American College of Radiology

ACR Summary Medicare Program; Transitional Coverage for Emerging Technologies [CMS–3421–FN]]

Summary of Final Procedure Notice
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Table of Contents

Overview 1
Background 2
A. Current Medicare Coverage Mechanisms 2
B. Differences Between FDA and CMS Review 4
C. FDA Breakthrough Devices Program 5
II. Summary of Proposed Provisions and CMS Response to Public Comments on the Proposed Notice 5
III. Provisions of the Final Notice 23
IV. Process and Procedure for the TCET Pathway 24
V. Collection of Information Requirements 33
VI. Resources 33
VII. Addendum 33

Overview

On August 7, 2024, the Centers for Medicare and Medicaid Services (CMS) released a final procedural notice outlining a Medicare coverage pathway to achieve more timely and predictable access to certain new medical technologies. CMS' Transitional Coverage for Emerging Technologies (TCET) Pathway uses current national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain U.S. Food and Drug Administration (FDA)-designated breakthrough devices. In addition to the TCET procedural notice, CMS finalized updated criteria in its 2024 CED guidance documents .

CMS, in its fact sheet , says the new TCET pathway increases the number of NCDs it will conduct per year, and supports both improved patient care and innovation by providing a clear, transparent and consistent coverage process while maintaining robust safeguards for the Medicare population. CMS anticipates accepting up to five TCET candidates per year and, for technologies accepted into and continuing in the TCET pathway, its goal is to finalize an NCD within six months after FDA market authorization.

Background

The TCET pathway is designed to deliver transparent, predictable, and expedited national coverage for certain eligible Breakthrough Devices that are Food and Drug Administration (FDA) market-authorized. It builds upon CMS' experience with the Parallel Review program and the Coverage with Evidence Development (CED) pathway.

The TCET pathway reflects the feedback received from multiple stakeholder groups, including beneficiaries, patient groups, medical professionals and societies, medical device manufacturers, other Federal partners, and others involved in developing innovative medical devices. This feedback was obtained from informal and formal meetings, the comments received through rulemaking for the Medicare Coverage of Innovative Technologies (MCIT) pathway, and subsequent listening sessions that were held following the repeal of the MCIT/Reasonable and Necessary (R&N) final rule (86 FR 62944, November 15, 2021). The MCIT rule never became legally effective and thus was not implemented. CMS explains how the new TCET pathway addresses stakeholder concerns identified and recognizes that new approaches are needed to improve the Medicare coverage process when making decisions on certain emerging technologies at the national level.

The TCET pathway is intended to balance multiple considerations when making coverage determinations:
(1) facilitating early, predictable, and safe beneficiary access to new technologies;
(2) reducing uncertainty about coverage by evaluating early the potential benefits and harms of technologies with manufacturers; and
(3) encouraging evidence development if notable evidence gaps exist for coverage purposes.

The TCET pathway aims to coordinate benefit category determination, coding, and payment reviews and to allow any evidence gaps to be addressed through fit-for-purpose studies. A fit-for-purpose study design is one where the study design, analysis plan, and study data are appropriate for the question the study claims to answer.

Medicare covers a wide range of items and services. In general, in order for an item or service to be covered under Medicare, it must meet the standard described in section 1862(a)(1)(A) of the Social Security Act (the Act) – that is, it must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. CMS makes reasonable and necessary coverage decisions through various pathways to facilitate expeditious beneficiary access to items and services that meet the statutory standard for coverage.

A. Current Medicare Coverage Mechanisms

The TCET pathway described in this notice will leverage the existing NCD pathway, and CED, to provide a streamlined coverage pathway for emerging technologies. CMS summarizes its current coverage pathways:

1. Claim-by-claim Adjudication
In the absence of an NCD or a local coverage determination (LCD), Medicare Administrative Contractors (MACs) make coverage decisions under section 1862(a)(1)(A) of the Act and may cover items and services on a claim-by-claim basis if the MAC determines them to be reasonable and necessary for individual patients. Though claims may be denied if they are not determined to be reasonable and necessary, the claim-by-claim adjudication pathway remains the fastest path to potential coverage. The majority of all Medicare Parts A and B claims have coverage determined through the claim-by-claim adjudication process.

2. Local Coverage Determinations (LCDs)
MACs develop LCDs under section 1862(a)(1)(A) that apply only within their geographic jurisdictions (see sections 1862(l)(6)(B) and 1869(f)(2)(B) of the Act). LCDs govern only the issuing MAC's claims adjudication and are not controlling authorities for qualified independent contractors or administrative law judges in the claims adjudication process. The MACs follow specific guidance for developing LCDs for Medicare coverage as outlined in the CMS Program Integrity Manual (PIM), Chapter 13. This manual is used in making determinations for items and services at the local level. LCDs generally take 9 to 12 months to develop. MACs are expected to finalize proposed LCDs within 365 days from opening.

3. National Coverage Determinations (NCDs)
The term "national coverage determination" is defined in section 1862(l)(6)(A) of the Act and means a determination by the Secretary of the Department of Health and Human Services (the Secretary) with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Act. In general, NCDs are national policy statements published to identify the circumstances under which a particular item or service will be considered covered (or not covered) by Medicare. NCDs serve as generally applicable rules to ensure that similar claims for items or services are covered in the same manner. Often an NCD is written in terms of defined clinical characteristics that identify a population that may or may not receive Medicare coverage for a particular item or service. Traditionally, CMS relies heavily on health outcomes data to make NCDs.

Medicare has provided coverage for certain promising technologies with limited evidence based on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. CMS has supported the Coverage with Evidence Development (CED) policy since July 12, 2006, and the most recent CED policy as described in the 2024 guidance document. CED enables providers and suppliers to perform high-quality studies that will produce evidence that may lead to positive national coverage determinations.

The Agency for Healthcare Research and Quality (AHRQ) reviews all CED NCDs and collaborates with CMS to define standards for clinical research studies to address the CED questions and meet the general standards for CED studies. NCDs also include a determination on whether the item or service under consideration has a Medicare benefit category under Part A or Part B. All items and services covered by Medicare must fall within the scope of a statutory benefit category. Also, to be covered, the item or service must not be excluded from coverage by

statute or our regulations. CMS notes benefit category determinations are made outside of the Coverage and Analysis Group and may take 3 months or longer to complete. CMS warns that in some cases benefit category reviews may not be completed within the accelerated timeframes needed for the TCET pathway. The NCD pathway has statutorily prescribed timeframes and generally takes 9 to 12 months to complete from the opening of the tracking sheet.

4. Clinical Trial Policy (CTP) NCD 310.1.
The CTP policy is applied when Medicare covers routine care items and services (but generally not the technology under investigation) in a clinical study that is supported by certain Federal agencies. The CTP coverage policy was developed in 2000. CMS notes that coverage under CED and CTP may not occur at the same time. Additionally, this coverage policy has not generally been utilized by device manufacturers because they usually seek coverage of the device under investigation, which is not always available under CTP.

5. Parallel Review Program
Parallel Review is a mechanism for FDA and CMS to simultaneously review the clinical data submitted by a manufacturer about a medical device to help decrease the time between FDA's approval of an original or supplemental premarket approval (PMA) application or granting of a de novo classification request (De Novo request) and the subsequent CMS proposed NCD. Parallel Review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial; and (2) FDA and CMS concurrently review ("in parallel") the clinical trial results submitted in the PMA application, or De Novo request.

FDA and CMS independently review the data to determine whether it meets their respective Agency's standards and communicate with the manufacturer during their respective reviews. This program relies upon a technology having a quality evidence base to support the clinical analysis for the NCD.

B. Differences Between FDA and CMS Review

While FDA and CMS have a well-established history of collaboration in the review of evidence for emerging medical technologies, FDA and CMS must consider different legal authorities and apply different statutory standards when making marketing authorization and coverage decisions, respectively, for medical devices. Generally, FDA makes marketing authorization decisions based on whether the relevant statutory standard for safety and effectiveness is met, while CMS generally makes NCDs based on whether an item or service is reasonable and necessary for the diagnosis or treatment of an illness or injury for individuals in the Medicare population. These two reviews are separate and are conducted independently by the two agencies. FDA approval or clearance alone does not entitle that technology to Medicare coverage, given Medicare statutory coverage requirements.

CMS looks to the evidence supporting FDA market authorization and the device's approved or cleared indications for use for evidence generalizable to the Medicare population, data on improvement in health outcomes, and durability of those outcomes. If there is no data on these

elements in the Medicare population, it is difficult for CMS to make an evidence-based decision on whether the device is reasonable and necessary for the Medicare population. Consequently, the potential benefits and harms of a device for older patients with more comorbidities may not be well understood at the time of FDA market authorization.

C. FDA Breakthrough Devices Program

Under the TCET coverage pathway, CMS will coordinate with FDA and manufacturers of Breakthrough Devices as those devices move through the FDA premarket review processes to ensure timely Medicare coverage decisions following any FDA market authorization. FDA's Breakthrough Devices Program is not for all new medical devices; rather, it is only for those that FDA determines meet the standards for Breakthrough Device designation.

