opportunity for a manufacturer to submit a nonbinding letter of intent to nominate a potentially eligible device approximately 18 to 24 months before the manufacturer anticipates FDA marketing authorization. While formal nominations will still be considered approximately 12 months before anticipated market authorization, the submission of a nonbinding letter of intent will improve CMS' ability to track potential candidates, coordinate with FDA, and make operational adjustments. Nominated devices will be assessed against eligibility criteria and then prioritized every quarter. We recognize that market authorization dates may change for various reasons. Delays in FDA market authorization would not affect acceptance into the pathway, though FDA market authorization is needed for coverage. Next question, please.

STEFANIE COSTELLO: Is there a lookback period? More specifically, are Breakthrough Devices nearing an FDA decision on market authorization (less than 12 months) or those recently achieving FDA market authorization eligible for TCET?

LORI ASHBY: We did not include a lookback period for the proposed and final notice. Devices already in the market are not appropriate for the TCET pathway. TCET is designed to accelerate the NCD process in the postmarket period by initiating reviews in the premarket phase. Developing an Evidence Development Plan generally takes considerable time and absent adequate lead time during the pre-market period, devices already available on the market or those close to market authorization are more appropriate for an NCD outside the TCET pathway or coverage at the local level through an LCD or claim by claim adjudication. Next question.

STEFANIE COSTELLO: Can CMS describe how software as a medical device and/or other digital health innovations fit into the TCET pathway?

LORI ASHBY: To the extent that these technologies meet the criteria described in the final procedural notice regarding appropriate candidates, they may be eligible. However, we note that any technology seeking Medicare coverage is required by statute to fall within a Medicare benefit category under part A or part B. Establishing one or more benefit categories for software as a medical device is an area of active exploration of policy development within CMS, and there is also interest at the Congressional level as well.

STEFANIE COSTELLO: In the TCET final notice, CMS generally excludes diagnostic lab tests citing that they consider diagnostic lab tests to be a highly specific area of coverage policy development. However, diagnostic lab tests are regulated as medical devices and equally eligible for FDA Breakthrough designation. What is it about diagnostics that is different from other medical devices that excludes them from the TCET pathway?

STEVE FARMER: We acknowledge that the Medicare coverage statute (section 1862 of the Act) applies to clinical diagnostic laboratory tests just like other items and services under

Part A and Part B. While the TCET pathway is open to FDA Breakthrough-designated devices, CMS expects that the majority of coverage determinations for Breakthrough-designated diagnostic laboratory tests will continue to be made by the Medicare Administrative Contractors. We acknowledge that there may be instances where manufacturers and CMS agree that an NCD is appropriate for a diagnostic laboratory test. In those instances where manufacturers believe that additional evidence generation may be needed to satisfy the Medicare coverage standard, we encourage manufacturers to contact CMS to discuss options for their specific technology.

STEFANIE COSTELLO: Thank you. We are going to go back to Lori for our next question. Can you elaborate on how CMS will prioritize TCET nominations? How is beneficiary impact defined? And will CMS consider the impact of Breakthrough-designated device treatment on Medicare beneficiaries suffering from high cost and/or less common diseases for which limited or no treatment options exist? Will CMS look at conditions that impact the greater -- the greatest number of beneficiaries regarding disease prevalence or employ some other criteria? And finally, will CMS consider health equity impact?

LORI ASHBY: Until we release more specific prioritization factors, CMS will prioritize eligible devices based on the 2013 Federal Register notice which states “In the event that we have a large volume of NCD requests for simultaneous review we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.” A high impact on the Medicare program may be assessed based on a significant benefit from a relatively small number of patients or a modest benefit for a relatively large number of patients. The current administration has engaged in extensive efforts to address health disparities through numerous initiatives. All things being equal, we will consider whether a device may have a health equity impact. Next question, please.

STEFANIE COSTELLO: This one is also for you. How will CMS prioritize nominations if qualified nominations are moved from one quarterly cycle to the next? Will these devices be re-prioritized against new nominations in the subsequent cycle? When reevaluating a device that was moved to the next review cycle, will priority be given to a device that may soon be outside of the optimal window for the pathway, specifically devices within six months of anticipated FDA market authorization?

LORI ASHBY: CMS will prioritize TCET devices within each quarterly review cycle. If not accepted in the initial quarterly review cycle, they will be automatically reconsidered in the subsequent cycle. Manufacturers do not need to resubmit their nominations. Within each quarterly review cycle, devices will be evaluated on their individual merits. Since TCET is forward-looking and premarket engagement is essential, nominations for Breakthrough Devices anticipated to receive an FDA decision on market authorization within six months may not be accepted since CMS will be unable to reach a final NCD within the expedited timeframes. A nominated device that is not accepted in a first review may be accepted during a subsequent review even though FDA's decision is anticipated within six months. If

this occurs, CMS will work with the manufacturer to expedite the review as practically achievable. If devices are approved with a shorter than ideal premarket review period, an NCD may be delayed postmarket. Next please.

STEFANIE COSTELLO: Thank you. What level of detail will CMS provide to manufacturers whose nominations are declined for reasons other than the cap being met?

