MEDPAC | Medicare Payment Advisory Commission

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–8013

Attention: CMS–3421–NC

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) notice entitled "Medicare Program; Transitional Coverage for Emerging Technologies" in the *Federal Register*, vol. 88, no. 122, pp. 41633–41644 (June 27, 2023). We appreciate your staff's ongoing efforts to administer coverage policies for items and services covered under Medicare, particularly considering the competing demands on the agency.

The Commission's comments relate to the new pathway—the Transitional Coverage for Emerging Technologies (TCET) pathway—that would provide national coverage for certain new breakthrough devices.

Transitional Coverage for Emerging Technologies (TCET) pathway

The proposed TCET pathway aims to provide more timely, predictable, and transparent access to certain new medical technologies.[1] It includes elements that will coordinate benefit category determination, coding, and payment reviews to create transparent, predictable, and expedited national coverage for certain new eligible devices that are approved or cleared under the Food and Drug Administration's (FDA's) Breakthrough Devices Program.[2] According to CMS, "the new pathway provides manufacturers with opportunities for increased pre-market engagement with CMS and a new and unprecedented level of flexibility to address any evidence gaps for

[1] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2023. Medicare Program; Transitional coverage for emerging technologies. *Federal Register* 88, no. 122 (June 27): 41633–41644.
[2] The FDA's Breakthrough Devices Program is an expedited review process available to medical devices and device-led combination products that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Devices subject to premarket approval applications, premarket notification, or requests for De Novo classification are eligible for Breakthrough Device designation so long as they meet certain criteria.

coverage."[3] The TCET pathway will use the national coverage determination (NCD) and coverage with evidence development (CED) processes to cover Breakthrough Devices accepted under the pathway. CMS anticipates that many of the NCDs that result from the TCET pathway will result in CED decisions.

Under the proposed TCET pathway, manufacturers self-nominate to participate on a voluntary basis, approximately 12 months prior to an anticipated FDA decision on a submission (as determined by the manufacturer). Candidates for the pathway include devices that are:

- Approved under the FDA's Breakthrough Devices Program,
- Not already the subject of an existing Medicare NCD,
- Determined to be within a Medicare benefit category, and
- Not otherwise excluded from coverage through law or regulation.[4]

The TCET pathway is designed to have three stages: (1) premarket (i.e., prior to a nominated device's FDA approval/clearance), (2) Medicare coverage under TCET, and (3) post-TCET coverage.

Key components under the premarket stage include:

- **Review the nominated device:** After receipt of a manufacturer's nomination under TCET, CMS will make a preliminary decision to provisionally accept or decline a nomination within 30 business days following confirmation that the nomination has been received.[5]
- **Conduct an early evidence review:** For accepted nominations, CMS will initiate an *Evidence Preview,* a systematic literature review of publicly available clinical evidence for the considered device that will be shared with the manufacturer. The agency will also discuss with the manufacturer the best available coverage pathways depending on the strength of the evidence. At this point, the manufacturer will decide whether to proceed under the TCET pathway or to withdraw from the TCET pathway.[6]
- **Address potential gaps in clinical evidence:** CMS will discuss with the manufacturer any evidence gaps for coverage purposes and the types of study designs that could address them. The manufacturer may then propose an Evidence Development Plan (EDP) to address such evidence gaps. As part of the EDP development process, CMS will work with manufacturers to efficiently meet both CMS evidence development and FDA post-market requirements.[7]

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[3] Fleisher L., S. Farmer, L. Ashby, et al. 2023. Transforming Medicare coverage: A new Medicare coverage pathway for emerging technologies and revamped evidence development framework. Centers for Medicare & Medicaid Services Blog. June 22.

[4] In general, in order for any item or service to be considered for Medicare coverage, the item or service must fall within at least one benefit category established in the Social Security Act, the item or service must not be specifically excluded by the Act, and the item or service must be "reasonable and necessary" according to Section 1861(a)(1)(A) of the Social Security Act.

[5] CMS will offer a meeting with the manufacturer of a nomination not accepted for TCET to explain that decision and discuss other potential coverage pathways.

[6] For those manufacturers that 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.

[7] Fleischer et al., 2023, op cit.

- **Initiate the NCD process:** Upon FDA marketing authorization of the considered device, CMS will initiate the NCD process.[8] The process for Medicare coverage under the TCET pathway would follow the NCD statutory timeframes in Section 1862(l) of the Social Security Act. CMS's goal is to finalize a TCET NCD within six months after the device's FDA market authorization.

The duration of the second stage, Medicare coverage under TCET, will be linked to the timeframes specified in the EDP. In general, CMS anticipates this transitional coverage period would last for three to five years as evidence is generated to address evidence gaps.

During the third stage, post-TCET coverage, CMS will conduct an updated evidence review within six calendar months of the review date specified in the EDP. Based on the updated evidence review and consideration of any applicable practice guidelines, CMS will follow its NCD reconsideration process and post a proposed decision which includes 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 a local Medicare Administrative Contractor discretion to make a decision. During this reconsideration process, 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.

Comment

The Commission recognizes the need to promote beneficiary access to new devices. We applaud CMS's aim to refine Medicare's coverage process in order to: (1) facilitate early, predictable and safe beneficiary access to certain new devices; (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.