The Breakthrough Devices Program is for medical devices and device-led combination products that meet two criteria. The first criterion is that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions. The second criterion is that the device must satisfy one of the following elements:

- It represents a breakthrough technology;
- No approved or cleared alternatives exist;
- It offers significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance); or establish long-term clinical efficiencies; or
- The device availability is in the best interest of patients.

Devices meeting these criteria are also likely to be highly relevant to the needs of the Medicare population if the item or service falls within a Medicare benefit category. FDA has explained in guidance that because decisions on requests for Breakthrough designation will be made prior to marketing authorization, FDA considers whether there is a "reasonable expectation that a device could provide for more effective treatment or diagnosis relative to the current standard of care in the U.S for purposes of the designation. This reasonable expectation can be supported by sources including "literature or preliminary data (bench, animal, or clinical)".

II. Summary of Proposed Provisions and CMS Response to Public Comments on the Proposed Notice

On June 28, 2023, CMS published a proposed notice to establish the TCET Pathway. CMS received approximately 150 public comments in response to the publication. Commenters included a broad range of interested parties, including physicians, professional societies, manufacturers, manufacturer associations, venture capital firms, health plans, and patient advocates. The following is a summary of the public comments that CMS received related to the proposed notice, and its responses to the public comments.

A. Overarching Comments Regarding CMS' Proposal to Establish the TCET Pathway

CMS proposed that the TCET pathway use the NCD and CED processes to expedite Medicare coverage of certain Breakthrough Devices. CMS states the TCET pathway would be voluntary and the goal of the pathway is to reduce uncertainty about coverage options through a pre-market evaluation of potential harms and benefits of technologies while identifying any important evidence gaps. Additionally, CMS' proposal for the TCET pathway provided an evidence-development framework to provide manufacturers with opportunities for increased pre-market engagement with CMS, to reduce manufacturer burden, increase flexibility to address evidence gaps to support Medicare coverage. In the proposed notice, CMS anticipated accepting up to five TCET candidates annually.

1. General Concerns

Public comments generally supported the TCET concept, expressing that it could result in faster access to newly FDA market-authorized technologies for Medicare beneficiaries. Commenters agree the proposal would promote innovation, decrease uncertainty and delays in coverage, and improve beneficiary access to cutting-edge treatments. Most commenters expressed support for the TCET proposal in principle, noting that it is a "good first step," and provided suggested modifications to improve the pathway. CMS responded that they appreciate the comments supporting the TCET proposals and appreciate suggestions provided to improve the pathway.

Several commenters expressed concerns that the TCET pathway is limited in scope in that it only applies to "certain FDA-designated Breakthrough Devices that fall within a Medicare benefit category." Some of these commenters expressed support for automatic, immediate coverage upon FDA market authorization.

CMS responded they do not believe that it is appropriate to grant all FDA market-authorized Breakthrough Devices' automatic coverage solely based on their Breakthrough Designation. CMS states when there is a lack of evidence specific to the Medicare population, it makes it difficult for CMS to ensure that devices are not posing additional risks in the Medicare population. CMS believes that it is important to require manufacturers participating in any innovative coverage pathway, such as TCET, to produce evidence that demonstrates the health benefit of the device and the related services for patients with demographics like that of the Medicare population. CMS focused on Breakthrough Devices because it is the area with the greatest need. As CMS gains experience with the TCET pathway, it may consider expanding its application to other items and services. In the absence of CED, technologies with limited evidence could be noncovered.

A commenter questioned if obtaining an NCD without CED would be possible under TCET. CMS responded and an NCD without CED is an option if there is sufficient evidence to support Medicare coverage.

Some commenters expressed that CMS should have issued the proposal as a proposed rule rather than a notice to facilitate meaningful changes and address key issues that hinder beneficiary access.

CMS disagrees that a proposed rule is required to establish a procedural rule. CMS explains it is establishing TCET through a proposed procedural notice enables CMS to consider public comments but also has the advantage that the procedures may be modified as necessary as CMS, manufacturers, and the public gain experience using the process. The procedural notice explains how the public and TCET sponsors can work with CMS concerning coverage for certain Breakthrough Devices and addresses key issues that may have hindered beneficiary access in the past.

2. TCET Timelines

CMS' goal is to finalize an NCD for technologies accepted into the TCET pathway within 6 months of FDA market authorization. Some commenters encouraged CMS to be forthcoming with realistic timelines. A few commenters suggested that CMS provide coverage for Breakthrough Devices sooner than the timeline proposed. Some commenters requested that CMS provide more definitive timelines. CMS has made one specific timeline update in the final notice to specify that it will consider TCET nominations on a quarterly basis, rather than acting upon them within 30 days of submission. This additional time provides a more realistic timeframe for CMS to coordinate with the manufacturer and, as appropriate, FDA on any outstanding issues and to begin internal discussions within CMS regarding operational issues.

Commenters expressed that CMS should be held accountable for meeting all timelines indicated in the notice. CMS expects to adhere to the timelines outlined in the notice barring unexpected complications based on current resources, and it expects that the manufacturer will do the same or at least provide as much notice as possible when complications are encountered. CMS does not believe that imposing consequences on the Agency or manufacturers for missed deadlines would be helpful. In the future, as it gains more experience, it may modify aspects of the TCET pathway, including timelines.

3. Limiting the TCET Pathway to Five Candidates Yearly

Commenters expressed concerns with the potential limit to five TCET candidates yearly. Some commenters contend that the limitation is arbitrary and would like CMS to clarify how this number was derived. CMS anticipates it will receive approximately eight nominations for the TCET pathway per year. Based on current resources, CMS does not plan to accept more than five candidates into the TCET pathway per year. As it gains more experience with TCET, they will re-evaluate and adjust based on available resources. Further, CMS acknowledges that existing coverage mechanisms remain available for manufacturers of Breakthrough Devices to pursue Medicare coverage.

4. Operational Issues

Numerous commenters expressed concerns that the proposed procedural notice did not adequately address the operational issues (e.g., coding and payment issues) that could inhibit the successful implementation of the TCET pathway and would still need to be addressed. Commenters requested that CMS provide more specific information on how these processes will be coordinated under TCET and include timelines. A commenter encouraged CMS to collaborate internally to improve alignment among these processes.

CMS agrees that coordination of coverage, coding, and payment processes supporting the TCET pathway is important. In response, CMS has established new internal collaborations to improve coordination going forward. CMS recently released the CMS Guide for Medical Technology Companies and Other Interested Parties website, which provides interested parties, including, but not limited to, medical device, pharmaceutical, and biotechnology companies, with information about Medicare's processes for determining coding, coverage, and payment as well as other key considerations. The Guide will be updated to include information related to TCET soon.

A commenter recommended that CMS offer a system readiness meeting within 45 days of acceptance that discusses coverage, benefit category determination, coding, and payment considerations to ensure overall alignment. A second system readiness meeting could be scheduled following the evidence preview meeting and the manufacturer's decision to continue in the TCET pathway. CMS responded that a more informal approach will provide more flexibility and be less burdensome for manufacturers since each technology and manufacturer may have unique circumstances that could impact the timing of these discussions. CMS continues to explore opportunities to better align coverage, coding, and payment considerations for devices in the TCET pathway.

B. Appropriate Candidates

CMS proposed to limit the TCET pathway to certain eligible FDA-designated Breakthrough Devices and stated that appropriate candidates for the TCET pathway would include those devices that are:

- certain FDA-designated Breakthrough Devices;
- determined to be within a Medicare benefit category;
- not already the subject of an existing Medicare NCD; and
- not otherwise excluded from coverage through law or regulation.

CMS clarifies that the majority of coverage determinations for diagnostic laboratory tests granted Breakthrough designation status should continue to be determined by the Medicare Administrative Contractors (MACs) through existing pathways.

1. Scope of Pathway and FDA-designated Breakthrough Devices

Commenters pointed out that there may be innovative technologies that they believe should be covered by Medicare that choose not to use FDA's Breakthrough Devices

Program or maybe an innovative technology that may not qualify for the designation. CMS appreciates these comments and the suggestions for expanding eligibility for the TCET pathway. CMS is focusing only on the need for more rapid coverage for Breakthrough Devices in this final notice. As the TCET pathway develops and proves successful, CMS may consider expanding its application to other items and services, contingent on sufficient available resources.

Some commenters expressed that Breakthrough Devices have very little evidence at the time of FDA market authorization to support Medicare coverage. A commenter encouraged caution in allocating Medicare resources for coverage of Breakthrough Devices under TCET, considering what the commenter described as the relatively low threshold of evidence required for Breakthrough Device designation. Several commenters noted potential safety concerns with Breakthrough Devices. Multiple commenters recommended that CMS maintain rigorous evidence development standards. Commenters stressed the need to monitor the use and outcomes of these devices and build a mechanism to trigger an NCD reconsideration if the FDA withdraws approval or there are post-market safety concerns.

CMS responds stating Medicare coverage of Breakthrough-designated devices would only occur if the device gains FDA marketing authorization. Breakthrough Devices are held to the same safety and effectiveness standards to receive FDA market authorization as other medical devices that do not have Breakthrough Device designation. For CMS to provide coverage for Breakthrough Devices, there must be sufficient evidence to conclude that the evidence is promising, and that the device is potentially important for the Medicare population even if the available evidence is insufficient to satisfy the reasonable and necessary standard.

