NOTICE WITH COMMENT PERIOD SUMMARY

AAHOMECARE
American Association for Homecare

MEMORANDUM

Date: June 22, 2023

Subject: Medicare Program; Transitional Coverage for Emerging Technologies [CMS-3421-NC]

OVERVIEW

On June 22, 2023, Centers for Medicare & Medicaid Services (CMS) published a notice with comment period titled, "Medicare Program; Transitional Coverage for Emerging Technologies" [CMS-3421-NC]. CMS' proposed Transitional Coverage for Emerging Technologies (TCET) pathway would aim to allow faster access and coverage of new technologies for Medicare beneficiaries. TCET pathway is a voluntary process for manufacturers to submit to CMS for expedited coverage for certain FDA-designated Breakthrough Devices. The TCET pathway would utilize the national coverage determination (NCD) and coverage with evidence development (CED) processes to accelerate Medicare coverage for certain new devices. In addition to the procedural notice, CMS published two related proposed guidance documents:

1. Coverage with Evidence Development
2. National Coverage Evidence Review

Stakeholders have until August 28, 2023, to submit comments to the Notice, and until August 21, 2023 to submit comments on the related proposed guidance documents. CMS will then issue a Final Notice with the final provisions and an effective date.

OVERVIEW OF PROPOSED TCET PATHWAY

CMS designed the proposed TCET pathway based on feedback from multiple stakeholder groups and comments received from the repealed Medicare Coverage of Innovative Technologies (MCIT) pathway. In the repeal announcement, CMS noted their plans to conduct further review to improve the coverage process for emerging technologies. For new innovative technologies that have limited clinical evidence, the TCET would provide an expedited process for those devices to come on the market as evidence for coverage is being developed.

With the TCET, CMS intends to:

1) *facilitate early, predictable and safe beneficiary access to new technologies;*
2) *reduce uncertainty about coverage by evaluating early the potential benefits and harms of technologies with innovators; and*
3) *encourage evidence development if notable evidence gaps exist for coverage purposes.*

CMS proposes to utilize their authority to use the NCD to provide certain promising technologies the Coverage with Evidence Development (CED). Manufacturers choosing to submit their product through the TCET pathway

would be voluntary. In addition to being an expedited Medicare coverage process, the TCET pathway would address coding, benefit category determination, and payment reviews. The TCET pathway would only be available for FDA-designated Breakthrough Devices.

PROPOSED TCET PROCEDURE

There would be three stages to the TCET process:

1. Premarket

   Manufacturers submit TCET pathway nomination one year prior to the expected FDA decision by submitting the nomination to *TCET@cms.hhs.gov*. The nomination would include the following information:

   - *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 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.*

   CMS would confirm the submission with the manufacturer and review the nomination with the goal of meeting with the manufacturer within 20 days of submission and completing the review within 30 days, with a decision back to the manufacturer. The determination of whether the new technology falls under an existing benefit category may take longer. In those situations, CMS would send a follow-up message to notify the manufacturer on the benefit category review.

   CMS would coordinate with the FDA to gain more knowledge on the nominated technology. After connecting with the FDA, CMS would begin reviewing the nomination for benefit category. To be accepted into TCET pathway, the device would need to fit into one or more benefit categories (e.g., DME, prosthetics, orthotic, etc.). If the device does not appear to fall under any existing benefit category, the nomination will be denied. If a nomination is denied, CMS will provide an opportunity to meet virtually with the manufacturer to discuss other potential coverage options.

   After CMS approves the nomination, CMS will start the Evidence Preview, which includes review of the relevant literature. CMS intends for the Evidence Preview to not be extensive and a process to inform CMS on the best available existing coverage options. The Evidence Preview would be conducted by a contractor and is expected to take 12 weeks. After the Evidence Preview is completed, CMS would meet with the manufacturer to discuss it. The Agency for Healthcare Research and Quality (AHRQ) and the FDA,

may be invited to participate. The meeting would provide an opportunity for manufacturers to correct errors. Manufacturers could also choose to withdraw from the TECT after the Evidence Preview. If a manufacturer chooses to withdraw their nomination, it would not be publicly posted, but the Evidence Preview would be shared with the MACs. CMS reasons that it is in the best interest of beneficiaries and the Medicare program to share this information with the MACs. CMS requests comments on this approach.

After the completion of the Evidence Preview, the manufacturer could submit a formal NCD letter requesting CMS to open a TCET NCD analysis. At this stage, manufacturers could submit additional materials to support the request. If the Evidence Preview identifies evidence gaps, the manufacturer would need to submit an evidence development plan (EDP) to address the evidence gaps. The EDP will be submitted along with the NCD request. TCET NCD would be finalized within six months of FDA market authorization. CMS strongly encourages manufacturers to complete the EDP within 90 days after the FDA market authorization.

