

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

Summary of Notice with Comment Period

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Overview

On June 22, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a notice with a comment period on the process they will use to provide [transitional coverage for emerging technologies \(TCET\)](#) through the national coverage determination (NCD) process under the Social Security Act (the Act). It also solicits public comment on the proposed TCET pathway. The 60-day comment period ends at the close of business on August 28, 2023. CMS will respond to public comments in a subsequent final notice.

Please note: Public comments about the proposed [coverage with evidence development \(CED\)](#) must be submitted by Aug. 21. CMS will respond to public comments in a subsequent final notice.

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 the Centers for Medicare & Medicaid Services (CMS)

experience with the Parallel Review program and the Coverage with Evidence Development (CED) pathway.

I. Background

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 innovators; 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.

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. 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.

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. 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.

II. Provisions of the Notice with Comment Period

The TCET pathway relies on existing authorities, CMS is establishing TCET through a procedural notice rather than rulemaking to allow for faster implementation and modifications as they gain new experience. In this notice, CMS describes the procedures for how stakeholders and the public can 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 will continue to develop and publish guidance documents on its website that describe its approach to analyzing scientific and clinical evidence to develop an NCD. In response to stakeholder feedback, CMS posted proposed CED and Evidence Review guidance documents that incorporate robust fit-for-purpose evidence development where manufacturers may use fit-for-purpose studies to close any evidence gaps. The public has an opportunity to provide comments on these guidance documents via the CMS Medicare Coverage Database website at <https://www.cms.gov/medicare-coverage-database/reports/national-coverage-medicare->

[coverage-documents-report.aspx?docTypeId=1&sortBy=title](#). Comments are encouraged by August 21, 2023.

A. TCET Pathway-An Opportunity to Accelerate Patient Access to Beneficial Medical Products While Generating Evidence

CMS relies heavily on health outcomes data, including but not limited to health outcomes data as it relates to the Medicare population, before proposing an NCD. If there is health outcome evidence for a new technology, it may not be generalizable to the Medicare population if Medicare beneficiaries are insufficiently represented in pivotal clinical studies. Medicare beneficiaries have been historically underrepresented in pivotal studies due to age, access, multiple comorbidities, and concurrent treatments. When there is little or limited evidence, CMS may not have enough information to make a favorable NCD due to gaps in research about health outcomes, including potential safety risks to the Medicare population. CMS recognizes that most emerging technologies are likely to have limited or developing bodies of clinical evidence that may not have included the Medicare population (that is, individuals over age 65, people with disabilities, and those with end-stage renal disease). Many Medicare beneficiaries have comorbid medical conditions, and those factors may have limited their participation in certain clinical trials.

CMS believes that the TCET pathway can support manufacturers that are interested in working with CMS to generate additional evidence that is appropriate for Medicare beneficiaries and that may demonstrate improved health outcomes in the Medicare population to support more expeditious national Medicare coverage. CED has been used to support evidence development for certain innovative technologies that are likely to show benefit for the Medicare population when the available evidence is not sufficient to demonstrate that the technologies are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act. In instances where there is limited evidence, CED may be an option for Medicare beneficiaries seeking earlier access to promising technologies. CED has been a pathway whereby, after a CMS and AHRQ review, Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. Participation in a CED trial is voluntary and beneficiaries are protected by regulations to protect human research subjects.

CMS has issued a total of 26 NCDs requiring CEDs over the last two decades to provide Medicare beneficiary access to promising items and services that could not otherwise be covered. CMS has approved 109 CED studies and five national registries to facilitate evidence development for these CED NCDs. Forty-two of these studies have generated evidence across 14 topics covered under CED. Three CED NCD topics have had the CED requirement removed following an NCD reconsideration and have received national coverage. With respect to evidence generation, the TCET pathway would build upon CMS and AHRQ's ongoing collaboration on the CED NCD process. CMS anticipates that many of the NCDs conducted under

the TCET pathway will result in CED decisions, and AHRQ will continue to review all CED NCDs consistent with current practice. Additionally, AHRQ will collaborate with CMS as resources allow for evidence development activities conducted to support Medicare coverage under the TCET pathway and will have opportunities to offer feedback throughout the process that will be shared with manufacturers. Approvals related to evidence development will be a joint CMS-AHRQ decision.