CMS believes the TCET evidence generation framework will facilitate the development of reliable evidence for patients and their physicians. It also provides safeguards to ensure that Medicare beneficiaries are protected and continue receiving high-quality care. Coverage under CED can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards including assurance that the technology is provided to clinically appropriate patients are in place to reduce the potential risks associated with new technologies, or to new applications of older technologies.

CMS reiterates in this final notice it will reconsider an NCD for Breakthrough Devices if safety concerns arise. CMS retains the right to reconsider an NCD at any point in time. If an NCD is repealed, MACs could deny coverage for particular devices. CMS may also issue a national non-coverage NCD that would bar all coverage for the device.

2. Necessity of Falling into an Existing Benefit Category

CMS proposed that a Breakthrough Device must fall into an existing benefit category to be included under TCET. In general, commenters supported this proposal. However, several commenters recommended the inclusion of Breakthrough Devices that do not fall within an existing benefit category. Several commenters requested CMS review and update the current benefit category definitions to reflect technological advances. These commenters

requested that CMS create new benefit categories or make a determination that an item or service (for example, software or other digital technologies) falls within a benefit category. CMS responded they do not have CMS does not have the authority to establish new Part B benefit categories; benefit categories are statutory and established by Congress. Consequently, some Breakthrough Devices will not fall within a Medicare benefit category and cannot be covered or paid by Medicare.

3. Limitations of Devices Already the Subject of an Existing NCD

Commenters requested that CMS expand TCET eligibility criteria to include technologies with an existing NCD that receive Breakthrough designation from FDA for a novel indication that is non-covered under an existing NCD or unrelated to the existing NCD. CMS will maintain this limitation. If devices are subject to an existing NCD, a reconsideration of the NCD may be required to establish coverage.

4. Diagnostic Laboratory Tests

Numerous commenters disagreed with CMS' proposal that coverage determinations for Breakthrough-designated diagnostic laboratory tests should continue to be made by Medicare Administrative Contractors under existing coverage mechanisms. A commenter claimed that the justifications CMS offers for its general exclusion of diagnostic laboratory tests from eligibility for the TCET coverage pathway do not adequately support exclusion from TCET eligibility and may delay Medicare beneficiary access to innovative tests. Some commenters requested that CMS permit diagnostic laboratory tests to be eligible for TCET or provide a similar pathway.

CMS expects the majority of coverage determinations for Breakthrough-designated diagnostic laboratory tests will continue to be made by Medicare Administrative Contractors. CMS acknowledged 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, They encourage manufacturers to contact CMS to discuss options for their specific technology.

Several commenters requested that CMS clarify whether the TCET pathway excludes diagnostic laboratory tests and diagnostic tests generally. In response to public comments seeking clarification regarding the scope of the references to diagnostic laboratory tests in the proposed notice, CMS has added language to clarify that it intends to refer to IVDs, including diagnostic laboratory tests, in the discussion of appropriate candidates. Other non-IVD diagnostic devices, such as diagnostic imaging devices, may be considered for TCET.

C. Nominations

CMS proposed that the appropriate timeframe for manufacturers to submit TCET pathway nominations are approximately 12 months before the anticipated FDA decision on a submission as determined by the manufacturer. In the proposal, CMS stated that manufacturers of certain FDA-designated Breakthrough Devices may self-nominate to

participate in the TCET pathway. The proposed notice outlined the information that manufacturers should include in the self-nomination packet.

Commenters generally agreed with the proposal that nominations be submitted approximately 12 months before anticipated FDA marketing authorization. Some noted that early engagement between CMS and manufacturers before FDA authorization can inform and enable a more efficient and effective evidence-generation strategy. In the final notice, CMS has modified the TCET pathway procedures to include 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.

CMS believes the proposal for nominations to be submitted approximately 12 months before anticipated FDA marketing authorization is minimally burdensome and provides adequate flexibility for manufacturers to: (1) provide supportive evidence for their technology; (2) develop an EDP to address material evidence gaps for CMS coverage; and (3) coordinate BCD, coding, and payment processes. There is an opportunity under TCET to leverage FDA-required post-market studies, if any, to address specific evidence gaps for Medicare beneficiaries.

Some commenters provided feedback regarding specific timeframes in the TCET nomination process. A few commenters supported CMS' proposal to respond to nominations within 30 days. Another commenter requested that CMS extend the nomination review period to 60 days rather than 30 to ensure rigorous evaluation and selection of the most promising technologies for the TCET pathway.

CMS agrees it is important to provide timely feedback to manufacturers on whether their technology is a suitable candidate for TCET. CMS is clarifying that suitable candidates will be approved for the TCET pathway quarterly. Consideration of TCET nominations every quarter will allow CMS to prioritize the most promising devices, facilitate TCET implementation, and establish a fair opportunity for eligible devices to be considered, regardless of the timing of FDA market authorization. If a nomination is not accepted into the pathway in one quarterly review cycle, it may be considered again in the following quarterly review cycle. Manufacturers will not need to resubmit a nomination for it to be considered in a subsequent quarter.

Many commenters recommended that CMS provide a lookback period, meaning that Breakthrough Devices that are nearing an FDA decision on market authorization (that is, less than 12 months) or those recently achieving authorization would be eligible for the TCET pathway. Several commenters recommended that a 3-year lookback period would be appropriate. CMS disagrees and did not include a lookback period in the proposed notice. The TCET pathway is designed to expedite national coverage through extensive premarket engagement. Developing an evidence development plan (EDP) generally takes considerable time, and absent an adequate lead time during the pre-market period, devices already available in the market are more appropriate for an NCD outside of the TCET pathway or for MAC determinations.

To provide greater transparency, consistency, and predictability CMS intends to release proposed prioritization factors for TCET nominations in the near future. CMS will communicate additional details on its plan and there will be an opportunity for public comment.

A commenter requested that in instances where CMS declines a nomination, it should provide a rationale and feedback mechanism for the manufacturer. Another commenter stated that applicants should be permitted to reapply. CMS reiterated it will provide a justification and contact information for additional information if they decline a nomination.

CMS clarifies since TCET is forward-looking and extensive pre-market engagement is essential, nominations for Breakthrough Devices anticipated to receive an FDA decision on market authorization within 6 months may not be accepted since CMS will be unable to reach a final NCD within the expedited timeframes.

Lastly, a commenter recommended that CMS permit manufacturers to provide information on how their devices promote health equity. CMS welcomes and strongly encourages any information manufacturers wish to provide regarding how their devices promote health equity.

D. Coordination with the FDA

Many commenters expressed their support for enhanced FDA-CMS collaboration to support the TCET pathway, and more specifically, to foster alignment between FDA and CMS evidence development needs to ensure CMS evidence development requirements are not duplicative or contradictory with FDA requirements. Further, commenters stated that FDA and CMS should provide early clarity about post-market evidence generation requirements to minimize provider and product developer burden.

Some commenters sought clarity as to whether manufacturers would be permitted to participate in meetings between FDA and CMS.

CMS outlined in the proposed notice and consistent with the FDA-CMS MOU, CMS may meet with the FDA when considering a TCET nomination submitted for CMS review so CMS can learn more about the technology, including potential timing considerations. Some of these meetings may be deliberative and not appropriate for manufacturers or any other non-governmental parties to participate. However, similar to meetings conducted for parallel review, there may be occasions where it will be helpful to have CMS, FDA, and manufacturers participate in a meeting, and CMS will consider these requests on a case-by-case basis.

E. Benefit Category Determination (BCD) Reviews

Commenters requested additional clarification regarding the process and timeline for benefit category determination reviews. These commenters note that the lack of an integrated, transparent, expedited BCD process will limit TCET's impact.

CMS notes that new products may fall within one or more benefit categories or no benefit category at all. As stated in the proposed notice, if CMS believes that the device, prior to a

decision on market authorization by FDA, is likely to be payable through one or more benefit categories, the device may be accepted into the TCET pathway. This is an interim step that is subject to change upon FDA's decision regarding market authorization of the device. Acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category. When CMS issues the proposed NCD following approval or clearance of the Breakthrough Device by FDA, the proposed NCD will include one or more benefit categories to which CMS has determined the Breakthrough Device falls. CMS will review and consider public comment on the proposed NCD before reaching a final determination on the BCD(s).

CMS states it is unable to commit to making all BCD decisions within 30 days of nomination submission because the BCD may rely on information generated during the process to obtain FDA market authorization making an earlier BCD infeasible.

A commenter stated that when there is an issue in determining the BCD, a meeting between CMS' Center for Medicare and the manufacturer should be scheduled immediately. CMS agrees that it is important for CMS to provide timely communication to the manufacturer when there are issues in determining the BCD.

F. Evidence Preview (EP)

CMS' proposal introduced the Evidence Preview (EP) concept, which is a focused literature review that would provide early feedback on the strengths and weaknesses of the available evidence, including any evidence gaps, for a specific item or service. CMS expressed the intent for EPs to be supported by a contractor using standardized evidence grading, risk of bias assessment, and applicability assessment. CMS proposed that the EP would be made publicly available on the CMS website when a tracking sheet is posted announcing the opening of the NCD. Additionally, CMS proposed to share the EP with the Medicare Administrative Contractors following a manufacturer's decision to withdraw from the TCET pathway.