LORI ASHBY: If we decline a nomination, CMS will provide a justification and contact information for additional information. We will identify why the nomination has been declined, including the absence of an FDA Breakthrough designation, a benefit category determination, the need to establish a BCD through the regulatory process, the device being subject to an existing Medicare NCD or it being excluded from coverage through law or regulation.

STEFANIE COSTELLO: The TCET final notice states that candidates not selected for TCET in a quarterly review cycle will be automatically considered in the next cycle. Will CMS notify applicants if they are no longer automatically considered in the next cycle due to proximity to anticipated FDA approval?

LORI ASHBY: CMS is developing a web-based system that will automatically notify manufacturers of any status updates for TCET nominations, including whether they are eligible, have been accepted into the pathway, will be automatically reconsidered in the subsequent quarter, or will no longer be considered for the pathway. We expect the system to be operational by the end of 2024. If devices are approved with a shorter than ideal premarket review period, an NCD may be delayed postmarket.

STEFANIE COSTELLO: One more question for you. How and when will CMS make the following information public after the close of each nomination cycle? First, is the number of TCET applications CMS received. The second is the number of device/procedure class of candidates accepted into the TCET program. And how long after the close of the nomination cycle will CMS update the NCD dashboard with the number of candidates and device/procedure classes accepted into the program? What level of detail will CMS share regarding how candidates were selected and what details will be given?

LORI ASHBY: TCET nominations are voluntary and confidential, and CMS cannot publish a nomination list. CMS will include information such as the number of devices in the TCET pathway, the date of nomination, the date of acceptance, and the date the NCD process is initiated into future iterations of the NCD Dashboard. We intend to update the NCD dashboard quarterly. The NCD dashboard can be found on our website.

STEFANIE COSTELLO: We will give you a little bit of a break and let Steven take the next question. How does CMS use the TCET nomination material to inform the Evidence Preview? Will the list of studies in the TCET nomination serve as the basis for the Evidence Preview or will a new literature search be conducted as part of the Evidence Preview?

STEVE FARMER: In piloting the Evidence Preview concept, we found that terminology changes happened for some emerging technologies during development, which resulted in some publications being omitted from our systematic literature review. To avoid revisions to that document and the delays that may entail, we request that manufacturers list all potentially relevant literature in their nomination request. To ensure completeness and avoid revisions, the contractor will conduct a systematic literature review and compare it against the manufacturer's submitted bibliography. And if a critical article was not included in the systematic literature review, it will be added into the review. I would also like to highlight the collaborative nature of the Evidence Preview process. With contractor support, CMS develops the draft Evidence Preview and shares it with the Agency for Healthcare Research and Quality for feedback. The manufacturer then has an opportunity to propose technical edits and corrections to the document and may add substantial language in the appendix if it needs to. The intent is to establish a shared understanding of the state of the evidence.

STEFANIE COSTELLO: Thank you. Back to Lori for our next question. According to the final notice, manufacturers can voluntarily submit letters of intent 18 to 24 months before anticipated FDA market authorization. Can CMS provide insight on the purpose of letters of intent and describe how submitting a letter of intent could benefit the manufacturer?

LORI ASHBY: Sure. To start, the voluntary letter of intent aims to provide CMS with greater predictability regarding the approximate timing and nature of potential TCET nominations. Advance notice will help CMS to optimize pathway. Specifically, the submission of a nonbinding letter of intent will improve the ability to track potential candidates, collaborate with FDA, and make adjustments. Additionally, a nonbinding letter of intent can help alleviate potential delays if a clinical endpoints review and/or MEDCAC is needed. Regardless of whether manufacturers have submitted a letter of intent, they are encouraged to nominate their device approximately 12 months before an anticipated FDA authorization to make optimal use of the premarket review time .

STEFANIE COSTELLO: Is CMS planning any best practice training on how to submit a nomination?

LORI ASHBY: Yes. We plan to conduct a workshop for manufacturers considering submitting letters of intent and nominations. We will have additional details soon.

STEFANIE COSTELLO: The final TCET notice recommends that nominations be submitted approximately 12 months before the manufacturer anticipates an FDA decision on market authorization for consideration in the pathway. This suggests heavy reliance on a process governed by another agency. How will CMS and FDA coordinate on the TCET process?

LORI ASHBY: Over the last year, CMS staff members have regularly met with FDA, AHRQ, manufacturers and others to help coordination across the government and with

innovators. CMS staff have also regularly engaged with the FDA Total Lifecycle Product Advisory Program. Additionally, as we stated in the final notice, representatives from CMS may meet with FDA to learn more information about specific technologies after CMS initiates a review of a complete, formal nomination. These discussions will help CMS better understand the device and the timing of potential FDA reviews. Initiation of the TCET process approximately one year before anticipated FDA market authorization is intended to be close enough to FDA market authorization that the Evidence Preview can incorporate pivotal trial results, and if there are material evidence gaps, the manufacturer has sufficient time to develop an Evidence Development Plan.

STEFANIE COSTELLO: How will CMS address coding and payment for devices accepted into TCET?

