Transitional Coverage for Emerging Technologies (TCET) Proposed Rule Summary (CMS-3421-NC)

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On June 27, 2023, the Centers for Medicare and Medicaid Services (CMS) issued the proposed rule for the Medicare Program; Transitional Coverage for Emerging Technologies (TCET).

The proposed rule is 37 pages in length and located in its entirety at the following link: https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies.

Highlights

CMS is proposing to provide transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process. This pathway is intended to provide more transparency, predictability, and expedited national coverage for eligible Breakthrough Devices, authorized by the Food and Drug Administration (FDA); and continue through procedural notice rather than rulemaking process as another way to expedite the process.

The TECT pathway proposal is intended to assist CMS when making coverage decisions through the following considerations:

1) Facilitate early, predictable and safe beneficiary access to new technologies;
2) Reduce uncertainty regarding coverage by early evaluation of the potential benefits and harms of technologies with innovators; and
3) Encourage evidence development if notable evidence gaps exist for coverage purposes.

In addition, 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.

Feedback and comments from previous rulemaking have requested CMS to create a better evidence-based review process that incorporates fit-for-purpose evidence. Also, requests have been made to shorten the time from device approval to coverage, especially considering how quickly many drugs and biologicals are approved, devices seem to take significantly longer. CMS is proposing to limit the TCET pathway to eligible FDA-designated Breakthrough Devices, as this is where there is the most immediate need.

The role of the FDA is important in the understanding of the TCET pathway. The FDA makes marketing authorization decisions, based on safety and effectiveness. They define how a manufacturer can claim or advertise and market their device based on what it was clinically claimed and accepted to accomplish. On the other side, CMS will create NCDs based on whether a service is reasonable and necessary for diagnosing and treating the Medicare population. It is this criterion that CMS strongly urged manufacturers to consider.

Many clinical trials do not include Medicare beneficiaries, or a population that fits the demographics and health status of whom CMS directs coverage. This is due to the many complicated comorbidities and complicated health-status of the Medicare population. Manufacturers are not required to include certain populations in their clinical studies. In addition, inclusion of sicker patients could produce less optimal or skewed outcomes, thereby delaying the process or acceptance of the new technology. The flip side is, without CMS' understanding of how the device will impact their beneficiaries based on the data, approving or outlining coverage can be arduous and/or nonexistent. Ultimately, it is the patient who may suffer because they will not have access to new technology which could improve their health and quality of life.

The Breakthrough Devices Program will have 2 levels of criterion that must be met in order to be eligible for the TCET pathway. CMS describes them as follows:

1) The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.
2) The device must satisfy one of the following elements:
    a) It represents a breakthrough technology;
    b) No approved or cleared alternatives exist;
    c) 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;
    d) Device availability is in the best interest of patients.

New technologies continue to enter the market sooner and faster, creating additional issues of limited or no clinical evidence yet available for CMS or other entities to make informed decisions regarding health outcomes of the technology. As mentioned previously, the lack of Medicare population in clinical studies also creates issues. CMS believes their proposal will create a way in which interested manufacturers can work with CMS to provide additional evidence specific to the Medicare population.

Currently the Medicare beneficiaries who may be looking for emerging technologies which have limited evidence, can participate in Coverage with Evidence Development (CED), in approved clinical studies. CMS believes this proposal will improve the current process of CED and the work they do in conjunction with the Agency for Healthcare Research and Quality (AHRQ), by making better, informed decisions about the potential health outcomes and ensure beneficiaries have equitable access to care as other parts of population.

Ultimately CMS' goal is to finalize an NCD accepted into the TCET pathway within 6 months of FDA market authorization. To do this, CMS has outlined several principles which must be met. A key provision is the NCD that requires CED would not continue indefinitely, but be time-limited to ensure evidence is timely and sufficient. They have also proposed the appropriate candidates for the TCET pathway. Specifically, devices which 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.

There are 3 stages of the TCET pathway proposed: 1) premarket, 2) coverage under TCET pathway, and 3) transition to post-TCET coverage. The details of the stages are the bulk of the proposal released by CMS. To better visualize the proposal, CMS has provided a diagram (see below) outlining the proposed pathway/timeline.

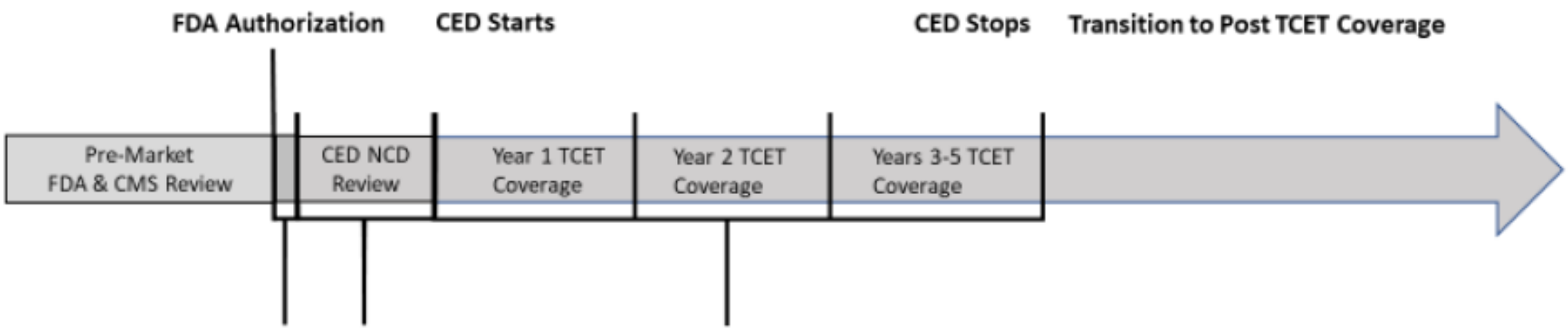
CMS has also listed the general roles of the participants in the TCET pathway: the manufacturer, CMS, FDA, and AHRQ. Open communication is the one component of this proposal which CMS identifies for each of the involved entities, while also preserving the sensitive nature of the data and proprietary technology.

TCET pathway limits who may be eligible, and CMS indicated there are other expedited options for coverage that may be available to those who do not qualify, namely a Parallel Review, will continue to be an option. CMS will work with the FDA to discuss potential updates to the current Parallel Review process between the two entities for greater efficiency and simplicity of coverage considerations for non-Breakthrough Devices.

Submitting Comments

Comments to CMS regarding the Medicare TCET must refer to file code **CMS-3421-N** and be received no later than **5 pm EST August 28, 2023**. Electronic submission is encouraged by CMS, http://www.regulations.gov. Follow the instructions under the "submit a comment" tab.

TCET Proposed Pathway/ Timeline



- Nomination
- CMS review and feedback
- CMS benefit category review
- Evidence Preview
- Stakeholder Meeting
- Approve EDP
- Open NCA
- Propose NCD
- Public comment
- Finalize NCD
- Intermittent EDP progress updates
- Evidence development stops and results are published
- CMS (re)reviews evidence
- NCD Reconsideration (possible outcomes include: an NCD without evidence development requirements; an NCD with CED; a non-coverage NCD; or MAC discretion)

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.