CMS believes that certain coverage decisions – in particular, those involving innovative devices – would benefit from a more systematic framework for CED that establishes a more predictable and transparent approach for the public when facilitating evidence development. CMS has been actively collaborating with AHRQ on potential revisions to the general criteria for CED studies, originally described in 2014, to ensure the criteria are up to date and continue to maintain rigorous evidentiary standards. In November 2022, to better inform the CED process, AHRQ released a final report on “The Analysis of Requirements for Coverage with Evidence Development (CED). The AHRQ report was first released in draft form in September 2022 and the public had an opportunity to provide comments on the draft report. The AHRQ report served as the basis for discussion at the February 13-14, 2023, MEDCAC meeting. CMS convened the MEDCAC to examine the general requirements for clinical studies submitted for CMS coverage under CED.

Specifically, the MEDCAC evaluated the CED criteria to assure that studies informing CED are assessed using consistent, feasible, transparent, and methodologically rigorous criteria. The MEDCAC advised CMS on whether the criteria are appropriate to ensure that studies approved to inform CED decisions will produce informative evidence that CMS can rely on when making future reasonable and necessary determinations. AHRQ and CMS collaboratively evaluated the information discussed at the MEDCAC meeting as well as the MEDCAC panel scores and are considering corresponding refinements to the proposed new criteria. CMS is proposing updated criteria in a proposed CED guidance document and the public will have an opportunity to provide comments on that document.

- [Proposed Coverage with Evidence Development](#)

Clinical Study Standards for CED under Section 1862(a)(1)(E)

Participation in CED studies is voluntary both for beneficiaries and trial sponsors and participating study sites. Following the recent MEDCAC meeting, CMS and AHRQ developed and refined the characteristics needed for CED clinical studies. This guidance is part of a broader CMS coverage modernization initiative that aims to provide a more transparent and predictable evidence-generation framework to facilitate Medicare coverage. As part of this effort, we are updating our CED guidance to better allow for a broader range of fit-for-purpose study designs. If a sponsor or study site would like to voluntarily participate in a CED study, we expect that they will sign an agreement for the specific CED trial under the NCD. The agreement would include the following general conditions:



1. Sponsor/Investigator:

The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. Milestones:

A written plan is in place that describes the schedule for completion of key study milestones, including results reporting, to ensure timely completion of the CED process.

3. Study Protocol:

The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation.

4. Study Context:

The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design:

The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice must be justified, and the sponsors/investigators must discuss in detail how the design contributes to the evidence base that allows for valid causal inference.

6. Study Population:

The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention. At a minimum, this includes attention to the intended population's racial and ethnic backgrounds, gender, age, disabilities, important comorbidities, and dependent on data availability, relevant social determinants of health.

7. Subgroup Analyses:

The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, must also be included.

8. Care Setting:



When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes:

The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions.

10. Objective Success Criteria:

In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality:

The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity:

Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses:

Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting:

Final results must be provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).

15. Sharing:

The sponsors/investigators commit to sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including section 165.514 of the Health Insurance

Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance:

The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. If a study is regulated by the FDA, it is also in compliance with 21 CFR Parts 50 and 56.

17. Legal:

The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR §312.81(a).

Coverage under a CED NCD can expedite earlier beneficiary access for individuals who volunteer to participate in the clinical studies of 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 of new technologies, or to new applications of older technologies. CMS' current CED guidance document contains specific criteria that detail patient protections under CED. With respect to beneficiary safeguards, the NCD process allows for coverage with appropriate safeguards for Medicare beneficiaries including coverage criteria based on evidence regarding eligibility, frequency, provider experience, site of service or availability of supporting services. Because the TCET pathway described in this document would utilize the existing CED NCD process, all of these safeguards would apply to TECT if finalized.

Stakeholder input is important to CMS, and they are particularly interested in engagement with patient advocacy organizations and medical specialty societies as they have valuable expertise and first-hand experience in the field that will help CMS develop Medicare coverage policies. Because the TCET pathway would utilize the current NCD process, these opportunities for stakeholder engagement would also be available in TCET.

Refer to the [Proposed Coverage with Evidence](#) guidance document for more details.