Some commenters requested that CMS provide more transparency regarding the evidence review contractor. CMS responds that the Secretary has broad authority to contract out functions. It reiterates the contractor's role is to conduct a rapid systematic literature review and summarize the evidence based on a modified Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) methodology. The contractor supports and accelerates CMS reviews, but CMS performs extensive quality assurance on contracted reviews, contributes substantial portions of the EP independently, and ultimately determines policy. If an NCD is opened, an evidence summary will be included with the tracking sheet for full public comment, including which contractor completed the review.

Several commenters sought clarity on how the contractor will perform evidence reviews under TCET, specifically the criteria that the contractor will use to do the evidence preview. Commenters also asked that CMS define the evidence grading system used and what kind of evidence review conclusions are possible.

When nominating devices for the TCET Pathway, manufacturers should submit a comprehensive bibliography of published studies for their devices. For some devices, studies will not yet be published in the peer-reviewed literature, and CMS will instead review unpublished reports of clinical studies intended to support the FDA marketing application provided by the manufacturer. The contractor will use standardized tables to summarize the characteristics of each study included in their focused literature review. These tables provide information about each study's design, quality, interventions assessed, target population, and outcomes assessed.

CMS states studies of different designs are graded within the context of their respective designs. Thus, RCTs are graded as good, fair, or poor, and observational studies are separately graded as good, fair, or poor. The contractor will also assess the applicability of the included studies to the Medicare population. Lastly, the contractor will identify and list any relevant evidence-based guidelines, specialty society recommendations, consensus statements, or appropriate use criteria that apply to the item or service addressed by the Evidence Preview (EP). The reviewed evidence is then qualitatively synthesized by the contractor. There are strict non-disclosure agreements in place with the contractor to ensure the protection of proprietary information.

Some commenters expressed concerns that CMS was ceding decision-making to the evidence review contractor. These commenters noted that the evidence review contractor should be prohibited from making qualitative assessments of the literature and providing any statements regarding medical necessity. Further, commenters stated that CMS should maintain ultimate decision-making responsibility and CMS staff should be fully engaged to ensure that feedback among all participants is transparent and timely. CMS in its response reiterates all decision-making resides with CMS. CMS does not delegate the Secretary's authority to establish NCDs to a contractor. The role of the evidence review contractor is to support the CMS review team by summarizing the available evidence in a standardized format. CMS staff specify the review requirements, supervise the contractor, and conduct extensive quality assurance of all reviews. Any formal determination regarding whether an item or service meets the reasonable and necessary statutory standard will be made by CMS and completed using the NCD process, which includes at least one public comment period.

Some commenters stated that manufacturers should be able to communicate directly with the evidence review contractor during the development of the EP. Several commenters suggested that CMS establish contact points to facilitate dialogue between the manufacturer and the contractor responsible for conducting the EP. CMS disagrees that manufacturers should be able to contact the contractors that the government has engaged to summarize the scientific evidence on its behalf. CMS notes that manufacturers must submit a full bibliography of published studies with their TCET nomination. Much of the EP is written directly by CMS staff, and manufacturers have an opportunity to provide feedback on a draft of the EP before it is finalized. CMS will establish CMS-staff-level contact points to facilitate timely communication with manufacturers.

CMS in its final notice states the EP is not a national coverage analysis (NCA) and is not a commitment to coverage. The EP is intended to inform decisions about the best available

coverage options for the nominated device. Further, a broader range of studies may be included in a full national coverage analysis (NCA) if one is opened. The EP reflects the best available information at the time it is conducted, but multiple elements of the EP may evolve during the review process.

A commenter suggested that CMS clarify circumstances where they can convene a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) or otherwise solicit broad public input to align on evidence gaps in the evidence preview stage and explain how this might affect evidence review timelines. CMS responded that if a MEDCAC is needed to clarify the appropriate clinical endpoints for a particular device, the TCET review timeframes could be substantially delayed. The need for MEDCACs during a TCET review may be mitigated by identifying potential TCET candidates earlier in the review cycle than the timeframe proposed in the June 2023 notice. CMS clarified in the final notice how a MEDCAC may affect evidence review timelines and how submitting a non-binding letter of intent 18 to 24 months in advance of FDA approval of the device can help alleviate potential delays if a clinical endpoints review and/or MEDCAC is needed.

Many commenters disagreed with CMS' proposal to share the Evidence Preview with the Medicare Administrative Contractors following a manufacturer's decision to withdraw from the TCET pathway. These commenters expressed concerns with how the MACs would use this information, specifically that it would lead to de facto noncoverage without going through the full national coverage process. CMS responds to the concerns raised and believes the EP will be a fair reflection of the strength of the available evidence to support Medicare coverage. CMS acknowledges that manufacturers may withdraw from the TCET pathway for reasons unrelated to the evidence. Based on the previous considerations and in response to public comments, CMS will publish an evidence summary without the evidence gap analysis if a manufacturer withdraws from the TCET pathway.

G. Manufacturer Decision to Continue or Discontinue

CMS' proposal stated that upon finalization of the EP, the manufacturer may decide to pursue national coverage under the TCET pathway or to withdraw from the pathway. CMS proposed that if the manufacturer decided to continue, the next step would include a manufacturer's submission of a formal NCD letter expressing the manufacturer's desire for CMS to open a TCET NCD analysis.

A commenter requested confirmation that CMS will not issue a noncoverage NCD if a manufacturer withdraws from TCET. CMS responded there could be rare instances where a non-coverage NCD would be in the best interest of Medicare beneficiaries, such as when the evidence points to potential serious beneficiary harm. CMS can conduct a national coverage analysis at any time to swiftly act in those circumstances.

H. Evidence Development Plans (EDP)

CMS' proposal introduced the Evidence Development Plan (EDP) concept. CMS proposed that EDPs would be developed by the manufacturer to address any evidence gaps identified in the

EP. In the proposal, CMS indicated that EDPs may include fit-for-purpose (FFP) study designs, including traditional clinical study designs and those that rely on secondary use of real-world data, provided that those study designs follow all applicable CMS guidance documents. CMS proposed that the development of an EDP would include CMS-AHRQ collaboration to evaluate the EDP to ensure that it meets established standards of scientific integrity and relevance to the Medicare population. The proposal stated that elements of the EDP, specifically the non-proprietary information, would be made publicly available on the CMS website when a proposed NCD is posted. CMS expects to propose FFP study guidance in the future, with a particular emphasis on study designs that make secondary use of real-world data.

Some commenters encouraged CMS to work with manufacturers to develop a reasonable, mutually agreed upon data collection and review period in the EDP. A commenter suggested that CMS consider structuring evidence development around the achievement of milestones rather than time. CMS is exploring ways that CMS can support manufacturers in efficiently developing FFP protocols, but manufacturers are responsible for developing their own EDPs. CMS agrees that a CMS and AHRQ-approved EDP should be in place before opening an NCD. CMS notes that prolonged delays by manufacturers in drafting EDPs may substantially delay the finalization of a CED NCD under the TCET pathway.

CMS is finalizing its proposal to have EDPs include a schedule of updates and interim analyses along with a projected NCD reconsideration window. CMS continues to believe that a core purpose of the EDP is to anticipate the appropriate timing of reconsideration but recognizes that timelines may in some cases need to be revised. Any changes to the anticipated NCD reconsideration window will be reflected on the CED website.
Some commenters asked that CMS clarify what parts of the EDP will be publicly posted. It was recommended that the technical information regarding a device remain confidential. CMS responded that a summary of the EDP, a linkage to CMS-approved CED studies on clinicaltrials.gov, and the anticipated CED NCD reconsideration window will be posted on the CMS website. CMS is actively developing guidance on the level of detail necessary to establish that a proposed study is FFP; while manufacturers may be able to demonstrate that these elements establish the scientific validity of a proposed study, it may not be necessary to make all details public.

A commenter recommended that CMS clarify that when the available evidence is promising but is insufficient to satisfy the reasonable and necessary standard for the Medicare population, CMS may extend coverage under the TCET pathway conditioned on completion of an FFP study that may convincingly address an evidence deficiency identified in the EP. CMS clarified in the final notice that EDPs must address material evidence deficiencies identified in the EP. FFP studies addressing specific evidence deficiencies identified in the EP may be proposed as part of a broader EDP. CMS agrees that FFP studies, especially those that make secondary use of real-world data, may require modifications to the pre-specified protocol for various reasons. CMS expects to publish detailed guidance on acceptable FFP studies in the coming months.

I. CMS NCD Review and Timing

CMS proposed that if a device that is accepted into the TCET pathway receives FDA marketing authorization, CMS will initiate the NCD process by posting a tracking sheet following FDA market authorization (that is, the date the device receives PMA approval; 510(k) clearance; or the granting of a De Novo request) pending a CMS and AHRQ-approved Evidence Development Plan (in cases where there are evidence gaps as identified in the Evidence Preview). In the proposal, CMS stated that the goal is to have a finalized EDP no later than 90 business days after FDA market authorization. Following further CMS review and analysis of public comments, CMS would issue a proposed TCET NCD and EDP within 6 months of opening the NCD. There would be a 30-day public comment period on the proposed TCET NCD and EDP, and a final TCET NCD would be due within 90 days of the release of the proposed TCET NCD.

