CAPITOL STREET

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Voluntary TCET Pathway: Extension of CED

No Automatic CMS Coverage for MedTech, Diagnostic Tests Excluded

Relevant Companies

Today, the Center for Medicare & Medicaid Services released their procedural notice for transitional coverage for emerging technologies (TCET) pathway which provides CMS coverage for new medical technologies. Link Here.

⋙ Our Take & Next Up

This is less positive for large companies and better for smaller device companies, but unhelpful for digital therapeutics that may not easily fit into a benefit category. The proposal is in in line with our preview: a voluntary, CED-type process by CMS for Breakthrough-only devices (not diagnostic tests). This is not economically significant and a far cry from 'automatic coverage' supported by AdvaMed and other companies over the last 3-4 years. Stakeholders (manufacturers, trade associations like AdvaMed) have 60 days to comment on the notice. A final notice will be released after the comment period. CMS is also seeking public comment on whether similar devices to the Breakthrough Device should be addressed under a separate NCD or should be subject to the same coverage conditions.

⋙ Key Points

The proposal is formatted as a procedural notice rather than rulemaking and is not economically significant. TCET will leverage the existing National Coverage Determination (NCD) pathway (specifically the Coverage with Evidence Development mechanism) to provide coverage for emerging technologies. CMS expects most TCET NCDs to result in CEDs.

Medical device coverage will likely be mainly provided for those in clinical trials or in patient registries. This falls far flat of the previous Medicare Coverage of Innovative Technologies (MCIT) pathway which would have provided expedited Medicare coverage for up to four years for certain “breakthrough” devices after FDA approval.

Only Breakthrough Devices will qualify for TCET, with a limit of 5 per year. CMS lists appropriate candidates as devices that are Breakthrough Devices, determined to be within a Medicare benefit category, not already the subject of an existing Medicare NCD, and not otherwise excluded from coverage through law or regulation.

Diagnostic lab tests will not qualify for TCET. CMS notes that diagnostic review is delegated to Medicare Administrative Contractors (MACs) who make local coverage determinations. CMS expects this to continue as a majority of coverage determinations for breakthrough diagnostic tests will continue to be determined by the MACs.

Devices will have to undergo an Evidence Preview (literature review), and an Evidence Development Plan (EDP) will have to be approved for a TCET NCD. An Evidence Preview, a focused literature review, will provide early feedback on the strengths and weaknesses of the available evidence, including any evidence gaps, for a specific item or service. An Evidence Development Plan (EDP) will be developed by the manufacturer to address any evidence gaps identified in the Evidence Preview. EDPs may include traditional clinical study designs and/or fit-for-purpose study designs, including those that rely on secondary use of real-world data.

Manufacturers may self-nominate to participate in the TCET pathway on a voluntary basis. Manufacturers must submit TCET pathway nominations to CMS 12 months prior to an FDA decision. CMS’ goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after FDA market authorization. If a manufacturer is granted a TCET NCD, the coverage is expected to last for 3-5 years or as needed for evidence generation.

Ipsita Smolinski

Managing Director | Capitol Street

ipsita@capitol-street.com

900 19th Street, NW 6th Fl
Washington DC 20006

202.250.3741

www.capitol-street.com