B. TCET General Principles

CMS' goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after FDA market authorization. The TCET pathway will meet the following principles:

- Medicare coverage under the TCET pathway is limited to certain Breakthrough Devices that receive market authorization for one or more indications for use covered by the Breakthrough Device designation when used according to those indications for use. Manufacturers of FDA-designated Breakthrough Devices that fall within a Medicare benefit category may self-nominate to participate in the TCET pathway on a voluntary basis.

CMS noted 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. Others are not indicated for use in a population that includes Medicare beneficiaries (for example, those devices that are targeted toward a pediatric population).

- CMS may conduct an early evidence review before FDA decides on marketing authorization for the device and discuss with the manufacturer the best available coverage pathways depending on the strength of the evidence.
- Prior to FDA marketing authorization, CMS may initiate discussions with manufacturers to discuss any evidence gaps for coverage purposes and the types of studies that may need to be completed to address the gaps, which could include the manufacturer developing an evidence development plan and confirming that there are appropriate safeguards for Medicare beneficiaries.
- If CMS determines that further evidence development (that is, CED) is the best coverage pathway, CMS will work with the manufacturers to reduce the burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements. CMS will work to ensure they do not require duplicative or conflicting evidence development with any FDA post-market requirements for the device.
- CMS does not believe that an NCD that requires CED as a condition of coverage should last indefinitely, including under the TCET pathway. If the evidence supports a favorable coverage decision under CED, coverage will be time-limited to facilitate the timely generation of sufficient evidence to inform patient and clinician decision-making and to support a Medicare coverage determination.
- Manufacturers and CMS have the option to withdraw from the TCET pathway up until the time CMS opens the NCD by posting a tracking sheet.

CMS will not publicly disclose the participation of a manufacturer in the TCET pathway prior to CMS' posting of an NCD tracking sheet unless the manufacturer consents or has already made

this information public or disclosure is required by law. If a manufacturer does not wish the information that would be revealed by the posting of the NCD tracking sheet to become public, it should withdraw from the TCET pathway prior to this point.

CMS requests that a manufacturer who wishes to withdraw from the TCET pathway notify CMS by email at TCET@cms.hhs.gov.

C. Appropriate Candidates

Appropriate candidates for the TCET pathway would include those devices that are

- 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.

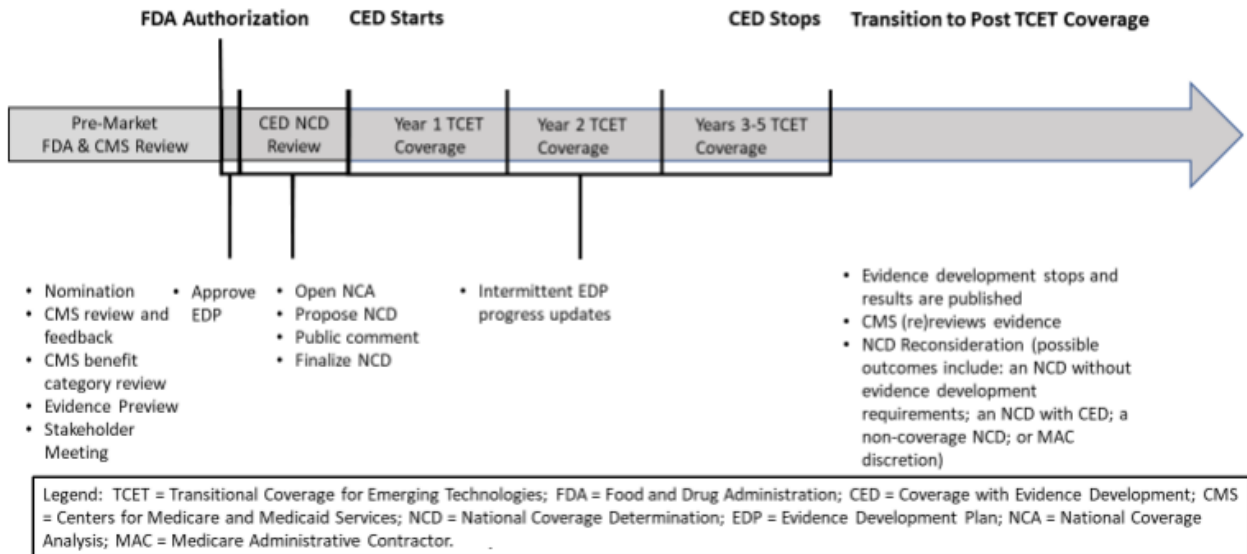
Diagnostic lab tests are a highly specific area of coverage policy development, and CMS has historically delegated the review of many of these tests to specialized MACs. CMS believes that the majority of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by the Medicare Administrative Contractors (MACs) through existing pathways.