Some commenters requested that the proposed decision memo for an initial TCET NCD should be posted at the same time as a tracking sheet, similar to what has previously been done for Parallel Review NCDs. CMS appreciates the suggestions to streamline the TCET process by providing for only one public comment period, but it believes posting a tracking sheet with a proposed NCD is operationally impractical for CMS and provides insufficient opportunity for public feedback on the coverage conditions that optimize patient outcomes. CMS states the evidence base for emerging technologies is often incomplete, and practice guidelines are not yet established, so it believes input from interested parties is critical to ensure that Medicare is providing appropriate coverage for new, innovative technologies that balance access with beneficiary safeguards.

Several commenters noted inconsistencies in the proposed TCET process timeline. They noted CMS' stated goal of finalizing an NCD within 6 months of FDA marketing authorization and pointed out that we also state that there would be a tracking sheet posted with a 30-day comment with a proposed NCD posted 6 months after that (~7 months) and a final NCD statutorily due a few months later. Another commenter noted that the Timeline Diagram has a stakeholder meeting and evidence preview meeting listed, but the stakeholder meeting is not described in the notice.

CMS notes that if material evidence deficiencies for Medicare coverage are identified in an evidence preview, manufacturers must have an approved evidence development plan before CMS will initiate a national coverage analysis. Delays in drafting an approvable evidence development plan may make it impossible to achieve coverage within 6 months of FDA authorization. The final notice clarifies that the initial 30-day comment period is concurrent with the national coverage analysis, and CMS aims to shorten the NCD review by initiating its evidence review in the premarket period. CMS has removed the "stakeholder meeting" from the Timeline Diagram in the final notice since it is synonymous with the evidence preview meeting in the notice.

J. Input from Interested Parties

CMS stated in its proposal that feedback from the relevant specialty societies and patient advocacy organizations, in particular, their expert input and recommended conditions of

coverage (with special attention to appropriate beneficiary safeguards), is especially important for technologies covered through the TCET pathway. In the proposal, CMS strongly encourages these organizations to provide specific feedback on the state of the evidence and their recommended best practices for the emerging technologies under review upon opening a national coverage analysis. CMS encourages these organizations to publicly post any additional feedback, including relevant practice guidelines, within 90 days of CMS' opening of the NCD. CMS specified that information considered by CMS to develop the proposed TCET NCD will become part of the NCD record and will be reflected in the bibliography as is typical for NCDs.

Numerous commenters agreed that engagement with all interested parties, particularly specialty societies, is important. Some commenters encouraged CMS to maintain close relationships with specialty societies and engage them as soon as an NCD is open. CMS agrees that engagement with specialty societies is important, and it intends to maintain collaborative relationships to facilitate timely coverage and provide appropriate beneficiary access to promising new technologies. CMS believes the TCET pathway includes adequate flexibility for specialty societies to provide important input. As is current practice, information sources that inform an NCD are documented in the decision memo and the bibliography of the proposed and final NCD. CMS carefully evaluates evidence and public comment when proposing and finalizing NCDs.

Several commenters requested that CMS establish a formal and robust patient engagement process. A few commenters stated that patients and patient organizations should be consulted regarding how CED affects access, outcomes, and caregiver experiences. They also stated that patient groups should be consulted to discuss study protocols and clinical endpoints. A commenter stated that CMS should agree to timely meetings with all interested parties. CMS reiterates most NCDs allow two opportunities for public comment when a national coverage analysis is initiated and when an NCD is proposed. Therefore, CMS believes the current process allows the public to express their views.

K. Coverage of Similar Devices

CMS proposed that to be eligible for coverage under a TCET NCD, similar devices would be subject to the same coverage conditions, including a requirement to propose an EDP. CMS sought public comment on whether similar devices to the Breakthrough Device should be addressed under a separate NCD or should be subject to the same coverage conditions as the Breakthrough Device, including a requirement to propose an EDP.

Commenters generally supported CMS' proposal to cover similar devices under NCDs. Some commenters noted that NCDs have generally covered a particular class of technologies and supported a similar approach in the TCET pathway. CMS notes NCDs are limited to particular items or services, but some NCDs apply to products for the same indication. In these instances, CMS will follow the existing NCD process. CMS recognizes that some differences may exist for technologies in a class that may result in a distinct benefit/risk profile, and each will be evaluated on its own merit.

Several commenters requested that CMS define "similar devices." For example, a commenter suggested that CMS define similar devices as either: (1) those with the same or similar intended use as the initial product; or (2) devices with the same FDA product code. A commenter noted that it may be unclear whether two devices are in "the same category." To preserve flexibility CMS is not defining "similar devices" in the final notice. If the similarity of two or more devices is uncertain, CMS will consult with FDA and the manufacturer(s), as appropriate, when determining whether a device could be considered individually or as part of a class of similar devices for coverage purposes.

Some commenters requested that CMS clarify how coverage for similar devices will be handled under TCET. Commenters expressed mixed opinions and offered various suggestions as to how CMS could provide coverage under TCET for follow-on devices. Many commenters indicated that follow-on devices should be subject to the same coverage conditions and evidence standards and should be required to develop a comparable EDP to the original device. Some commenters recommended that the first device to market should have privileged status, such as a 1-year coverage exclusivity period. These commenters suggested that CMS should balance rewarding the first-to-market device with granting coverage to follow-on devices. CMS does not believe that a coverage exclusivity period for the first-to-market device is necessary and notes that it would considerably complicate TCET implementation. Further, CMS believes that granting privileged status to the first-to-market device could impede Medicare beneficiary access to the best available device for their circumstances.

Many commenters supported coverage of similar devices but recommended that follow-on devices not count against the annual cap of devices accepted into the TCET pathway. The final notice clarifies that follow-on devices will not count against the limit on TCET reviews.

CMS notes in the proposed procedural notice and reiterates in this final notice that CMS retains the right to reconsider an NCD at any point in time. Any reconsideration undertaken by CMS would be informed by the relevant evidentiary and safety information available at the time.

L. Duration of Coverage

CMS proposed that the duration of transitional coverage through the TCET pathway would be time-limited and be tied to the CMS- and AHRQ-approved Evidence Development Plan (EDP). In the proposed notice, CMS stated it anticipates the transitional coverage period would last for 3 to 5 years as evidence is generated to address evidence gaps identified in the Evidence Preview.

Many commenters supported CMS' proposal for time-limited coverage under TCET with the coverage period specified in the EDP. CMS agrees that the duration of transitional coverage should be tied to an EDP that sufficiently addresses the material evidence gaps identified in the EP, and CMS will work with manufacturers to define an appropriate NCD reconsideration window. Particularly where longer periods of transitional coverage is anticipated, CMS agrees that EDPs should incorporate interim

reporting to ensure adequate progress, public transparency, and timely completion. These updates are in the interest of CMS, manufacturers, and the public because they provide early confirmation of the viability of planned studies that use real-world data and early feedback on real-world outcomes. CMS reiterates in the final notice it will be flexible when working with manufacturers if unavoidable delays occur during the TCET coverage period.

A commenter suggested that CMS consider including in the original TCET NCD, when appropriate, automatic termination of CED evidence collection requirements and conversion of the policy to a regular NCD in situations where all endpoints are met, and there are no serious adverse events or other significant problems during the CED study. CMS appreciates the suggestion, but an NCD with CED requirements remains in place until an NCD reconsideration is finalized. CMS is unable to include an automatic termination provision in the original TCET NCD.

Some commenters expressed that if a study has met the endpoints, a change in coverage status should proceed without delay, and peer-reviewed publication should not be required. CMS disagrees with the commenter regarding peer-reviewed publications. CMS believes that rigorous and publicly available evidence is necessary to inform beneficiaries, the clinical community, and the public about the benefits and harms of available treatment options.

CMS generally considers peer-reviewed evidence of higher quality and evidentiary value than study results that are not peer-reviewed. Published studies are also necessary for devices to be included in evidence-based guidelines, which feature heavily in CMS' assessment of accepted standards of medical practice. Therefore, it is essential that evidence is published in the peer-reviewed clinical literature, and CMS applies rigorous methodologic standards in evidence review supporting local or national coverage analyses. However, CMS' 2024 CED guidance document states, "If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (for example, for studies with incomplete results)." CMS mentions it is in the manufacturer's best interest to have their studies published in peer-reviewed journals.

M. Transition to Post-TCET Coverage

CMS proposed to conduct an updated evidence review within 6 calendar months of the review date specified in the EDP. As part of this process, CMS would review applicable practice guidelines and consensus statements and consider whether the conditions of coverage remain appropriate. Based upon this assessment, when appropriate, CMS would open an NCD reconsideration by posting a proposed decision that includes one of the following outcomes: (1) an NCD without evidence development requirements; (2) an NCD with continued evidence development requirements; (3) a non-coverage NCD; or (4) Medicare Administrative Contractor (MAC) discretion.

A few commenters stated that 6 months may not be enough time to complete the updated evidence review, and one of these commenters recommended 12 months. In this final notice,

CMS clarifies it intends to initiate an updated evidence review within 6 calendar months of the date specified in the EDP.

A commenter recommended that CMS look for opportunities to streamline the reconsideration process to preserve resources so that more technologies can be considered under the TCET pathway. This commenter suggested that CMS could eliminate the initial 30-day comment period for the NCD reconsideration and post a proposed decision along with the tracking sheet. CMS stated in the proposed notice and reiterated in this final notice it would open a TCET NCD reconsideration with a proposed NCD.