LORI ASHBY: TCET allows CMS to better align coding and payment processes within existing review timeframes by initiating a review well before FDA market authorization. CMS encourages manufacturers to proactively pursue codes and not delay submitting TCET nominations to facilitate coding and payment decisions. To help manufacturers navigate the process, CMS has established a Pharmaceutical and Technology Ombudsman to help coordinate coverage, coding and payment and has published an online guide, the CMS Guide for Medical Technology Companies and Other Interested Parties, which provides information to assist manufacturers with these processes. The guide will soon be updated to include information on TCET.

STEFANIE COSTELLO: Thank you. Steven, a few for you. For a manufacturer of a follow-on device, how much time before FDA approval can the Evidence Preview and Evidence Development Plan be initiated? Should manufacturers contact CMS to initiate an Evidence Preview if a TCET candidate for a similar device has been accepted and an NCD is underway?

STEVE FARMER: If an applicable NCD with CED requirements has been opened or is anticipated, second-to-market devices are encouraged to engage with CMS approximately 12 months before anticipated market authorization so that we can initiate an Evidence Preview specific to the device and the manufacturer has sufficient time to develop an Evidence Development Plan. If CMS is aware of a second market device, CMS may also proactively engage with the manufacturer to initiate both of those processes.
Delays in developing an Evidence Preview or Evidence Development Plan may delay the establishment of an NCD after the device is in the market.

STEFANIE COSTELLO: If a manufacturer-sponsored CED study is required for coverage for a follow-on technology, is there noncoverage for a follow-on device until there is a CMS-approved CED study? And how can this be minimized?

STEVE FARMER: Under Section 1862 (a)(1)(E) of the Social Security Act, CMS will nationally cover an item or service only in the context of a CMS-approved clinical study or

with the collection of additional clinical data. The second-to-market device will be noncovered until a device specific EDP and CED study is approved. This delay could be avoided entirely by initiating the Evidence Preview as soon as possible if there is an expected or established CED NCD.

STEFANIE COSTELLO: How will CMS prioritize the Evidence Preview and EDP review of follow-on devices? Has CMS accounted for this in its TCET resource allocation?

STEVE FARMER: We believe CMS has sufficient resources to conduct timely Evidence Previews and work with manufacturers on Evidence Development Plans for follow-on devices as well as those that are in the pathway.

STEFANIE COSTELLO: One more for you. We understand that CMS now utilizes a contractor to help with the technical analyses. Has this decreased the processing time for new NCD requests and reconsiderations? How will CMS accomplish the TCET workload in addition to the typical number of non-TCET NCDs?

STEVE FARMER: With the addition of TCET, the volume has more than doubled. CMS has leveraged operational efficiencies to streamline and standardize the evidence review process wherever possible. We have augmented our available resources with contractor support, often allowing us to incorporate specialized clinical expertise into the review. These operational improvements will apply to all of our reviews and finding efficiencies across all of our work was necessary in order to add the additional workload of TCET. Additionally, we note some potential overlap--some Breakthrough Devices would have also featured on the NCD waitlist if they weren't accepted into the TCET pathway.

STEFANIE COSTELLO: Thank you. Back to Lori now. What is the anticipated timing of future CMS guidance such as fit for purpose (FFP), real-world data study protocol, and prioritization guidance?

LORI ASHBY: We anticipate releasing fit-for-purpose study and real-world data guidance soon. We anticipate publishing the proposed prioritization guidance after we have worked through several quarterly review cycles.

STEFANIE COSTELLO: Thank you. CMS states that technologies within six months of FDA market authorization will not be accepted into the TCET pathway. How will CMS prioritize coverage for these technologies under the traditional coverage pathway?

LORI ASHBY: We stated in the final notice that since TCET is forward-looking and extensive engagement is essential, nominations for Breakthrough Devices anticipated to receive an FDA decision on market authorization within six months may not be accepted since CMS will be unable to reach a final NCDs within the expedited timeframes. A nominated device not accepted in the first review may be accepted during a subsequent review even though the FDA's decision on market authorization is anticipated within 6 months. If this occurs,

CMS will work with the manufacturer to expedite the review as practically achievable. If devices are approved with a shorter than ideal premarket review period, an NCD may be delayed postmarket. The manufacturer of a Breakthrough Device not accepted into the TCET pathway may submit a complete, formal national coverage determination request if they wish to pursue a conventional NCD. The 2013 Federal Register notice states that in the event we have a large volume of requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

STEFANIE COSTELLO: Okay great. Our last question of the day is, if Medicare Advantage plans must cover all medically necessary services that original Medicare covers, would that include devices under TCET?

LORI ASHBY: Yes. Medicare Advantage plans must comply with TCET NCDs just as they do with conventional NCDs.

STEFANIE COSTELLO: Thank you. And thank you both for answering those questions in a lot of detail. Hopefully, that was helpful for everybody on the call today. I want to thank everyone for being here. I want to turn it back over to Dr. Farmer for any final words.

STEVE FARMER: We want to thank everybody for participating today and for your support of the TCET pathway. We look forward to working through the initial submissions and making this a success. Thank you so much for your time.