September 15, 2023
Health Law Weekly

CMS Proposes New Medicare Coverage Pathway for Breakthrough Devices

This Featured Article is brought to you by AHLA's Regulation, Accreditation, and Payment Practice Group.

September 15, 2023

Judith A. Waltz, Foley & Lardner LLP | **Kyle Faget**, Foley & Lardner LLP |

Jessa Boubker, Foley & Lardner LLP

To facilitate Medicare coverage for certain devices designated as "breakthrough devices" by the Food & Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS) announced a proposed Transitional Coverage for Emerging Technologies (TCET) pathway on June 27, 2023. CMS outlined its proposed pathway via a proposed procedural notice and proposed guidance documents (CMS National Coverage Analysis Evidence Review Guidance and CMS Coverage with Evidence Development Guidance). Following the 60-day comment period that concluded on August 28, 2023, CMS will respond to public comments in a subsequent final notice.

What Is a Breakthrough Device?

FDA-designated breakthrough devices are devices that the FDA has determined provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The devices must meet at least one of the following criteria: (a) represents breakthrough technology, (b) no approved or cleared alternatives exists, (c) offers significant advantages over existing approved or cleared alternatives, or (d) device availability is in the best interest of patients. To expedite the Medicare coverage process for such FDA-designated breakthrough devices, CMS has proposed a voluntary TCET Pathway to reduce uncertainty regarding coverage options and assist in the evidence review process. According to CMS, the proposed 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."

How Can Breakthrough Devices Secure Medicare Coverage?

Just because a device has been approved for market by the FDA does not mean that Medicare will cover the device. In order for Medicare to cover an item or service (including in a national coverage determination (NCD)), the item or service: (1) must fall within at least one Medicare benefit category established by statute, (2) must not be specifically excluded by statute, and (3) must be "reasonable and necessary" as determined through an evidence-based process. The current gap between when a device is approved by the FDA and when a device obtains an NCD is nine-12 months. For certain FDA-designated breakthrough devices, this gap can significantly delay access to critical technology for Medicare beneficiaries.

What Devices Might Qualify for Medicare Coverage Under the Proposed TCET Pathway?

According to the proposed procedural notice, the TCET Pathway is applicable to devices that are:

1. FDA-designated breakthrough devices;
2. Determined to be within a Medicare benefit category;
3. Not already the subject of an existing Medicare NCD; and
4. Not otherwise excluded from coverage through law or regulation.

The voluntary TCET Pathway provides manufacturers an opportunity to expedite Medicare coverage through a pre-market evaluation of potential harms and benefits of the technologies to

identify evidence gaps and to address those gaps through "fit-for-purpose" studies. A fit-for-purpose study means that "the study design, analysis plan, and study data are appropriate for the question the study aims to answer." CMS believes that fit-for-purpose study designs will be "more convenient for manufacturers because many of these studies may use data already collected through care delivery."

In its proposed notice, CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints and "intends to prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare."

What Are the Key Features of the Proposed TCET Pathway?

The voluntary TCET Pathway includes the following features:

1. Applies to certain FDA-designated breakthrough devices that fall within a Medicare benefit category.
2. Participation is voluntary.
3. CMS may conduct an early evidence review (i.e., "Evidence Preview") before the FDA decides on marketing authorization to discuss the best coverage pathways depending on the evidence.
4. CMS may initiate discussions with manufacturers regarding any evidence gaps prior to the FDA marketing authorization. Manufacturers may propose an "Evidence Development Plan" to address the gaps.
5. CMS' goal is to finalize the TCET NCD for breakthrough devices within six months after the FDA market authorization. The TCET NCD will continue as long as needed to generate evidence necessary for a long term NCD.

Are There Exclusions from the Proposed TCET Pathway?

Notably, despite its name, the TCET Pathway is only applicable to breakthrough devices and excludes other "emerging technologies," such as digital therapeutics. In addition, while the FDA states that diagnostic tests are eligible for the TCET Pathway, CMS notes that coverage determinations for most diagnostic tests should continue to be made by the Medicare Administrative Contractor through existing pathways.

How Does MedPAC View the Proposed TCET Pathway?

The Medicare Payment Advisory Committee (MedPAC), an independent Congressional agency that provides advice to the U.S. Congress on issues affecting the Medicare program, submitted comments on the proposed TCET Pathway on August 25, 2023. While indicating its support for the Proposed TCET Pathway, MedPAC also asserted that CMS should adjudicate Medicare coverage and spending determinations based on the specific needs of the Medicare population. In MedPAC's view, the evaluation of the evidence of whether a new technology improves Medicare beneficiaries' outcomes should rest with CMS. In accordance with that view, MedPAC expressed its support for Coverage with Evidence-Based Development (CED). Under CED, Medicare beneficiaries have access to medical services while clinical evidence is collected in registries and prospective clinical studies. According to MedPAC's comments, CED ultimately enables the Medicare program to

develop evidence-based policies that are specific to the Medicare population. MedPAC also noted the limited number of applicants that could be accepted to the Proposed TCET Pathway and made some suggestions as to how those selections should look to factors beyond benefits to the greatest number of Medicare beneficiaries, specifically including fiscal implications.

What Is the Significance of the Proposed TCET Pathway?

In its current form, the Proposed TCET Pathway would provide an accelerated and more transparent approach to coverage determinations for breakthrough devices, at least for a small number of voluntary participants. However, the Proposed TCET Pathway does not necessarily make certain aspects of obtaining Medicare coverage easier for many products. Medicare is a defined benefit program, and for an item to be considered for Medicare coverage it must fall within a statutory benefit category. Breakthrough devices do not have their own designated Medicare benefit category and it may not be possible to identify an existing benefit category that would aptly include the breakthrough device. Identifying an appropriate benefit category is a requirement to be eligible for the TCET Pathway and to obtain an NCD—and that factor alone may serve as a significant barrier to entry.

While there has been a congressional effort to statutorily establish a benefit category for breakthrough devices (see H.R. 4043-Ensuring Patient Access to Critical Breakthrough Products Act of 2023 and H.R. 5333-Ensuring Patient Access to Critical Breakthrough Products Act of 2019), manufacturers of these products seeking Medicare coverage must continue to ensure that a benefit category exists and is identified at an early stage when developing products intended for the Medicare population.

Succinctly stated, without an available benefit category, coverage by Medicare may be impossible for many breakthrough devices and for other emerging technology. While this accelerated TCET Pathway would be a step forward in CMS' support of emerging technologies, the TCET Pathway is limited to breakthrough devices and only a legislative change can establish new benefit categories to facilitate the coverage of breakthrough devices and other emerging technologies overall.

ARTICLE TAGS

Regulation, Accreditation, and Payment Practice Group Government Reimbursement

1099 14th Street NW, Suite 925, Washington, DC 20005 | P. 202-833-1100
For payments, please mail to P.O. Box 79340, Baltimore, MD 21279-0340