Policy Update

CMS Releases Procedural Notice with Comment Period on Transitional Coverage for Emerging Technology

On June 22, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a procedural notice with comment period on Transitional Coverage for Emerging Technologies (TCET), a new pathway that uses existing national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain breakthrough devices.

Under this new pathway, eligible US Food and Drug Administration (FDA) designated breakthrough devices that fall within a Medicare benefit category can obtain national coverage for three to five years as the manufacturer develops evidence to address gaps identified through a contractor-generated evidence preview and pursuant to an evidence development plan (EDP).

TCET is the successor to the Medicare Coverage of Innovative Technology (MCIT) pathway that was finalized in January 2021 rulemaking by the previous Administration and repealed in November 2021 by the current Administration.

Along with the proposed procedural notice for TCET, CMS published a blog post and a fact sheet. CMS also issued three guidance documents:

- Updated CED guidance document
- National Coverage Analysis Evidence Review guidance document on fit-for-purpose study designs
- Clinical Endpoints guidance document on knee osteoarthritis. This document is the first in a series of clinical endpoints guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas.

Background

Currently, medical devices can obtain coverage under the Medicare program through several pathways:

- NCD, including CED
- Local coverage determination (LCD)
- Claim-by-claim adjudication by the Medicare Administrative Contractors (MACs)
- Clinical trial policy NCD
- Parallel review program with concurrent review by FDA and CMS.

The gap between the date of FDA approval or authorization and the effective date of an NCD poses a key challenge for manufacturers pursuing national coverage under Medicare. Under the existing process, it can take several years for CMS to finalize an NCD.[1,2] Similar to the pursuit of national coverage, obtaining an LCD from the applicable MACs can take multiple years.[3] These two existing coverage pathways can be unpredictable for manufacturers, often leading to delays in coverage (where coverage is granted) for patients and providers.

[1] 78 FR 48169.
[2] There is no time limitation between when CMS accepts an NCD consideration (or reconsideration) request as "valid" and when CMS initiates the substantive NCD development/reconsideration process by publishing a tracking sheet.
[3] Ruggles, S. W., Perl, J., *et al*. "The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem." December 2021.

Another challenge in pursuing Medicare coverage is potential gaps in the evidence necessary for FDA to make a decision and the evidence CMS needs to make a coverage determination. 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. CMS looks to the evidence supporting FDA market authorization and an item or service'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 are no data on those elements in the Medicare population, it is difficult for CMS to make an evidence-based decision as to whether an item or service is reasonable and necessary for the Medicare population.

To address the challenges inherent in the existing coverage pathways, in January 2021 CMS finalized the MCIT rule designed to establish a new national coverage pathway for items and services comprising new medical technologies. This pathway was designed with the stated goal "to accelerate the coverage of new, innovative devices to Medicare beneficiaries."[4] Under this pathway, items and services involving medical technologies that received FDA breakthrough device designation status would have been eligible to automatically receive up to four years of national Medicare coverage. However, with the change in the Administration, CMS reevaluated the MCIT pathway, initially delaying and ultimately repealing the rule in November 2021. While CMS appreciated that the MCIT pathway was designed to address "concerns that delays and uncertainty in Medicare coverage impaired beneficiary access to important new and innovative technologies," the agency repealed the rule because of several concerns, including lack of assurance that FDA review guarantees that a product will improve health outcomes for Medicare beneficiaries, and limited ability to remove coverage for devices that prove ineffective.[5]

Acknowledging that the repeal of the rule left the underlying problem unresolved, CMS committed to exploring policy options that would ensure more timely access for Medicare beneficiaries to emerging and innovative technologies. Over the last 15 months, the agency has held stakeholder listening sessions and engaged in multiple discussions with stakeholder groups, soliciting feedback as it contemplated a new pathway to expand timely access to emerging, innovative technologies while safeguarding Medicare beneficiaries and seeking to improve patient health outcomes.

