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MEMORANDUM

To: ITEM Coalition

From: Peter Thomas and Michael Barnett

Date: August 20, 2024

Subject: **Summary of Transitional Coverage for Emerging Technologies Final Notice**

On August 7, 2024, the Centers for Medicare and Medicaid Services ("CMS") issued a final notice ("Final Notice") outlining the new Medicare coverage pathway designed to achieve more timely and predictable access to breakthrough technologies for Medicare beneficiaries.[1] The new Transitional Coverage for Emerging Technologies ("TCET") pathway, which was originally proposed in June 2023, uses current national coverage determination ("NCD") and coverage with evidence development ("CED") processes to expedite Medicare coverage for "Breakthrough Devices" as determined by the Food and Drug Administration ("FDA").

The Final Notice largely finalizes CMS's proposals in the June 22, 2023, Notice with Comment Period,[2] with some notable changes. These changes include an expanded timeframe for CMS to review nominations (i.e., a quarterly basis as opposed to within 30 days of submission) and providing an opportunity for manufacturers to begin the nomination process for potentially eligible devices up to two years prior to receiving FDA marketing authorization. In light of the existing shortcomings of the NCD and CED processes, it remains unclear whether this finalized pathway will provide the needed streamlined access to innovative medical devices that stakeholders, including the ITEM Coalition, has been encouraging CMS to pursue for years. For instance, CMS still anticipates accepting only five TCET candidates annually, which is a disappointment to those who hoped this new pathway would make coverage available for a wide variety of breakthrough devices. **This Final Notice is effective as of August 12, 2024.**

Background

For an item or service to be covered under Medicare, it must be "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under current policies, CMS makes reasonable and necessary coverage decisions

[1] Medicare Program; Transitional Coverage for Emerging Technologies, 89 Fed. Reg. 155 (August 12, 2024), https://www.federalregister.gov/documents/2024/08/12/2024-17603/medicare-program-transitional-coverage-for-emerging-technologies

2 Medicare Program; Transitional Coverage for Emerging Technologies, 88 Fed. Reg. 41,633 (June 27, 2023), https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies.

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through various pathways (e.g., NCDs, local coverage determinations, claim-by-claim adjudication, CED, etc.). CMS recognizes that new approaches are needed to make decisions on certain new items and services, such as medical devices, more quickly to provide Medicare beneficiaries with expedited access to new and innovative medical technologies.

A. Existing CED Pathway

Since 2005, CED has been used to support evidence development for certain innovative technologies that lack sufficient evidence to demonstrate that the item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under the CED pathway, Medicare covers items and services on the condition that they are provided in connection with approved clinical studies or the collection of additional clinical data. This pathway has been subject to considerable criticism, and it has been utilized in recent years with minimal success. Johns Hopkins University Evidence-based Practice Center recently published an analysis of CED, stating:

> A recent review described 27 CED determinations from 2005 to 2022 in 8 therapeutic areas. The duration of these CED activities ranged from 1 to 16 years. Only 4 of these CEDs led to a NCD for continued coverage, and 2 CEDs led to coverage revocation and deferral to local coverage decisions.

B. Medicare Coverage of Innovative Technology Pathway

On November 15, 2021, CMS published a final rule that repealed the final rule ("MCIT Final Rule") establishing the Medicare Coverage of Innovative Technology ("MCIT") coverage pathway that would have generally provided Medicare coverage to FDA authorized Breakthrough Devices for four years starting on the date of FDA market authorization, or a manufacturer chosen date within two years thereafter.[3] The MCIT Final Rule would have also implemented regulatory standards to be used in making reasonable and necessary determinations for Medicare coverage. Although the MCIT Final Rule was widely supported by both the consumer and provider communities, the MCIT Final Rule never became effective and thus was not implemented. A major reason is that the standard for FDA approval is "safety and effectiveness" while the standard for Medicare coverage is "reasonableness and necessity."

CMS stated that it repealed the MCIT Final Rule because the rule could potentially provide Medicare coverage without adequate evidence that the Breakthrough Device would be reasonable and necessary for Medicare patients that have the particular disease or condition that the device was intended to treat or diagnose. CMS' prior policies permitted the Medicare program to deny coverage for particular devices if it was determined that a particular device may be harmful to Medicare beneficiaries. However, under the MCIT Final Rule, CMS would only be able to remove a Breakthrough Device from the MCIT coverage pathway for limited reasons, such as if the FDA issued a safety communication or warning letter regarding the Breakthrough Device or removed the marketing authorization for a device.