D. Procedures 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 Proposed Pathway/Timeline



1. Premarket

a. Nominations for the TCET Pathway

The appropriate timeframe for manufacturers to submit TCET pathway nominations to CMS is approximately 12 months prior to the anticipated FDA decision on the Breakthrough device. CMS encourages manufacturers not to delay submitting nominations to facilitate alignment among CMS benefit category determination, and coverage, coding, and payment considerations.

The manufacturer may submit a nomination for the TCET pathway by sending an email to TCET@cms.hhs.gov, which indicates their interest in the pathway. CMS will acknowledge receipt of nominations by e-mail. The following information will assist CMS in processing and responding to nominations:

- Name of the manufacturer and relevant contact information.
- Name of the product.
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat.
- State of development of the technology (that is, in pre-clinical testing, in clinical trials, currently undergoing premarket review by FDA).
- The submission of a copy of the FDA’s letter granting Breakthrough Designation and the PMA application, De Novo request or premarket notification (510(k)) submission, if available, is preferred.



- A comprehensive list of peer-reviewed, English-language publications that support the nominated Breakthrough Device as applicable/available.
- 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 to facilitate benefit category and coding determinations.
- A statement describing how the medical device addresses the health needs of the Medicare population.
- A brief statement explaining why the device is an appropriate candidate for the TCET pathway.

CMS will contact the manufacturer by email to confirm that a submitted nomination appears to be complete and is under review by CMS. This email will include the date that CMS initiated the review of the complete nomination. If the nomination is not complete, CMS will contact the manufacturer for more information.

To facilitate the development of nomination submissions CMS is working on releasing a new CMS Guide for Medical Technology Companies and Other Interested Parties, which will be released in the coming weeks.

b. CMS Consideration

CMS may contact the manufacturer to request supplemental information to ensure a timely review of the nomination. CMS commits to making at least a preliminary decision to provisionally accept or decline a nomination within 30 business days following the date CMS initiated the review; manufacturers will be notified by email. CMS notes that determining a benefit category may require more time and, in those instances, CMS will send a subsequent email to the manufacturer communicating a final decision when the benefit category review is completed.

c. 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.

d. Coordination with FDA

After CMS initiates review of a complete, formal nomination, representatives from CMS will meet with their counterparts at the FDA to learn more information about the technology. These

discussions may help CMS gain a better understanding of the device and potential FDA review timing. The Memorandum of Understanding between the FDA and CMS recognizes that certain information must be protected from unauthorized disclosure.

e. Benefit Category Review

Following discussions with FDA, CMS may initiate a benefit category review if all other pathway criteria have been met. Emerging devices may fit within a Medicare benefit category but that does not mean that all medical devices will fall within a benefit category. If CMS believes that the device, prior to a decision on its approval or clearance by FDA, is likely to be coverable 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 the FDA's decision regarding approval or clearance of the device by the FDA. Acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category.

if it appears that a device, prior to a decision on its approval or clearance by FDA, will not fall under an existing benefit category, the TCET nomination will be denied, and this rationale will be discussed in the denial letter. CMS will likely not assess every submitted application for a benefit category review, as the TCET pathway is limited in its size.

f. Manufacturer Notification

CMS will notify the manufacturer by email whether the product is an appropriate candidate for 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.

g. Evidence Preview (pg.24)

Following CMS' determination that the product is an appropriate candidate, CMS will initiate an Evidence Preview, which is a systematic literature review that would provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service. CMS believes the review conducted for the Evidence Preview will offer greater efficiency, predictability, and transparency to manufacturers and CMS on the state of the evidence and any notable evidence gaps for coverage purposes.