Proposed Coverage Pathway: Transitional Coverage for Emerging Technology

On June 22, 2023, CMS issued a procedural notice describing how the agency will leverage the current NCD process to create the TCET pathway. CMS states that establishing TCET through a procedural notice leveraging existing coverage structures, rather than rulemaking establishing a novel structure, will create a faster, more easily modifiable pathway. The notice addresses the following topics:

- TCET general principles
- Appropriate candidates for the TCET pathway
- Procedures for the TCET pathway
- General participant roles.

CMS expects only a limited number of devices to be nominated and approved for TCET each year. CMS expects to receive approximately eight nominations per year and to approve no more than five candidates based on resource constraints. CMS will prioritize innovative medical devices that have the potential to benefit the greatest number of Medicare beneficiaries.

Appropriate candidates for the TCET pathway would include devices with the following characteristics:

- Granted FDA breakthrough device designation
- Determined to be within a Medicare benefit category
- Not already the subject of an existing Medicare NCD

[4] 85 FR 54328.
[5] Fleisher, Lee. "Medicare Coverage of Innovative Technologies (MCIT)." Sept. 13, 2021.

- Not otherwise excluded from coverage through law or regulation.

CMS acknowledges that diagnostic tests, as devices, would be eligible for the TCET pathway. However, the agency states that coverage determinations for most diagnostic laboratory tests granted breakthrough designation should continue to be determined by the MACs through existing pathways, as opposed to leveraging the new pathway.

TCET Versus MCIT

Criteria	Transitional Coverage for Emerging Technologies	Medicare Coverage for Innovative Technologies
Eligible Technologies	FDA-designated breakthrough devices	FDA-designated breakthrough devices
Enrollment	Voluntary, opt-in by manufacturer	Voluntary, opt-in by manufacturer
Evidentiary Requirements	As required under EDP based on evidence preview	None
Length of National Coverage	In general, CMS anticipates transitional coverage would last for three to five years. CMS retains the right to reconsider an NCD at any point in time.	Up to four years
Effective Date	CMS's goal is to finalize a TCET NCD within six months after FDA market authorization.	Date requested by manufacturer
Retroactive Application	Not addressed, but unlikely	Yes, for eligible devices that received FDA marketing authorization within two calendar years
Coverage Options After Transitional Coverage Period	Possible outcomes: 1. NCD with affirmative coverage 2. NCD with CED 3. Non-coverage NCD 4. MAC discretion (*e.g.*, LCD or claim-by-claim determination)	Possible outcomes: 1. NCD with affirmative coverage 2. Non-coverage NCD 3. MAC discretion (*e.g.*, LCD or claim-by-claim determination)

Overview of TCET Pathway

The TCET pathway has three stages:
- Premarket
- Coverage under TCET
- Transition to post-TCET coverage.

Premarket

TCET Nomination

Manufacturers should submit TCET nominations to CMS at TCET@cms.hhs.gov approximately 12 months prior to the anticipated FDA decision. CMS suggests including the following information with the nomination:
- Name of the manufacturer and relevant contact information
- Name of the product
- Succinct description of the technology and disease or condition that the device is intended to diagnose or treat

- State of development of the technology (*e.g.*, pre-clinical testing, in clinical trials, undergoing FDA premarket review), preferably including a copy of FDA's letter granting breakthrough designation and the premarket approval application, *de novo* request or premarket notification (510(k)) submission, if available
- Comprehensive list of peer-reviewed, English-language publications that support the nominated breakthrough device as applicable/available
- 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
- Statement describing how the medical device addresses the health needs of the Medicare population
- Brief statement explaining why the device is an appropriate candidate for the TCET pathway.

CMS Consideration
CMS will make a preliminary decision to provisionally accept or decline a nomination within 30 business days following confirmation that the nomination has been received. Determining whether a technology falls within a benefit category may take longer, and in those instances CMS will communicate a final decision when the benefit category review is complete.

Intake Meeting
CMS will offer an initial 30-minute virtual meeting with the manufacturer within 20 business days of receipt of a complete nomination. At the 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 timeline for FDA review.

Coordination with FDA
CMS will meet with FDA to learn more about the technology and potential FDA review timing.