CMS would work with AHRQ in reviewing the EDP and provide a written response to the manufacturer within 30 business days, and will schedule a meeting. In the meeting, manufacturers would need to justify their evidence development plan. After the EDP meeting, CMS would provide a 60-day period for manufacturers to refine the EDP. If the EDP does not meet CMS and AHRQ's standards, CMS may choose to withdraw the device from TCET.

2. Coverage Under the TCET Pathway

If the device receives FDA marketing authorization, CMS would initiate the NCD process and will publicly post a tracking sheet and Evidence Preview, which would start the 30-day public comment period. Within six months of opening the NCD, CMS will issue a proposed TCET NCD and EDP, and will provide a 30- day public comment period. CMS will publish the finalized TCET NCD within 90 days of the publishing of the proposed TCET NCD.

TCET pathway devices are anticipated to have 3–5-year coverage period.

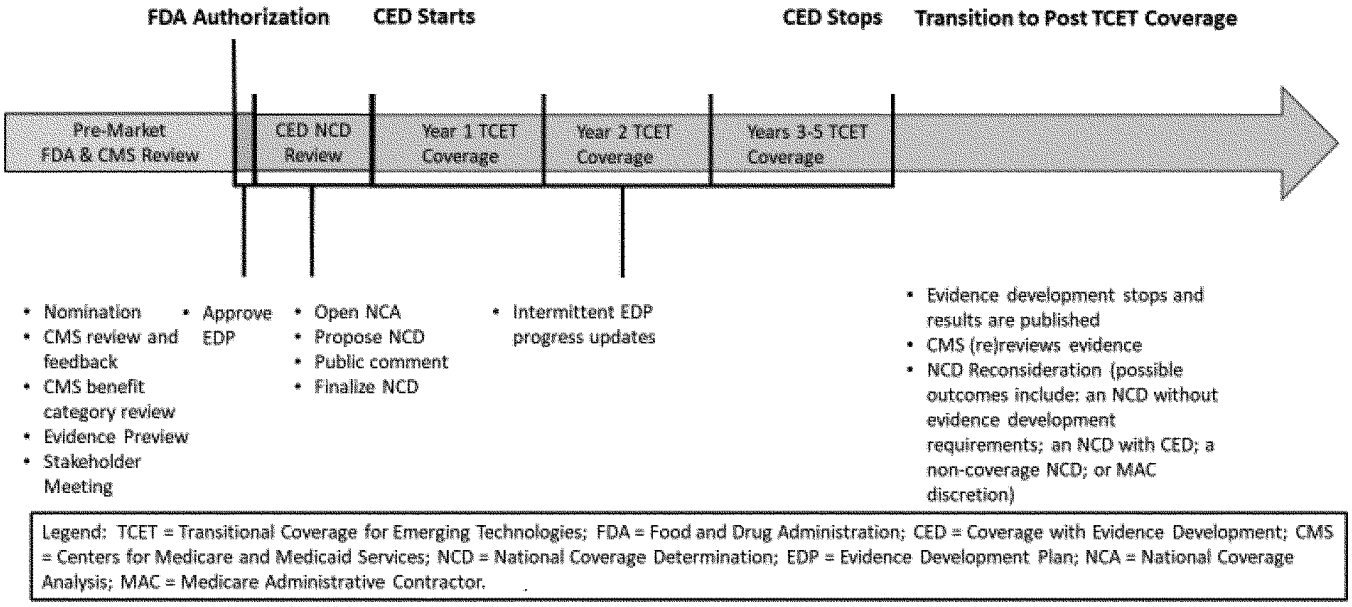
3. Transition to Post-TCET Coverage

CMS plans to have a contractor conduct an updated evidence review within six months of the review date stated in the EDP. CMS would determine if the qualitative evidence and findings are sufficient to meet the reasonable and necessary standard. As needed, CMS would work with AHRQ and FDA on the updated evidence review. After the evidence review is completed, CMS would open an NCD reconsideration and propose one of the following:

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 decision under section 1862(a)(1)(A) of the Act.*

There would be a 30-day public comment period and then a final decision will be made within 60 days.

TCET Proposed Pathway/ Timeline



Legend: TCET = Transitional Coverage for Emerging Technologies; FDA = Food and Drug Administration; CED = Coverage with Evidence Development; CMS = Centers for Medicare and Medicaid Services; NCD = National Coverage Determination; EDP = Evidence Development Plan; NCA = National Coverage Analysis; MAC = Medicare Administrative Contractor.

COLLECTION OF INFORMATION REQUIREMENTS

CMS anticipates receiving about eight nominations to the TCET pathway every year. However, due to CMS resource constraints, CMS does not expect reviewing more than five nominations. Due to their estimate of reviewing less than 10 submissions per year, CMS is exempted from the Paperwork Reduction Act's requirement to analyze burden data.