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CMS Advances Plans for Developing Early Coverage for Innovative Devices

Transitional Coverage for Emerging Technologies

Recent announcements by CMS points to potential resumption of the agency's plan to provide expedited coverage for certain eligible products that have been designated by the FDA as "Breakthrough Devices."
Replacing the prior proposed MCIT program that was withdrawn by CMS in 2021 before activating it, CMS has recently published a draft of a new program called The Transitional Coverage for Emerging Technologies (TCET).

The TCET pathway is intended to accelerate access to medical products intended to serve Medicare beneficiaries by enabling manufacturers of Breakthrough Designated devices to evaluate with CMS coverage possibilities *while* working to obtain FDA market approval. CMS' goal is to finalize coverage policies for technologies in the TCET pathway within 6 months of FDA market authorization.

The TCET will be an addition rather than a replacement of existing CMS programs, such as the Coverage with Evidence Development (CED) pathway and the Parallel Review.

Coverage with Evidence Development (CED)

CED allows Medicare to cover items and services that have promising clinical evidence, but not enough to meet coverage standards. Under CED, Medicare beneficiaries can participate in clinical trials to help generate more evidence.

CMS has issued a proposed guidance document concerning the CED program.

National Coverage Analysis (NCA)

CMS evaluates clinical evidence to determine if an item or service falling within a benefit category meets the statutory 'reasonable and necessary' criteria.

A proposed NCA evidence review guidance document provides a framework for more predictable and transparent evidence development. Among the considerations applied by CMS - the quality of studies and strength of the clinical evidence, patient selection criteria, whether the comparison group received treatment that reflects current practice, relevancy of the findings to Medicare beneficiaries, etc.

Boston MedTech Advisors can assist manufacturers of medical technologies and their investors to address relevant issues associated with the current initiatives of the FDA and CMS, such as:

- Can your product meet the criteria for a Breakthrough device?
- When to start discussions with CMS regarding coverage?
- What is the optimal strategy for developing coverage for a new product following FDA approval?
- How can Breakthrough Designation by the FDA and CMS TCET programs affect the company's go-to-market plans?
- How to develop the appropriate clinical evidence to meet CMS criteria for TECET, CED, and other coverage criteria?

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About Boston MedTech Advisors

Boston MedTech Advisors assists medical technology companies and healthcare providers to achieve their business goals by offering ethical, result-oriented, professional and cost effective advice and services.

- Market Analysis and Business Strategy
- Business Development
- Regulatory Affairs and Clinical Trial Management
- Reimbursement and Contracting Strategies
- Financing Support
- Other Services

Boston MedTech Advisors provides practical business services to:

- Established and growing medical technology companies
- Healthcare providers
- Startups and entrepreneurs
- Private and institutional investors

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You can also contact us by phone at 781-407-0900, or email
info@bmtadvisors.com

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