N. TCET and Parallel Review

In the proposed notice, CMS noted that other potential expedited coverage mechanisms, such as Parallel Review, remain available. CMS stated in the proposal that eligibility for the Parallel Review program is broader than for the TCET pathway and could facilitate expedited CMS review of non-Breakthrough Devices. Further, CMS' proposal expressed CMS' intent to work with the FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

A commenter requested that CMS clarify whether technologies already accepted into parallel review are eligible for TCET. CMS confirms technologies accepted into the Parallel Review Program may be considered for TCET if they align with the criteria for the TCET pathway.

O. Prioritizing Requests

CMS stated in the proposed notice that it intends to prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare.

Several commenters recommended that CMS establish and make public the prioritization factors used to triage TCET nominations when there are many candidates at a given time. CMS acknowledges the importance of clarifying how it will prioritize TCET nominations. To provide greater transparency, consistency, and predictability, CMS intends to release proposed prioritization factors for TCET nominations in the near future. There will be a public comment period on CMS' proposed approach.

CMS will prioritize TCET candidates based on the language from the August 7, 2013, Federal Register notice (78 FR 48164) stating that in the event CMS has a large volume of NCD requests for simultaneous review, it will prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources. Of note, CMS states the Social Security Act prohibits the Secretary from using QALYs or similar measures to determine coverage, reimbursement, or incentive programs under Medicare.

P. TCET Transparency

Several commenters requested that CMS be transparent regarding devices in the TCET pathway. Suggestions for more transparency included publicly posting 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. A commenter also recommended that information regarding TCET NCDs be included in the annual Report to Congress on NCDs.

In response to public comments, CMS agrees that including the number of devices in the TCET pathway, the date of nomination, the date of acceptance, and the date the NCD process is initiated would be helpful and will incorporate this information into future iterations of the NCD Dashboard available at https://www.cms.gov/Medicare/Coverage/DeterminationProcess. CMS intends to update the NCD Dashboard every quarter. TCET NCDs will be reflected in the annual Report to Congress.

Q. Miscellaneous Comments

CMS received comments that are out of scope for this final notice. A commenter recommended that CMS explain how the Clinical Endpoints Guidance documents will interact with and facilitate the TCET pathway and clarify whether CMS will prioritize TCET candidates in disease areas for which Clinical Guidance Documents have already been developed. CMS intends to develop clinical endpoint guidance documents in therapeutic areas with a great deal of active research and development or in areas with considerable uncertainty about appropriate outcomes. The decision to develop a Clinical Endpoints Guidance (CEG) document is unrelated to the evaluation of a specific TCET nomination, and CMS may develop CEGs unrelated to the TCET pathway. Publication of a CEG does not imply that CMS intends to open an NCD.

Commenters generally supported CMS collaboration with other HHS Agencies and encouraged further collaboration with FDA, NIH, and ARPA-H. CMS intends to continue its collaboration with its fellow HHS sister agencies.

A commenter requested that CMS clarify the following sentence from the proposed notice: "that many Breakthrough Devices are currently coverable without the TCET pathway because they are not separately payable (that is, the device may be furnished under a bundled payment, such as payment for a hospital stay) or they are addressed by an existing NCD." CMS states this sentence has caused unintended confusion. It was not intended to communicate a universal statement regarding Medicare coverage. CMS has deleted the sentence from the final notice.

CMS anticipates that most devices considered for the TCET pathway will be devices reviewed under a De Novo request or PMA submission. However, CMS notes that devices subject to the 510(k) clearance pathway may qualify for Breakthrough designation.

CMS is currently testing aspects of the TCET process, specifically, the EP and EDP concepts within the existing NCD review process. More information will be provided as these NCDs are opened. CMS cannot provide information on the timing for opening any of these pilots.

III. Provisions of the Final Notice

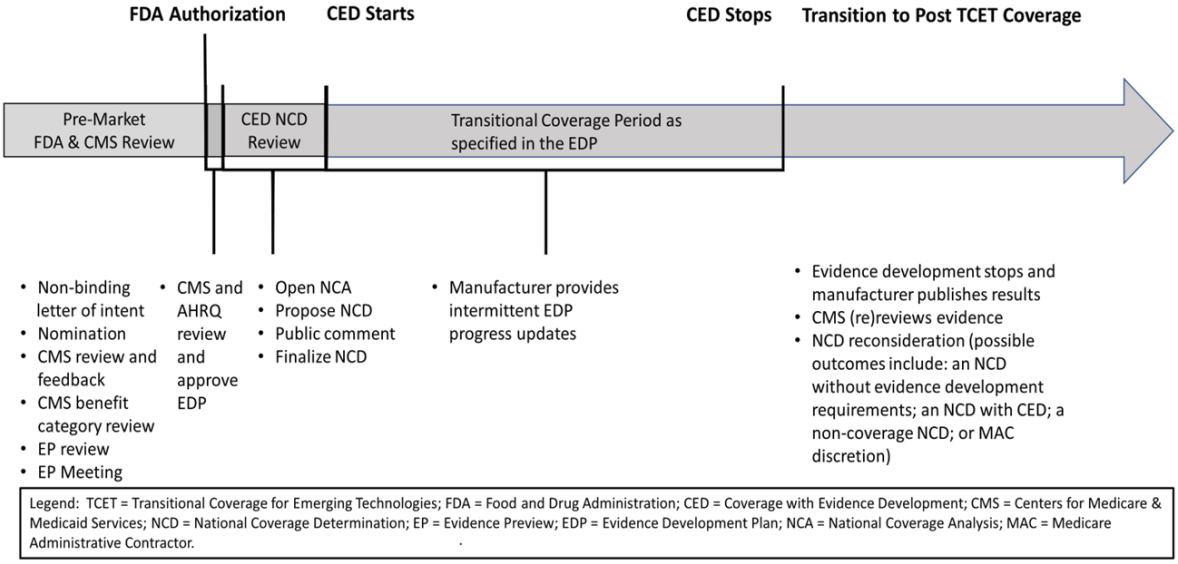
After reviewing the public comments received, CMS is finalizing the TCET pathway with the modifications and clarifications. The following section lists changes between the proposed and final notice:

- Manufacturers can submit a non-binding letter of intent to nominate a potentially eligible device approximately 18 to 24 months before they anticipate FDA market authorization.
- When CMS is aware that manufacturers will likely pursue the TCET pathway for devices where appropriate clinical endpoints are uncertain, CMS may preemptively conduct clinical endpoints review and may convene a MEDCAC.
- CMS will consider TCET nominations on a quarterly basis.
- Nominations for devices that are already FDA market authorized or those anticipated to receive an FDA decision on market authorization within 6 months of nomination will not be accepted for TCET because TCET relies on extensive pre-market engagement to expedite coverage reviews.
- The evidence review contractor's role is to support the CAG staff by conducting a rapid systematic literature review and summarizing the evidence based on a modified GRADE methodology. CMS clarifies the contractor's role is to support and accelerate CMS reviews, but CMS will perform extensive quality assurance on contracted reviews, independently complete substantial portions of the EP, and determine coverage policy.
- If an NCD is opened, an evidence summary, including a disclosure of which contractor completed the review, will be posted with the tracking sheet on the CMS website for public comment.
- CMS will publicly post an evidence summary for devices that are withdrawn from the TCET pathway without an evidence gap assessment.
- EDPs should incorporate interim reporting to ensure adequate progress and timely completion. Interim reports should also disclose any meaningful changes to prespecified study protocols, which are essential to transparency.
- CMS will provide information on study Designs and analysis methods that are FFP. TCET CED studies should be registered and listed on the clinicaltrials.gov website. A summary of the EDPs and the anticipated CED NCD reconsideration window will be posted on the CMS website so the public can stay informed throughout the process.
- NCDs, including those adopted using the TCET process, may apply to products for the same indication. Follow-on devices will not count toward the 5 applications CMS plans to accept through the TCET process.
- CMS intends to provide criteria for prioritizing among TCET requests.
- Devices undergoing TCET will be part of the NCD Dashboard.

IV. Process and Procedure for the TCET Pathway

The TCET pathway has three stages: (1) premarket; (2) coverage under the TCET pathway; and (3) transition to post-TCET coverage. CMS Summarizes these steps in a diagram below:

TCET Pathway



A. Premarket

1. Non-binding Letter of Intent for the TCET Pathway

Manufacturers may submit a non-binding letter of intent to nominate a potentially eligible device for the TCET pathway approximately 18 to 24 months before anticipated FDA marketing authorization as determined by the manufacturer.

The letter of intent to nominate a device for the TCET pathway may be submitted electronically via the Coverage Center Web site using the "Contact Us" link.

The following information will assist CMS in processing and responding to letters of intent:

- Name of the manufacturer and relevant contact information (name of contact person,
- address, email, and telephone number).
- Name of the product.
- Succinct description of the technology and the disease or condition the device is
- intended to diagnose or treat.
- Date of FDA Breakthrough Device Designation
- Expected regulatory pathway (for example, PMA, De Novo, 510(k))
- Expected completion date for pivotal clinical study.