The Commission recognizes the unique roles across federal agencies with respect to approving new technologies for marketing in the U.S. and their coverage and payment for Medicare beneficiaries. CMS's role as a payer is distinct and separate from the role the FDA plays in approving or clearing medical devices and drugs. The FDA approval process may or may not include the new device's or pharmaceutical product's safety or effectiveness with regard to the Medicare population. By contrast, the Commission asserts that CMS should adjudicate Medicare coverage and spending determinations based on the specific needs of the Medicare population. The evaluation of the evidence of whether a new technology improves Medicare beneficiaries' outcomes should rest with CMS.

The Commission supports the agency's plan to use its established NCD process to cover technologies under the TCET pathway. We also support coverage via CED, if necessary, for certain new technologies (including devices) that lack clear evidence showing their clinical effectiveness in the Medicare population. Under CED, beneficiaries have access to medical services while clinical evidence is being collected in registries and prospective clinical studies. We agree that CED may be warranted for devices that have a breakthrough designation because the

[8] The manufacturer may also request that its device be withdrawn from the TCET pathway at this stage in the process, in which case CMS would not proceed with the NCD.

FDA, in some instances, may accept a greater level of uncertainty of the benefit-risk profile for certain devices; for example, in cases in which the uncertainty is sufficiently balanced by other factors, such as the probable benefits for patients to have earlier access to the device (e.g., a device that treats a life-threatening disease when no alternative treatments are available).[9]

Because CED provides Medicare with the opportunity to gather clinical evidence that otherwise might not be collected, it ultimately enables the program to develop evidence-based policies specific to the Medicare population. CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. For example, researchers have reported that older adults are underrepresented in cancer and cardiovascular clinical trials. In addition, through CED, Medicare can collect evidence on long-term outcomes and effectiveness in different practice settings that are not always collected in clinical trials.

Due to resource constraints, CMS anticipates accepting a maximum of five TCET candidates annually, and it intends to prioritize innovative medical devices that, as determined by the agency, have the potential to benefit the greatest number of individuals with Medicare. The Commission understands the need to prioritize certain devices due to resource constraints. However, we urge CMS to consider additional factors beyond whether the device benefits the greatest number of beneficiaries, such as:

- Whether the devices could fundamentally change the trajectory of an illness or injury. Such consideration should be given to conditions that have historically been irreversibly debilitating and/or life threatening, even if a relatively small patient population is affected. For example, wearable and implantable artificial kidney devices that are authorized by the FDA could have the potential to help improve the quality of life and outcomes of patients with end-stage renal disease (ESRD).
- The fiscal implications of the considered device on beneficiaries and taxpayers. For example, a high-priced device indicated for a relatively small population has the potential to affect the financial viability of the Medicare program and could impose financial hardship on beneficiaries due to increased out-of-pocket costs and Part B premiums.
- Whether a device with significant risks for Medicare beneficiaries has clear potential benefit, especially where uptake is expected to be rapid.

CMS anticipates that it will receive fewer than ten device nominations for the TCET pathway per year.[10] In processing and responding to nominations, information that CMS will review includes: a description of the technology and condition the device is intended to diagnose or treat, the state of development of the technology, how the device addresses the needs of the Medicare population, why the device is an appropriate candidate for the TCET pathway, and the potential timing of FDA's review process.

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[9] Food and Drug Administration. 2018. *Breakthrough Devices Program: Guidance for industry and Food and Drug Administration staff.* Rockville, MD: FDA.

[10] According to the notice, this estimate is based on CMS's initial assessment of Breakthrough Devices after applying certain characteristics (having the FDA's breakthrough designation, inclusion in a Medicare benefit category, not already subject to an NCD, and not otherwise excluded from coverage through law or regulation).

The Commission is concerned about how CMS will address instances in which it receives: (1) substantially more nominations than it anticipates in a given year and (2) nominations in an irregular pattern in a given year. We urge the agency to provide additional guidance concerning how it will treat nominations in an equitable manner under such circumstances. According to the FDA, the number of devices that have received market authorization under the breakthrough status was 11 in 2020, 15 in 2021, 19 in 2022, and 5 through March 31, 2023. However, the number of devices that have received the breakthrough designation (and may be self-nominated in a given year) is much larger than the number of breakthrough devices that receive market authorization: 151 in 2020, 206 in 2021, 166 in 2022, and 64 through March 31, 2023.[11] In addition, market authorization is not evenly distributed throughout the year; for example, in 2022, one breakthrough device received market authorization during the first calendar quarter, 10 during the second calendar quarter, 2 during the third calendar quarter, and 6 during the fourth calendar quarter.

CMS seeks public comments on its approach for providing coverage for similar devices under the TCET pathway. To establish a level playing field and to promote competition, the Commission supports extending national coverage using CED to devices that are similar to the device covered using the TCET pathway. Such an approach is similar to that used when the agency established a national coverage with CED for all anti-amyloid monoclonal antibody drugs for the treatment of Alzheimer's disease.

The Commission appreciates the opportunity to comment on this procedural notice. We value the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues and look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Dana Kelley, MedPAC's Deputy Director at (202) 220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

[11] Food and Drug Administration. 2023. *Breakthrough Devices Program.* Rockville, MD: FDA.