FDA and CMS Coordinate to Streamline Medicare Coverage for Certain New Medical Devices

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PROFESSIONAL

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Last week, the Food & Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) announced the creation of the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway, a new initiative intended to synchronize the two agencies' respective market authorization and Medicare coverage approval processes. This new pathway could mean that device innovators are able to obtain Medicare National Coverage Determinations as early as two months after FDA authorization—a substantial acceleration to the timeline that can reach a year or more under the current paradigm. By speeding up this process, regulators anticipate that RAPID will facilitate timely access to newly approved medical devices for Medicare beneficiaries.

Eligible Devices

Only certain Class II (moderate to high risk criteria) and Class III (high risk) Breakthrough Devices will be eligible for the RAPID coverage pathway. The Breakthrough Device designation, an existing program already intended to speed up device approval timelines, includes products that are determined to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions. To participate in the RAPID pathway, qualifying Class II and Class III Breakthrough Devices must also: (1) in the case of a Class II device, participate in the FDA's Total Product Life Cycle Advisory Program (TAP), a voluntary pilot program intended to facilitate early engagement between regulators, manufacturers, and other key parties, (2) address unmet medical needs among Medicare beneficiaries, and (3) be the subject of an Investigational Device Exemption (IDE) study that enrolls Medicare beneficiaries.

NCD Process

Historically, companies have experienced a lag between the FDA market authorization and the CMS National Coverage Determination (NCD) process. Although NCDs are not a prerequisite to Medicare coverage, an NCD establishes consistent national coverage criteria. Medicare's NCD process typically proceeds subsequent to FDA authorization. The lag between the two processes can be due, at least in part, to sponsors' lack of awareness that different clinical evidence may be needed for each, independent process. Innovators may not learn, until after they obtain FDA market authorization, that the evidence they have collected to demonstrate that the product is safe and effective for FDA approval is insufficient to demonstrate that the same product is reasonable and necessary for Medicare beneficiaries to obtain NCD coverage—prompting more research and further

delays.

The RAPID pathway is intended to facilitate better coordination between FDA and CMS in two ways. First, the two process timelines will be better aligned: CMS will issue a proposed NCD the same day that the device receives FDA market authorization, triggering the 30-day public comment period. And second, CMS will engage with device sponsors during the premarket review process, advising them on the clinical outcomes most relevant for the NCD process. That way, sponsors may be able to use evidence generated for FDA review to better support Medicare national coverage determinations.

Takeaways

Getting a device to market and obtaining Medicare coverage can be thought of as two distinct, disparate processes, but they are both critical to the success of a new product. Instead of focusing on each process in succession, the RAPID pathway may help device sponsors to strategize obtaining the premarket evidence necessary for FDA approval and an NCD concurrently. Regulators anticipate that this cross-agency coordination and the opportunities for earlier engagement with regulators in both agencies will improve predictability and efficiency for sponsors throughout the device development lifecycle and, ultimately, speed up access to new technology for Medicare beneficiaries.

There are many open questions about implementation, however, including how both agencies will adapt to this additional workload. HLB will track additional information as it becomes available, including monitoring risks for sponsors not apparent from the agencies' press release and evaluating how the RAPID pathway will differ in practice from existing pathways, like the Transitional Coverage for Emerging Technologies (TCET) Pathway.

The RAPID pathway will not go into effect immediately. In the near term, CMS will issue a Federal Register notice describing the proposed RAPID coverage pathway. A public comment period on that proposed procedural notice will open for 60 days, and device sponsors should consider providing comment on the proposal to CMS during that window. Potential candidates for the RAPID pathway should also review CMS' notice to begin considering how to demonstrate eligibility for the initiative's requirements. Importantly, the TCET Pathway will not be available to new candidates, at least temporarily, as RAPID is rolled out; innovators who were planning to use that pathway should consider their candidacy for the RAPID pathway in the alternative.

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