CMS intends for the Evidence Preview to be conducted by a contractor using standardized evidence grading, risk of bias assessment, and applicability assessment according to a protocol initially developed in collaboration with AHRQ in 2020. In order to initiate an Evidence Preview, CMS will request written permission from the manufacturer to share any confidential commercial information (CCI) included in the nomination submission with the contractor. CMS anticipates that the Evidence Preview will take approximately 12 weeks to complete once the review is initiated, following acknowledgment of an accepted nomination in the TCET pathway. CMS states more time may be needed to complete the review in the event the product is novel, has conflicting evidence or other unanticipated issues arise.

h. Evidence Preview Meeting

CMS will share the Evidence Preview with the manufacturer via email and will offer a meeting to discuss it. The Evidence Preview 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 Evidence Preview meeting. Manufacturers will have an opportunity to propose corrections to any errors and raise any important concerns with the Evidence Preview. CMS will review the manufacturer's feedback on the Evidence Preview and work with our contractor to revise the draft, as appropriate, prior to finalization. Upon finalizing the Evidence Preview, 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 Evidence Preview may be conducted virtually or in person and will be scheduled for 60 minutes.

CMS notes for manufacturers who withdraw from the TCET pathway following the completion of an Evidence Preview, there will be no publicly posted tracking sheet and no public notification that an Evidence Preview was completed. However, 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 in a thorough evidence review for pre-market devices. **CMS solicits public comment on this approach.**

i. Manufacturer's Decision to Continue or Discontinue with the TCET Pathway

Upon finalization of the Evidence Preview, the manufacturer may decide to pursue national coverage under the TCET pathway or to discontinue with the pathway. If the manufacturer decides to continue, the next step will include a manufacturer's submission of a formal NCD 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, however, CMS invites the manufacturer to submit any additional materials the manufacturer believes would support the TCET NCD request.

j. Evidence Development Plan (EDP)

If evidence gaps are identified by CMS and/or AHRQ during the Evidence Preview, the manufacturer should also submit an evidence development plan (EDP) to CMS that sufficiently addresses the evidence gaps identified in the Evidence Preview. The EDP should be submitted to CMS at the same time as the formal NCD request cover letter. The EDP 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.

CMS is partnering with AHRQ to consider how to incorporate greater flexibility into the CED paradigm by allowing fit-for-purpose (FFP) study designs (including those that make secondary use of real-world data) that meet rigorous CMS evidence requirements. **Any updates will be communicated in guidance documents and potential rulemaking as applicable and will include an opportunity for public comment.**

CMS notes that FFP study designs will be less burdensome for manufacturers. CMS believes that by incorporating FFP study designs, they will address one of 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 warns manufacturers that FFP studies require considerable planning in data validation, linkage, and transformation; specification of the study protocol; data analysis; and reporting. The study design, patient inclusion criteria, primary and secondary endpoints, treatment setting, analytic approaches, timing of outcome assessment, and data sources should be fully pre-specified in the submitted protocol. When writing EDPs, manufacturers should propose clinically meaningful benchmarks for each study outcome and provide supporting evidence.

CMS strongly encourages manufacturers to conceive a continued access study that maintains market access between the period when the primary EDP is complete, the evidence review is refreshed, and a decision regarding post-TCET coverage is finalized. The continued access study may rely on a claims analysis, with a focus on device utilization, geographic variations in care, and access disparities for traditionally underserved populations.

k. EDP Submission Timing

To assist CMS with achieving its 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 Evidence Preview. To meet the goal of having a finalized EDP 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.

1. EDP Meeting and Finalization of the EDP

Once CMS receives the EDP from the manufacturer, it will share the document with AHRQ. CMS will have 30 business days to review the proposed EDP and provide written feedback to the manufacturer. CMS will collaborate with AHRQ to evaluate the EDP to ensure that it meets established standards of scientific integrity and relevance to the Medicare population. CMS will incorporate AHRQ's feedback on the EDP and will share the consolidated feedback with the manufacturer by email. 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 are all fit for purpose; and (3) 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. Manufacturers should present and justify their study outcomes and performance benchmarks.

Following the EDP meeting, the manufacturer and CMS will have another 60 business days from the date of the EDP meeting to make any adjustments to the EDP.

Elements of the CMS and AHRQ-approved EDPs, specifically the non-proprietary information, will be made publicly available on the CMS website upon posting of the proposed TCET NCD. If the manufacturer's EDP is insufficient to meet CMS' and AHRQ's established standards, CMS may exercise its option to withdraw participation from the TCET pathway.

2. Coverage Under the TCET Pathway
 - a. CMS NCD Review and Timing

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).

