Issue Brief

FEDERAL ISSUE BRIEF

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CMS Issues Notice with Comment Regarding Transitional Coverage for Emerging Technologies

The Centers for Medicare & Medicaid Services (CMS) have issued a a proposed procedural notice outlining a new Medicare coverage pathway to achieve more timely and predictable access to new medical technologies. CMS says the new Transitional Coverage for Emerging Technologies (TCET) pathway for Breakthrough Devices "supports both improved patient care and innovation by providing a clear, transparent, and consistent coverage process while maintaining robust safeguards for the Medicare population."

The notice describes in detail the process CMS will use to provide transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process.

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.

A copy of the 37-page notice is currently available at: https://public-inspection.federalregister.gov/2023-13544.pdf. The notice is scheduled for publication in the ***Federal Register*** on June 27. A 60-day comment period is provided.

Comment

While this notice is aimed at improving and speeding approval for Medicare coverage of new procedures and devices, the major thrust of the document is aimed at manufacturers. The material is heavily weighted with procedure narratives. However, the outcomes may mean new, and sooner reimbursement for providers.

Provisions of the Notice with Comment Period

The TCET pathway relies on existing authorities. CMS says it believes that "establishing TCET through a procedural notice rather than rulemaking has the advantages that it is faster to implement and can be more easily modified as we gain experience with the approach."

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

CMS says 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.

B. TCET General Principles

CMS says it is committed to ensuring Medicare beneficiaries have access to emerging technologies. CMS' goal is to finalize national coverage determinations (NCDs) for technologies accepted into and continuing in the TCET pathway, within six months after Food and Drug Administration (FDA) market authorization. The TCET pathway will meet the following principles:

- Medicare coverage under the TCET pathway is limited to certain Breakthrough Devices. 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 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.

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
- Not otherwise excluded from coverage through law or regulation

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.

E. Roles

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

1. The manufacturer initiates the consideration for TCET by voluntarily submitting a complete nomination.

2. CMS will provide a secure and confidential nomination and review process.

3. The FDA will keep open lines of communication with CMS on Breakthrough Devices seeking coverage under the TCET pathway as resources permit.

4. The Agency for Healthcare Research and Quality (AHRQ) will collaborate with CMS as resources allow to evaluate the Evidence Preview and Evidence Development Plan (EDP) and will have opportunities to offer feedback throughout the process that will be shared with manufacturers.

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.