Viewpoint

The Transitional Coverage for Emerging Technologies Pathway—Enhancing Innovation While Establishing Patient Safeguards

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Last year, the Centers for Medicare & Medicaid Services (CMS) committed to ensuring Medicare patients have better access to emerging technologies and outlined principles that would underpin this approach.1 On June 22, 2023, CMS announced that it was seeking public comments on its Transitional Coverage for Emerging Technologies (TCET) pathway, which we believe is a balanced approach that promotes faster access to new technologies by implementing transparent, predictable, and efficient coverage review processes. Simultaneously, it reduces uncertainty about CMS’s evidence expectations for manufacturers seeking national coverage of emerging technologies, thereby promoting innovation.

As part of a broader coverage modernization initiative, TCET focuses on certain US Food and Drug Administration (FDA) devices designated by the Breakthrough Devices Program.2 This program aims to accelerate the development of new medical devices for patients with life-threatening or irreversibly debilitating diseases or conditions that meet particular criteria. Smaller studies using nontraditional study designs and data analysis methods, surrogate outcomes, and real-world evidence may be used to support market authorization of these devices.3 At the time of FDA market authorization, many devices that use these strategies have important evidence gaps relative to the reasonable and necessary legal standard required for Medicare coverage.4 For coverage decisions, CMS specifically requires evidence of benefit in the Medicare population, which is often older, has more complex medical needs, and is inadequately represented in clinical studies used to obtain FDA market authorization. The TCET pathway will support coverage for promising new technologies as manufacturers develop additional evidence after the devices enter the market. The pathway also includes safeguards that protect Medicare beneficiaries while promoting high-quality care.

The TCET Pathway

When developing TCET, CMS solicited extensive stakeholder feedback.5,6 Stakeholders expressed support for a coverage pathway that is more transparent, predictable, and collaborative. They also asked that it allow fit-for-purpose study designs and that CMS better coordinate benefit category, coding, and payment determinations. To address these needs, CMS has published details of the TCET pathway7 and multiple related components (Table). To reduce the potential risks associated with new technologies, TCET includes safeguards that ensure emerging technologies are provided to clinically appropriate patients and may define clinician experience, support services, and site of service requirements expected to optimize patient outcomes. Furthermore, CMS has allocated additional resources for coverage reviews to facilitate the additional work that will be entailed in the TCET pathway.

Early Premarket Authorization

When developing premarket clinical studies, we believe that manufacturers will be better positioned for multiple product development stages if they anticipate both FDA and CMS requirements. Therefore, we are articulating these evidence expectations so that manufacturers may efficiently demonstrate the appropriateness of their technology for Medicare beneficiaries. As such, CMS intends to publish a series of guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas. The first such example is a review of clinical end points for knee osteoarthritis.8 We have also updated the CMS National Coverage Analysis

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Evidence Review guidance document and Coverage With Evidence Development (CED) study requirements to more clearly allow fit-for-purpose study designs. Fit-for-purpose studies include a study design, analysis plan, and study data that are appropriate for the research question and often rely on real-world data. We expect to publish detailed fit-for-purpose guidance later this year.

Near Market
The TCET pathway may begin as early as 1 year before the anticipated FDA decision on market authorization for eligible devices. The pathway aims to initiate benefit category and coding reviews before market to improve the coordination of these functions. It also includes a focused evidence review (Evidence Preview) that will inform discussions between CMS and manufacturers about the state of the evidence and available coverage options. For technologies with a well-developed evidence base, manufacturers may pursue an accelerated National Coverage Determination (NCD). For others, the review will identify specific evidence gaps that may be addressed through an NCD with CED requirements (CED-NCD) to make the process more collaborative with manufacturers. Where a CED-NCD is expected, CMS encourages manufacturers to promptly develop an Evidence Development Plan that includes clinically meaningful objective success criteria. In many cases, studies that use real-world data, as well as advanced designs and analytic methods, may be sufficient for credible causal inference from observational data.

Early Postmarket
If eligible devices are FDA market-authorized and certain conditions are met, CMS will publish a proposed NCD. Some devices may have strong clinical evidence that applies to the Medicare population, and an NCD can be quickly completed. For devices where the Evidence Preview identified material evidence gaps for coverage purposes, CMS will promptly open an NCD with a defined review date linked to the completion of a CMS-approved Evidence Development Plan. The NCD process will remain open and transparent, and the public will have opportunities to comment. During the CED period, the manufacturer is expected to provide CMS with progress updates on their evidence development and notification of any serious safety concerns.

Postmarket
The TCET pathway represents a substantial advancement in CMS's approach to CED. Furthermore, CMS agrees with stakeholder feedback that CED requirements should not be open-ended and will commit to reviewing the available evidence again after an approved Evidence Development Plan is completed. At the prespecified review date, CMS will systematically review the published evidence

Table. Development Stages, Transitional Coverage for Emerging Technologies (TCET) Pathway Objectives, and CMS Actions

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<th>Development stage</th>
<th>Pathway objective</th>
<th>CMS actions</th>
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| Early premarket authorization     | Set clear expectations for CMS coverage                | • New: CMS Evidence Review guidance document  
• Updated: Coverage with Evidence Development guidance document  
• New: Clinical Endpoints guidance series  
• Forthcoming: Fit-For-Purpose Study guidance document |
| Near market                       | Engage manufacturers early to identify optimal coverage options | • Enhanced CMS-FDA coordination  
• New: Initiate benefit category and coding reviews before FDA market authorization  
• New: Evidence Preview that summarizes the available evidence  
• New: Stakeholder meeting(s) to review Evidence Preview, discuss options |
| Early postmarket                  | Deliver consistent national coverage for technologies with safeguards | • New: With sufficient evidence, expedited NCD  
• New: With material evidence gaps, time-limited CED-NCD that allows fit-for-purpose study designs  
• New: Manufacturer-driven Evidence Development Plan  
• Periodic study progress updates; safety surveillance |
| Postmarket                        | Reduce burden through timely CED-NCD reconsiderations   | • New: NCD reconsideration date specified in CED-NCD  
• New: Streamlined reconsideration process incorporating prespecified objective success criteria |

Abbreviations: CED-NCD, National Coverage Determination with Coverage With Evidence Development requirements; CMS, Centers for Medicare & Medicaid Services; FDA, US Food and Drug Administration; NCD, National Coverage Determination.
against the agreed objective success criteria in the CED-NCD. Then, CMS will expedite the NCD reconsideration consistent with statutory requirements, and the public will have an opportunity to comment on the proposed decision. After transitional coverage, TCET devices may have coverage at the national level, as appropriate.

Conclusions

In summary, CMS remains committed to modernizing its coverage pathways to deliver efficient, predictable, and transparent coverage of emerging medical technologies. We are equally committed to covering devices based on scientifically sound clinical evidence and with appropriate safeguards. The TCET pathway aims to accelerate national coverage where the evidence supports it but may offer transitional coverage for technologies that do not yet satisfy the reasonable and necessary standard when they first enter the market. By defining objective success criteria and dates for review in advance, CMS aims to increase predictability while reducing the burden of evidence development.