[3] Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 86 Fed. Reg. 62,944 (Nov. 15, 2021), https://www.govinfo.gov/content/pkg/FR-2021-11-15/pdf/2021-24916.pdf

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According to CMS, this limitation on its authority was impracticable as it could have led to preventable harm to Medicare beneficiaries and it impeded Medicare's ability to make case-by-case determinations regarding whether a device is reasonable and necessary based on clinical evidence. CMS also pointed to the fact that there is no FDA requirement that Medicare beneficiaries must be included in clinical studies needed for market authorization, lessening the relevance of the evidence base for coverage of the elderly and disabled Medicare population.

TCET Pathway

In recognition that most emerging technologies are likely to have limited or developing bodies of clinical evidence that may not have included the Medicare population, CMS is establishing a new voluntary pathway for Medicare coverage for certain FDA-designated Breakthrough Devices that receive market authorization. This pathway uses current NCD and CED processes to support manufacturers that are interested in working with the agency to generate additional evidence that is appropriate for Medicare beneficiaries. CMS anticipates that many of the NCDs published under the TCET pathway will result in CED decisions.

Currently, the Agency for Healthcare Research and Quality ("AHRQ") reviews all CED NCDs, and it will continue to review all CED NCDs consistent with current practice. It is CMS' goal to finalize a TCET NCD within six months after FDA market authorization. If the evidence supports a favorable coverage decision under CED, coverage will not last indefinitely. Instead, a NCD that requires CED as a condition of coverage will be time-limited to facilitate the generation of sufficient evidence to support a Medicare coverage determination under the reasonable and necessary standard.

A. Appropriate Candidates

As already stated, Medicare coverage under the TCET pathway is limited to certain FDA-designated Breakthrough Devices that receive market authorization. The Breakthrough Devices Program is for medical devices and device-led combination products[4] that meet two criteria. First, the device must provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. Second, the device must satisfy one of the following elements:

> (1) It represents a breakthrough technology;
>
> (2) No approved or cleared alternatives exist;
>
> (3) 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, or establish long-term clinical efficiencies; or

[4] Information on device-led combination products can be accessed here: https://www.fda.gov/media/119958/download.

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(4) The device's availability is in the best interest of patients.[5]

The device must not already be subject to an existing Medicare NCD or otherwise excluded from coverage through law or regulation. Lastly, the FDA-designated Breakthrough Devices must fall within an existing Medicare benefit category. If CMS does not accept a nomination, the agency will offer to virtually meet with the manufacturer to answer any questions and discuss other potential coverage pathways.

B. Procedures for the TCET Pathway

The TCET pathway can be broken down into three stages: (1) premarket; (2) coverage under the TCET pathway; and (3) transition to post-TCET coverage.

1. Premarket

a. Non-Binding Letter of Intent for the TCET Pathway

Manufacturers may submit to CMS a non-binding letter of intent to nominate a potentially eligible device for the TCET pathway approximately 18 to 24 months before anticipated FDA marketing authorization as determined by the manufacturer. The letter of intent to nominate a device for the TCET pathway may be submitted electronically via the Coverage Center Website using the "Contact Us" link at http://www.cms.gov/Medicare/Coverage/InfoExchange/contactus.html. The following information will assist CMS in processing and responding to letters of intent:

- Name of the manufacturer and relevant contact information (name of the contact person, address, email, and telephone number).
- Name of the product.
- Succinct description of the technology and the disease or condition the device is intended to diagnose or treat.
- Date of FDA Breakthrough Device Designation.
- Expected regulatory pathway (for example, PMA, De Novo, 510(k)).
- Expected completion date for pivotal clinical study.

CMS will email the manufacturer to confirm that a submitted letter of intent has been received.

b. Formal Nominations for the TCET Pathway

A manufacturer interested in the TCET pathway may submit a nomination for the TCET pathway electronically via the Coverage Center Website using the "Contact Us" link at http://www.cms.gov/Medicare/Coverage/InfoExchange/contactus.html approximately 12 months prior to the FDA's anticipated decision on the device.[6] Manufacturers should provide the following information to CMS:

- Name of the manufacturer and relevant contact information.

[5] 21 U.S.C. 360e-3(b)(2)
[6] CMS notes that "FDA has agreed to review time goals as part of its device user fee program."