CMS will email the manufacturer to confirm that a submitted letter of intent has been

received by CMS.

2. Nominations for the TCET Pathway
The appropriate timeframe for manufacturers to submit nominations to CMS is approximately 12 months prior to when the manufacturer anticipates an FDA decision on a submission. CMS encourages manufacturers not to delay submitting nominations to facilitate alignment among CMS benefit category determination, coverage, coding, and payment considerations.

Additionally, when CMS is aware that manufacturers will likely pursue the TCET pathway for devices where appropriate clinical endpoints are uncertain, it may preemptively conduct a clinical endpoints review and may convene a MEDCAC at a later date. In these instances, there may be a delay of several months due to the logistics involved in conducting these activities so the submission of a non-binding letter of intent may avoid potential delays.

Under the TCET pathway, CMS will conduct extensive work in the pre-market period to shorten coverage review timeframes after devices are FDA market-authorized. CMS will not accept nominations for already FDA market-authorized devices or those anticipated to receive an FDA decision market authorization within 6 months of nomination. The following information will assist CMS in processing and
responding to nominations:

- Name of the manufacturer and relevant contact information (name of contact person, address, email, and telephone number).
- Name of the product.
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat.
- The submission of a copy of the FDA's letter granting Breakthrough Device Designation and the PMA application, De Novo request, or premarket notification (510(k)) submission, if available, is preferred.
- A brief statement explaining why the device is an appropriate candidate for the TCET pathway
- A statement describing how the medical device addresses the health needs of the Medicare population.
- A statement that the medical device is not excluded by statute from Part A or Part B Medicare coverage or both, and a list of Part A or Part B or both Medicare benefit categories, as applicable, into which the manufacturer believes the medical device falls. Additionally, manufacturers are encouraged to provide additional specific information to help facilitate benefit category determinations.

CMS will email the manufacturer to confirm that a submitted nomination appears to be complete and is under review. This email will include the date that CMS initiated the review of the complete nomination. CMS will contact the manufacturer for more information if the nomination is incomplete.

3. CMS Nomination Cycles and Consideration of Nominations
CMS will accept suitable TCET candidates quarterly. If a suitable nomination is not selected in the first review, it will be automatically considered in the subsequent quarter. Manufacturers will not need to resubmit to be considered in a subsequent quarter.

CMS may contact the manufacturer to request supplemental information to ensure a timely review of the nomination. Once CMS decides to provisionally accept or decline a nomination, CMS will communicate its decision to the manufacturer by email with their designated point of contact. Acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category.

When CMS issues the proposed NCD or a Breakthrough Device that has received FDA marketing authorization, the proposed NCD will include one or more benefit categories to which CMS has determined the Breakthrough Device falls. CMS will review and consider public comment on the proposed NCD before reaching a final determination on the BCD(s).

4. Intake Meeting
Following the submission of a complete TCET nomination, CMS will offer an initial meeting with the manufacturer to review the nomination within 20 business days of receipt of a complete nomination. In this initial meeting, the manufacturer is expected to describe the device, its intended application, place of service, a high-level summary of the evidence supporting its use, and the anticipated timeframe for FDA review. CMS will answer any questions about the TCET process. CMS intends for these meetings to be held remotely to reduce the travel burden on manufacturers and expeditiously meet these timeframes. These meetings will have a duration of 30 minutes. If a manufacturer declines to meet or if there is difficulty finding a mutually convenient time for the meeting, then CMS action on the nomination may be delayed.

5. Coordination with the FDA
After CMS initiates a review of a complete, formal nomination, representatives from CMS will meet with their counterparts at the FDA to learn more information about the technology in the nomination to the extent the Agencies have not already done so. These discussions may help CMS gain a better understanding of the device and potential FDA review timing. The Memorandum of Understanding between FDA and CMS, FDA and CMS recognizes that the following types of information transmitted between them in any medium and from any source must be protected from unauthorized disclosure.

6. Benefit Category Review
Following discussions with the FDA, CMS may initiate a benefit category review if all other pathway criteria have been met. If CMS believes that the device, before a decision on market authorization by the FDA, is likely to be payable through one or more benefit categories, the device may be accepted into the TCET pathway. Acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category. However, if it appears that a device, before a decision on market authorization by the FDA, will not fall under an existing

benefit category, the TCET nomination will be denied, and the rationale will be discussed in the denial letter. CMS will likely not assess every submitted application for a benefit category review.

7. Manufacturer Notification

Upon completion of CMS' review of the nomination, including the initial meeting with the manufacturer, discussions with the FDA, and benefit category determination, CMS will notify the manufacturer by email whether the product has been accepted into the TCET pathway. In instances where CMS does not accept a nomination, CMS will offer a virtual meeting with the manufacturer to answer any questions and discuss other potential coverage pathways.

8. Evidence Preview (EP)

Following acceptance into the TCET pathway, CMS will initiate an Evidence Preview, which is a systematic literature review that will provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service. The EP is intended to efficiently inform judgments by CMS and manufacturers about the best available coverage options for an item or service. CMS intends for the EP to be supported by a contractor using established rigorous review criteria that were developed in collaboration with AHRQ, have undergone detailed testing during the past year, and are reflected in the CMS NCA Evidence Review guidance. The contractor supports and accelerates CMS reviews, but CMS performs extensive quality assurance on contracted reviews, independently contributes substantial portions of the EP, and ultimately determines appropriate coverage policy. CMS will request written permission from the manufacturer to share any confidential commercial information (CCI) included in the nomination submission with the contractor.

Following acknowledgment of an accepted nomination in the TCET pathway, CMS anticipates that the EP will take approximately 12 weeks to complete once the review is initiated. More time may be needed to complete the review in the event the product is novel, has conflicting evidence, or other unanticipated issues arise.

9. Evidence Preview Meeting

CMS will share the EP with the manufacturer via email and will offer a meeting to discuss it. The EP will have been previously shared with AHRQ and may also be shared with FDA to obtain their feedback, as relevant. Representatives from those Agencies may participate in the EP meeting at their discretion. Manufacturers will have an opportunity to propose corrections to any errors, contribute supplemental materials, and raise any important concerns with the EP before it is finalized.

Upon finalizing the EP, manufacturers may request a meeting to discuss the strengths and weaknesses of the evidence and discuss the available coverage pathways (examples include an NCD, which could include CED, or seeking coverage decisions made by a MAC). These meetings to discuss the EP may be conducted virtually or in person and will be scheduled for 60 minutes.

If an NCD is opened, an evidence summary, including a disclosure of which contractor completed the review, will be posted with the tracking sheet on the CMS website for public comment. There will be no publicly posted tracking sheet for manufacturers who withdraw from the TCET pathway after the completion of an EP. CMS acknowledges that manufacturers may withdraw from the TCET pathway for reasons unrelated to the strength of evidence. CMS will publicly post a summary of the evidence. This summary will not include an evidence gap assessment.

10. Manufacturer's Decision to Continue or Discontinue the TCET Pathway
Upon finalization of the EP, the manufacturer may decide to pursue national coverage under the TCET pathway or to withdraw from the pathway. If the manufacturer decides to continue, the next step will include submitting a formal NCD request cover letter expressing the manufacturer's desire for CMS to open a TCET NCD analysis. Most, if not all, of the information needed to begin the TCET NCD, would be included in the initial TCET pathway nomination and the EP. However, CMS invites the manufacturer to submit any additional materials the manufacturer believes would support the TCET NCD request.

11. Evidence Development Plan
If CMS and/or AHRQ identify evidence gaps during the EP, the manufacturer should also submit an evidence development plan (EDP) to CMS that sufficiently addresses the evidence gaps identified in the EP. The EDP should be submitted to CMS simultaneously with the formal NCD request cover letter. The EDP may include fit-for-purpose (FFP) study designs including traditional clinical study designs and those that rely on secondary use of real-world data, provided that those study designs follow all applicable CMS guidance documents.

CMS believes that permitting FFP study designs will be less burdensome for manufacturers and address the public's concerns that CED should be time-limited to facilitate the timely generation of evidence that can inform patient and clinician decision-making and lead to predictable Medicare coverage.

CMS encourages manufacturers to incorporate a continued access study into their EDP to maintain market access between the completion of the primary EDP, the refresh of the evidence review, and the finalization of a decision regarding post-TCET coverage. The continued access study may rely on a claims analysis, focusing on device utilization, geographic variations in care, and access disparities for traditionally underserved populations.

12. EDP Submission Timing
To obtain CMS' goal of finalizing a TCET NCD within 6 months after FDA market authorization, manufacturers are strongly encouraged to begin developing a rigorous proposed EDP as soon as possible after receiving the finalized EP. To meet the goal of having a finalized EDP within approximately 90 business days after FDA market authorization, the manufacturer is encouraged to submit an EDP to CMS as soon as possible after FDA market authorization.

13. EDP Meeting and Finalization of the EDP

Once CMS receives the EDP from the manufacturer, CMS will have 30 business days to review the proposed EDP and provide written feedback to the manufacturer. During this time, CMS will collaborate with AHRQ to evaluate the EDP to ensure that it addresses the material evidence gaps identified in the EP and meets established standards of scientific integrity and relevance to the Medicare population.