At this stage in the process, the manufacturer may request that their device be withdrawn from the TCET pathway, in which case CMS would not proceed with the NCD review described in this section. 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 would start the process by posting a tracking sheet and elements of the finalized Evidence Preview, specifically the non-proprietary information, 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 6 months of opening the NCD. There would be a 30-day public comment period on the proposed TCET NCD and EDP.
- A final TCET NCD would be due within 90 days of the release of the proposed TCET NCD. CMS' goal is to release the proposed and final NCD in advance of the statutory deadline that applies to all NCDs.

More information on the NCD process is set forth in the August 7, 2013, Federal Register notice (78 FR 48164).

b. Request for Specific Stakeholder 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 is seeking feedback from the relevant specialty societies and patient advocacy organizations, in particular, expert input and recommended conditions of coverage (with special attention to appropriate beneficiary safeguards), is especially important for technologies covered through the TCET pathway.**

Upon the opening of an NCD analysis, CMS strongly encourages organizations to provide specific feedback on the state of the evidence and their suggested approaches to best practices for the emerging technologies under review. Specifically, CMS encourages organizations to publicly post on their website any additional feedback, including relevant practice guidelines, within 90 days of CMS' opening of the NCD. Organizations are encouraged to notify CMS when recommendations have been posted. 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.

c. Coverage of Similar Devices

FDA market-authorized Breakthrough Devices are often followed by similar devices that other manufacturers develop. CMS believes that it is important to let physicians and their patients make decisions about the best available treatment depending upon the patient's individual situation. Rather than extending privileged coverage status only to the first device that achieves FDA market authorization, CMS is seeking 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. To be eligible for coverage under a TCET NCD, similar devices will be subject to the same coverage conditions, including a requirement to propose an EDP. **CMS seeks public comments on its approach to provide coverage for similar devices under the TCET pathway.**

d. 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 would last for a period of 3 to 5 years as evidence is generated to address evidence gaps identified in the Evidence Preview. CMS retains the right to reconsider an NCD at any point in time.

3. 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.

a. Updated Evidence Review

CMS intends to conduct an updated evidence review within 6 calendar months of the review date specified in the EDP. To conduct the review, 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 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.

b. NCD Reconsideration

Based on 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) permitting local MAC discretion to make a coverage decision

Neither an FDA market authorization nor a CMS approval of an Evidence Development Plan 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.

E. Roles

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

1. Manufacturer

The manufacturer initiates consideration for TCET by voluntarily submitting a complete nomination as outlined previously. In the interest of expediting CMS decision-making, the

manufacturer should be prepared to quickly and completely respond to all issues and requests for information raised by the CMS reviewers. If CMS does not receive information from manufacturers in a timely fashion, CMS review timelines will be lengthened. 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 as outlined previously. CMS will initiate a review of nominations for the TCET pathway by retrieving applications from the secure mailbox and communicating with FDA regarding Breakthrough Devices seeking coverage under the TCET pathway. Throughout all stages of the TCET pathway, CMS intends to maintain open communication channels with 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

Currently, AHRQ reviews all CED NCDs. AHRQ collaborates 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 of the NCDs conducted under the TCET pathway will result in CED decisions, AHRQ will continue to review all CED NCDs consistent with current practice. AHRQ will be a partner with CMS as the Evidence Preview and EDP are being developed and approvals for these documents will be a joint CMS-AHRQ decision.

F. 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 for the TCET pathway and could facilitate expedited CMS review of non-Breakthrough Devices. To achieve greater efficiency and to simplify the coverage process generally, CMS intends to work with FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

G. Prioritizing Requests

CMS intends to review TCET pathway nominations and respond within 30 days after receipt of the email. At present, CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints. CMS intends to prioritize innovative medical devices that, as

determined by CMS, have the potential to benefit the greatest number of individuals with Medicare.

III. Collection of Information Requirements

CMS expects they will receive approximately eight nominations for the TCET pathway per year. Due to current CMS resource constraints, they do not anticipate the TCET pathway will accept more than five candidates per year. CMS will provide an updated analysis if it receives a higher number of respondents.

IV. Resources

- [The procedural notice for the TCET pathway](#)
- [A Fact Sheet on the TCET pathway](#)
- [The CMS guidance documents open for comment](#)