Benefit Category Review
Following discussions with FDA, CMS may initiate a benefit category review if all other TCET criteria have been met. If CMS believes that the device is likely to be coverable through one or more benefit categories, the device may be accepted into TCET. CMS notes that acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category.

Manufacturer Notification
After CMS completes its review of the nomination, including the initial meeting with the manufacturer, discussions with FDA and benefit category determination, CMS will notify the manufacturer whether the device is an appropriate candidate for TCET. If a nomination is not accepted for TCET, CMS will offer a meeting with the manufacturer to explain that decision and discuss other potential coverage pathways.

Evidence Preview
If a nomination is accepted as a candidate for TCET, CMS will initiate an evidence preview, which is a systematic literature review to provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service. The evidence preview is expected to take approximately 12 weeks and will be conducted by a contractor using standardized evidence grading, risk of bias assessment and applicability assessment according to Agency for Healthcare Research and Quality (AHRQ) protocol. CMS believes that the evidence preview will offer greater efficiency, predictability and transparency to both manufacturers and CMS on the state of the evidence and any notable evidence gaps for coverage purposes.

Evidence Preview Meeting
CMS will share the evidence preview with the manufacturer via email and offer a meeting to discuss the findings. Manufacturers may propose corrections to any errors and raise any important concerns.

If a manufacturer withdraws from TCET following completion of the evidence preview, there will be no publicly posted tracking sheet and no public notification that an evidence preview was completed. However, in those circumstances, CMS believes it is in the best interests of patients and the Medicare program to share the evidence preview with the MACs to aid them in their decision-making, since the development of an evidence

preview represents a substantial investment of public resources. **CMS solicits public comment on this approach.**

Manufacturer's Decision to Continue or Discontinue with the TCET Pathway
Once the evidence preview is finalized, manufacturers can decide to pursue national coverage under TCET or to discontinue with the pathway. If the manufacturer decides to continue, the manufacturer would submit a formal NCD letter so that CMS may open a TCET NCD analysis. Manufacturers would likely have shared the majority of information required to begin the analysis as part of their initial TCET nomination, but they have the opportunity to submit additional materials that they believe would support the TCET NCD request.

Evidence Development Plan
If CMS and/or AHRQ identify evidence gaps during the evidence preview, the manufacturer should also submit an EDP to CMS. EDPs may include traditional clinical study designs or fit-for-purpose study designs, or both, including those that rely on secondary use of real-world data, provided that those study designs follow all applicable CMS guidance documents.

In response to stakeholder feedback, CMS is partnering with AHRQ to consider how to incorporate greater flexibility into the CED paradigm by allowed fit-for-purpose evidence study designs that meet rigorous CMS evidence requirements. CMS believes that fit-for-purpose study designs will be less burdensome for manufacturers and will address the public's concern that CED should be time-limited to facilitate timely generation of evidence that can inform patient and clinician decision-making and lead to predictable Medicare coverage.

EDP Submission Timing
Manufacturers are strongly encouraged to begin developing a rigorous proposed EDP as soon as possible after receiving the finalized evidence preview.

EDP Meeting and Finalization of the EDP
CMS will have 30 business days to review the proposed EDP, including sharing it with AHRQ, and provide written feedback to the manufacturer. After the initial review, CMS will schedule a meeting with the manufacturer and, where appropriate, AHRQ to discuss any recommended EDP refinements and address any questions.

In the EDP meeting, the manufacturer should be prepared to demonstrate the following:
- A compelling rationale for its EDP
- That the study design, analysis plan and data are all fit for purpose
- That the study sufficiently addresses threats to internal validity.

The EDP should include clear enrollment, follow-up, study completion dates, and the timing and content of scheduled updates to CMS on study progress.

Following the EDP meeting, the manufacturer will have another 60 business days to make any adjustments to the EDP. Manufacturers may request additional time, but CMS notes that such delays may "substantially impact" the overall timeline for coverage under TCET. Non-proprietary information in approved EDPs will be publicly available on the CMS website when a proposed TCET NCD is posted.

CMS's goal is to have a finalized EDP no later than 90 business days after FDA market authorization.