CMS will incorporate AHRQ's feedback on the EDP and will email the consolidated feedback to the manufacturer. Soon after providing written feedback, CMS will schedule a meeting with the manufacturer, which may also include AHRQ, to discuss any recommended refinements and address any questions. In the EDP meetings, the manufacturer should be prepared to demonstrate: (1) a compelling rationale for its evidence development plan; (2) the study design, analysis plan, and data for any CED studies are all fit for purpose; and (3) any CED studies sufficiently address threats to internal validity. The EDP should include clear enrollment, follow-up, study, completion dates for included studies, and the timing and content of scheduled updates to CMS on study progress. For FFP studies with expected completion timeframes longer than 5 years, EDPs should incorporate interim reporting to ensure adequate progress and timely completion.

Following the EDP meeting, the manufacturer and CMS will have another 60 business days to make any adjustments to the EDP. CMS may provide additional time to manufacturers, but we note that delays in submitting and revising an EDP may substantially impact the overall timeline for providing coverage under the TCET pathway.

In instances where the manufacturer's EDP is insufficient to meet CMS' and AHRQ's established standards and cannot be approved, CMS may exercise its option to withdraw acceptance into the TCET pathway. CMS anticipates this will be a rare occurrence as CMS will make every effort to provide flexibility and information to manufacturers to facilitate the development of EDPs.

B. Coverage Under the TCET Pathway

1. CMS NCD Review and Timing

When a device accepted into the TCET pathway receives FDA market authorization, CMS will initiate the NCD process by posting a tracking sheet following FDA market authorization (that is, the date the device receives PMA approval; 510(k) clearance; or the granting of a De Novo request) pending a CMS and AHRQ-approved Evidence Development Plan. As previously noted, the goal is to have a finalized EDP no later than 90 business days after FDA market authorization.

The process for Medicare coverage under the TCET pathway would follow the NCD statutory timeframes in section 1862(l) of the Act.

- CMS posts a tracking sheet and an evidence summary from the finalized Evidence Preview, specifically the non-proprietary information, which would initiate a 30-day public comment period.
- CMS reviews public comments and issues a proposed TCET NCD and EDP within 6 months of opening the NCD. There would be a 30-day public comment period on the proposed TCET NCD and EDP.
- CMS issues a final TCET NCD within 90 days of the release of the proposed TCET NCD.

2. Request for Specific Input on the Evidence Base and Conditions of Coverage
Since the evidence base for these emerging technologies will likely be incomplete and practice standards not yet established, CMS believes that feedback from the relevant specialty societies and patient advocacy organizations, in particular, their expert input and recommended conditions of coverage (with special attention to appropriate beneficiary safeguards), is especially important for technologies covered through the TCET pathway.

CMS encourages these organizations to publicly post any additional feedback, including relevant practice guidelines, within 90 days of CMS' opening of the NCD. All information considered by CMS to develop the proposed TCET NCD will become part of the NCD record and will be reflected in the bibliography as is typical for NCDs.

3. Coverage of Similar Devices
FDA market-authorized Breakthrough Devices are often followed by similar devices that other manufacturers develop. NCDs are limited to particular items or services but it is possible that more than one device could fall under the same NCD because it addresses the same indication. CMS recognizes that some differences may exist for technologies in a class that may result in a distinct benefit/risk profile, and each will be evaluated on its own merit. In these instances, CMS will follow the existing NCD processes.

4. Duration of Coverage Under the TCET Pathway
The duration of transitional coverage through the TCET pathway will be tied to the CMS and AHRQ-approved EDP. The review date specified in the EDP will provide one additional year after study completion to allow manufacturers to complete their analysis, draft one or more reports, and submit them for peer-reviewed publication. Given the short timeframes in the TCET pathway, an unpublished publication draft that a journal has accepted may also be acceptable.

CMS anticipates this transitional coverage period may last for 5 or more years as evidence is generated to address evidence gaps. However, CMS retains the right to reconsider an NCD at any point in time.

C. Transition to Post-TCET Coverage

TCET provides time-limited coverage for devices with the potential to deliver improved outcomes to the Medicare population but does not yet meet the reasonable and necessary standard for coverage. TCET coverage is conditioned on further evidence development as agreed in a CMS and AHRQ-approved EDP.

1. Updated Evidence Review

CMS intends to initiate an updated evidence review within 6 calendar months of the review date specified in the EDP. CMS intends to engage a third-party contractor to conduct a systematic literature review using detailed requirements that CMS developed in collaboration with AHRQ. The contractor will then perform a qualitative evidence synthesis and compare those findings against the benchmarks for each outcome specified in the original NCD. After conducting quality assurance on the contractor review, CMS will assess whether the evidence is sufficient to reach a reasonable and necessary standard.

CMS will also review applicable practice guidelines and consensus statements and consider whether the conditions of coverage remain appropriate. CMS will collaborate with AHRQ and FDA as appropriate as the updated Evidence Review is conducted and will share the updated review with them.

2. NCD Reconsideration

Based upon the updated evidence review and consideration of any applicable practice guidelines, CMS, when appropriate, will open an NCD reconsideration by posting a proposed decision that proposes one of the following outcomes:

1. an NCD without evidence development requirements;
2. an NCD with continued evidence development requirements;
3. a non-coverage NCD; or
4. No national decision with coverage at local MAC discretion

Standard NCD processes and timelines will continue to apply, and following a 30-day public comment period, CMS will have 60 days to finalize the NCD reconsideration.

D. Roles

CMS has outlined the general roles of each participant in the TCET pathway.

1. Manufacturer

The manufacturer may voluntarily choose to email a non-binding letter of intent to CMS to express intent to nominate a device for the TCET pathway. The manufacturer initiates formal consideration for TCET by voluntarily submitting a complete nomination. Manufacturers are encouraged to submit any materials they plan to present during meetings with CMS at least 7 days in advance of the scheduled meeting. Manufacturers should be prepared with the

resources and skills to successfully develop, conduct, and complete the studies included in the EDP.

2. CMS

CMS will provide a secure and confidential nomination and review process. CMS will initiate a review of nominations for the TCET pathway by retrieving applications from the secure mailbox and communicating with the FDA regarding Breakthrough Devices seeking coverage under the TCET pathway.

CMS will also oversee the work of the contractor conducting evidence reviews and will perform extensive quality assurance on contracted reviews, independently contribute substantial portions of the EP, and ultimately determine appropriate coverage policy. Along with AHRQ, CMS will review and make decisions regarding EDPs.

Throughout all stages of the TCET pathway, CMS intends to maintain open communication channels with the FDA, AHRQ, and the relevant manufacturer and fulfill its statutory obligations concerning the NCD process.

3. FDA

FDA will keep open lines of communication with CMS on Breakthrough Devices seeking coverage under the TCET pathway as resources permit. Participation in the TCET pathway does not change the review standards for FDA market authorization of a device, which are separate and distinct from the standards governing a CMS NCD.

4. AHRQ

AHRQ will continue to review all CED NCDs and will collaborate with CMS to define standards for clinical research studies to address the CED questions and meet the general standards for CED studies. CMS anticipates that many NCDs conducted under the TCET pathway will result in CED decisions. Additionally, AHRQ will collaborate with CMS as appropriate, to evaluate the EP and EDP and will have opportunities to offer feedback throughout the process that will be shared with manufacturers. AHRQ will partner with CMS as the Evidence Preview and EDP is being developed, and approvals for these documents will be a joint CMS-AHRQ decision.

E. TCET and Parallel Review

While the TCET pathway will be limited to Breakthrough Devices, other potential expedited coverage mechanisms, such as Parallel Review, remain available. Eligibility for the Parallel Review program is broader than the TCET pathway and could facilitate expedited CMS review of non-Breakthrough Devices. CMS intends to work with the FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

F. Prioritizing Requests

CMS intends to review TCET pathway nominations quarterly. CMS anticipates accepting up to five TCET candidates annually based on current resources. CMS intends to release proposed prioritization factors soon. The public will have an opportunity to provide comments on CMS'

proposed prioritization factors. In the interim, CMS intends to prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare.

G. TCET Transparency

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. CMS plans to update the NCD Dashboard quarterly.

V. Collection of Information Requirements

CMS anticipates receiving approximately eight nominations for the TCET pathway per year. Based on current resources, it does not anticipate the TCET pathway will accept more than five candidates per year. As CMS gains experience with the TCET pathway, it will provide an updated analysis if it receives a higher number of respondents than anticipated.

VI. Resources

- The procedural notice for the TCET pathway
- A Fact Sheet on the TCET pathway
- The CMS guidance documents
- Radiology Business article - CMS expands coverage pathway for emerging technologies, drawing imaging industry criticism

VII. Addendum

CMS describes in this Addendum the process and procedures for how interested parties and the public may engage with CMS to facilitate the TCET pathway. The topics addressed in the notice include the following: (1) TCET general principles; (2) appropriate candidates for the TCET pathway; (3) procedures for the TCET pathway; and (4) general roles.

CMS continues to work with various sectors of the scientific and medical communities to develop and publish guidance documents on its website that describe its approach when analyzing scientific and clinical evidence when developing NCDs. Additionally, CMS intends to publish a series of guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas. The public will be able to comment on these guidance documents available on the CMS coverage website.

For more details refer to pgs. 84-108 in the final notice.