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- 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 (e.g., 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 Premarket Approval application, De Novo request or premarket notification (510(k)) submission, if available, is preferred.
- A brief statement explaining why the device is an appropriate candidate for the TCET pathway.
- A comprehensive list of peer-reviewed, English-language publications that are relevant to 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 specific information to help to facilitate benefit category and coding determinations.
- A statement describing how the medical device addresses the health needs of the Medicare population.
- A brief statement explaining why the device is an appropriate candidate for the TCET pathway.

CMS will contact the manufacturer via email to confirm that a nomination submission is complete and is under review by the agency. CMS intends to review TCET pathway nominations on a quarterly basis (as opposed to the proposed 30 business days timeframe). CMS will email the manufacturer to confirm that a submitted nomination appears to be complete and is under review. This email will include the date that CMS initiated the review of the complete nomination. CMS will contact the manufacturer for supplemental information if the nomination is incomplete.

c. CMS Nomination Cycles and Consideration of Nominations

As previously mentioned, CMS will accept TCET candidates quarterly. If a suitable nomination is not selected in the first review, it will be automatically considered in in the subsequent quarter, and manufacturers will not need to resubmit to be considered in the subsequent quarter. Nominations for Breakthrough Devices anticipated to receive an FDA decision within 6 months may not be accepted since CMS will be unable to reach a final NCD within the expedited timeframes. CMS also notes that it is possible that a nominated device that is not accepted within in the first review may be accepted during a subsequent review even through FDA's decision on market authorization is anticipated within 6 months. If this occurs, CMS will work with the manufacturer to expedite the review as practically achievable.

Once CMS decides to provisionally accept or decline a nomination, CMS will communicate their decision to the manufacturer via email with their designated point of contacts. CMS notes that acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category. When CMS issues the proposed NCD for a Breakthrough Device that has

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received FDA marketing authorization, the proposed NCD will include one or more benefit categories to which CMS has determined the Breakthrough Device falls. CMS will then review and consider public comment on the proposed NCD before reaching a final determination on the benefit coverage decision.

d. Intake Meeting

After the manufacturer submits a TCET nomination, CMS will offer the manufacturer an initial 30-minute meeting within 20 business days of receipt of a complete nomination to review the nomination. In this initial meeting, "the manufacturer is expected to describe the device, its intended application, place of service, a high-level summary of the evidence supporting its use, and the anticipated timeframe for FDA review."

e. Coordination with FDA

CMS representatives will meet with their FDA counterparts to better understand the technology to the extent the agencies have not already done so.

f. Benefit Category Review

After meeting with the FDA, CMS "may initiate a benefit category review if all other pathway criteria have been met." If, prior to the FDA's decision, the device appears to not fall under an existing benefit category, CMS will deny the TCET nomination, and the agency's rationale will be discussed in the denial letter. The agency notes that "[a]cceptance into TCET should not be viewed as a final determination that a device fits within a benefit category." Unfortunately, this means that CMS may ultimately deny coverage for TCET-approved breakthrough devices even if they are adjudged to meet a benefit category upon initial inspection.

g. Evidence Preview

Following acceptance into the TCET pathway, CMS will initiate an Evidence Preview, which "is a systematic literature review that will provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service." The Evidence Preview will be "conducted by a contractor using standardized evidence grading, risk of bias assessment, and applicability assessment according to a protocol initially developed in collaboration with AHRQ in 2020." CMS will ask the manufacturer to share any confidential commercial information ("CCI") included in the nomination submission with the contractor. In general, CMS anticipates that the Evidence Preview will take approximately 12 weeks to complete.

CMS will share the Evidence Preview with AHRQ and FDA to obtain their feedback. In addition, CMS will share the Evidence Preview with the manufacturer and will offer to meet with the manufacturer. During the meeting, manufacturers may propose corrections and raise concerns regarding the Evidence Preview.

After the Evidence Preview is finalized, manufacturers may request a 60-minute virtual or in-person meeting to discuss the strengths and weaknesses of the evidence and the available coverage pathways. At this time, the manufacturer may discontinue with the pathway; however, if the manufacturer decides to continue, the manufacturer will submit a formal NCD letter asking CMS to open a TCET NCD analysis.

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h. Evidence Development Plan

If CMS or AHRQ identifies evidence gaps during the Evidence Preview, the manufacturer should also submit an evidence development plan ("EDP") to CMS. This should be submitted simultaneously with the formal NCD request cover letter. "The EDP may include traditional clinical study designs or fit-for-purpose ("FFP") study designs or both, including those that rely on secondary use of real-world data, provided that those study designs follow all applicable CMS guidance documents."