Coverage Under TCET

CMS NCD Review and Timing
If a device that is accepted into TCET receives FDA marketing authorization, CMS will initiate the NCD process by posting a tracking sheet. The manufacturer may also request that its device be withdrawn from TCET at this stage, in which case CMS would not proceed with the NCD review.

The process for Medicare coverage under TCET would follow the NCD statutory timeframes. CMS would start the process by posting a tracking sheet and elements of the finalized evidence preview, which would initiate the start of a 30-day public comment period. Following further CMS review and analysis of public comments, CMS would issue a proposed TCET NCD and EDP within six 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. CMS notes that its goal is to release the proposed and final NCD in advance of the statutory deadlines outlined above.

Request for Specific Stakeholder Input on the Evidence Base and Conditions of Coverage

CMS strongly encourages expert input and recommended conditions of coverage (with special attention to appropriate beneficiary safeguards) from relevant specialty societies and patient advocacy organizations. CMS encourages these organizations to publicly post on their website any additional feedback, including relevant practice guidelines, within 90 days of CMS's opening of the NCD, and to notify CMS when recommendations have been posted.

Coverage of Similar Devices

To be eligible for coverage under a TCET NCD, devices similar to the specific breakthrough-designated device would be subject to the same coverage conditions, including a requirement to post an EDP. **CMS seeks public comments on whether coverage of similar devices using CED would establish a level playing field and avoid delays in access that would occur if a separate NCD were required to ensure coverage for each specific device.**

Duration of Coverage Under the TCET Pathway

In general, CMS anticipates that this transitional coverage period would last for three to five years as evidence is generated to address gaps identified in the evidence preview. The duration of transitional coverage will be tied to the 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 TCET, an unpublished draft that a journal has accepted may also be acceptable. CMS retains the right to reconsider an NCD at any point in time.

Transition to Post-TCET Coverage

Updated Evidence Review

CMS intends to conduct an updated evidence review within six calendar months of the review date specified in the EDP. To do this, CMS will engage a third-party contractor to conduct systematic literature review using detailed requirements developed by CMS 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 the 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.

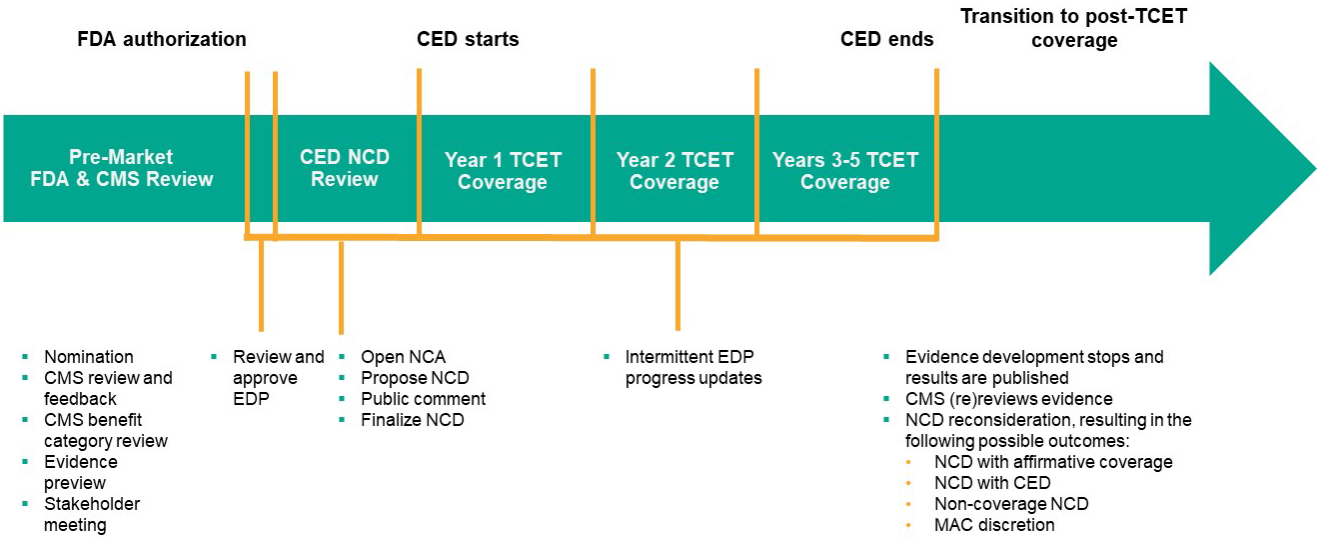
NCD Reconsideration

When appropriate, based upon the updated evidence review and any applicable practice guidelines, CMS will open an NCD reconsideration by posting a proposed decision for one of the following outcomes:

- An NCD without evidence development requirements
- An NCD with CED requirements
- A non-coverage NCD
- Local MAC discretion.

Neither an FDA market authorization nor a CMS EDP approval guarantees a favorable coverage decision. 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.

TCET Proposed Pathway and Timeline



CED

In a proposed CED guidance document, CMS proposes updated CED criteria that reflect the feedback received on the November 2022 AHRQ report and at the February 2023 Medicare Evidence Development and Coverage Advisory Committee meeting. Because the TCET pathway would use the existing CED NCD process, all of the beneficiary safeguards of that process would apply if TCET is finalized.

General Roles of Participants in the TCET Pathway

Participant	Role in the TCET Pathway
Manufacturer	• The manufacturer initiates consideration for TCET by voluntarily submitting a complete nomination. • To expedite CMS decision-making, manufacturers should respond quickly and completely to all issues and requests raised by CMS reviewers. • Manufacturers are encouraged to submit any materials they plan to present during meetings with CMS at least seven days in advance. • Manufacturers should have the requisite resources and skills to successfully develop, conduct and complete the studies in the EDP.
CMS	• CMS will provide a secure and confidential nomination and review process. • Throughout all stages of TCET, CMS will maintain open communication channels with FDA, AHRQ and the relevant manufacturer to fulfill its statutory obligation concerning the NCD process.
FDA	• FDA will maintain open lines of communication with CMS on breakthrough devices seeking coverage under TCET. • Participation in TCET does not change the FDA market authorization review standards, which are separate and distinct from CMS NCD standards.
AHRQ	• Currently, AHRQ reviews all CED NCDs and collaborates with CMS as appropriate. • Since CMS anticipates that many NCDs under TCET will result in CED decisions, AHRQ will continue to review all CED NCDs consistent with current practice. • AHRQ will collaborate with CMS to evaluate the evidence preview and EDP. • Evidence preview and EDP approvals will be made jointly by CMS and AHRQ.

Participant	Role in the TCET Pathway
Third-Party Contractor	• Contractor will conduct the evidence preview—a focused literature review to identify material evidentiary pitfalls, evaluating the strengths and weaknesses of available evidence. Evaluation will be conducted using standardized evidence grading as well as an assessment of the risk of bias and the applicability to the Medicare population. • Contractor will conduct an updated evidence review, specifically a systematic literature review, following completion of the EDP. The contractor will compare the evidence compiled against the benchmarks articulated in the original NCD.

Key Implications

TCET would create an expedited pathway to coverage for breakthrough devices. However, while dozens of devices receive breakthrough designation each year, CMS expects to receive approximately eight TCET nominations per year and approve only five candidates from those nominations. Moreover, the proposal does not change the underlying "benefit category" requirement, which may exclude many innovative device types from eligibility for Medicare coverage. As a result, while industry may rightfully look upon these changes as a step in the right direction, the impact of this pathway may be somewhat limited.

Next Steps

Comments on the TCET notice are due through www.regulations.gov 60 days from the publication in the *Federal Register*. **Comments on the three draft guidance documents are due through the CMS website by August 21, 2023.**

CMS also indicated that more documents and activities will be forthcoming, including the following:

- More detailed fit-for-purpose guidance document
- NCD pilot, incorporating "aspects of the new evidence development framework outlined in the TCET procedural notice and guidance documents"
- CMS Guide for Medical Technology Companies and Other Interested Parties
- Future guidance documents to review meaningful health outcomes in other priority therapeutic areas.