The agency's goal is to finalize the EDP no later than 90 business days following FDA market authorization. The agency will review the proposed EDP and provide written feedback to the manufacturer within 30 business days. CMS will schedule a meeting with the manufacturer, at which time the "manufacturer should be prepared to demonstrate: (1) a compelling rationale for its evidence development plan; (2) the study design, analysis plan, and data are all fit for purpose; and (3) the study sufficiently addresses threats to internal validity." Manufacturers should also present their study outcomes and performance benchmarks.

Within 60 business days from the date of the EDP meeting, the manufacturer and CMS will have the opportunity to make any adjustments to the EDP. If the manufacturer's EDP is insufficient, CMS may withdraw participation from the TCET pathway.

2. Coverage Under the TCET Pathway

The TCET pathway will follow the NCD statutory timeframes. Manufacturers and CMS may withdraw from this pathway until CMS opens the NCD by posting a tracking sheet. If a device receives FDA marketing authorization, CMS will commence the NCD process by posting a tracking sheet and the non-proprietary elements of the finalized Evidence Preview. This will initiate a 30-day comment period. Following further review and analysis of public comments, "CMS will issue a proposed TCET NCD and EDP within 6 months of opening the NCD." CMS encourages stakeholders to "publicly post on their website any additional feedback, including relevant practice guidelines, within 90 days of CMS' opening of the NCD." The public will have 30 days to submit comments on the proposed TCET NCD and EDP. Within "90 days of the release of the proposed TCET NCD, a "final TCET NCD would be due."

Coverage through the TCET pathway will depend on the EDP. "The review date specified in the EDP will provide one additional year after study completion to allow manufacturers to complete their analysis, draft one or more reports, and submit them for peer-reviewed publication." The agency notes that an unpublished draft that a journal has accepted may be acceptable. CMS generally anticipates that this coverage period may last for "5 or more years as evidence is generated to address evidence gaps identified in the Evidence Preview." However, CMS notes that it retains the right to reconsider a NCD at any point in time.

3. Transition to Post-TCET Coverage

Within six months of the review date in the EDP, CMS intends to conduct an updated evidence review. CMS will engage a third-party contractor to systematically review literature using requirements set forth by CMS and AHRQ. The contractor will conduct a qualitative evidence synthesis and "compare those findings against the benchmarks for each outcome specified in the

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original NCD." CMS will also assess whether the evidence meets the reasonable and necessary standard. To determine whether the conditions of coverage remain appropriate, CMS will review applicable practice guidelines and consensus statements.

When "appropriate," CMS will open an NCD reconsideration and propose 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) MAC discretion to make a local coverage decision.

Standard NCD processes and timelines will continue to apply. After a 30-day public comment period, CMS will have 60 days to finalize the NCD reconsideration.

Analysis of the Final Rule

Given the expansiveness of the earlier—but repealed—iterations of this accelerated coverage system for Breakthrough Devices, this Final Notice has received a muted response as stakeholders digest how the system will function, and whether it will meaningfully achieve the goals of the program. There is little doubt that publication of this Final Notice is a net gain as it adds a new opportunity for Medicare coverage, but demand for coverage of breakthrough technologies may overwhelm this new process. In addition, the track record for CED suggests this Final Notice may be more problematic than CMS suggests, unless significant resources are appropriated to improve and streamline the CED process.

With respect to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) designated as breakthrough technologies, the fact that a benefit category must first be determined before a technology is eligible for consideration under the CED process remains concerning. Many innovations in the DMEPOS space straddle the definitions within the DMEPOS benefit category, and delay in coverage consideration is, therefore, the likely outcome. Finally, CMS' own estimate that only five breakthrough technologies will be subject to this new process annually demonstrates that it may not materially resolve the problem of lengthy delays in coverage of breakthrough devices under the Medicare program.

Major stakeholders have complimented the Biden Administration for pressing forward with publication of the Final Rule, but remain focused and committed to legislative efforts to expand new coverage pathways for breakthrough devices. Traditionally, implementation of regulatory solutions, even if not viewed as particularly effective, delays meaningful consideration in Congress of legislation to address the similar issues. While the Final Rule may further delay legislative efforts while stakeholders and policymakers assess whether this new process meaningfully improves coverage of breakthrough devices, support for further improvements in this area appear to continue growing in Congress and among stakeholders.

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