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Alert | Health Care & FDA Practice

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CMS Releases Highly Anticipated Medicare 'Breakthrough' Coverage Final Rule

On Jan. 14, 2021, the Centers for Medicare & Medicaid Services (CMS) published a final rule creating a new Medicare coverage and reimbursement pathway for "breakthrough" medical devices. Known as the Medicare Coverage of Innovative Technology (MCIT) pathway, this coverage mechanism provides national Medicare coverage for a period of four years after the date of FDA approval. The final rule is effective March 1, 2021.

Historically, national and local coverage determinations (NCDs and LCDs) have struggled to keep pace with innovation in the medical device industry. Because no regulations have ever codified the definition of "reasonable and necessary," medical device coverage determinations are typically left to the discretion of Medicare administrative contractors (MACs) tasked with applying NCDs and LCDs on an individual, case-by-case basis. Individual coverage determinations like these do not establish "agency [coverage] policies for future claims," let alone coverage determinations beyond the MAC's designated jurisdiction. Even those devices previously designated by the FDA as "breakthrough" devices were coverable at the individual MAC's discretion only.

Furthermore, the administrative burden necessary to create an NCD or an LCD, or even modifying their terms, may take 9-12 months (or longer). Device manufacturers also frequently face a period of coverage uncertainty between the point of FDA market authorization and the point at which CMS finalizes an NCD (or a MAC finalizes an LCD). For hospitals operating under a bundled payment system (e.g., IPPS DRG)

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utilize breakthrough devices, a separate coverage policy for each item or service is not always available, which may cause coverage and payment inconsistencies.

Derived from Executive Order 13890 (EO 13890) entitled "Protecting and Improving Medicare for Our Nation's Seniors, the MCIT pathway is designed to provide some measure of administrative relief for new and innovative breakthrough devices.

KEY TAKEAWAYS

A. The final rule codifies the definition of "reasonable and necessary."

The definition is taken from Chapter 13 of the Medicare Program Integrity Manual (PIM), which states that an item or service is considered "reasonable and necessary" if it is:

1. Safe and effective;
2. Not experimental or investigational; and
3. Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service in terms of whether it is:
    a. Furnished in accordance with the accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    b. Furnished in a setting appropriate to the patient's medical needs and condition;
    c. Ordered and furnished by qualified personnel;
    d. One that meets, but does not exceed, the patient's medical need; and
    e. At least as beneficial as an existing and available medically appropriate alternative.

B. The final rule establishes a four-Year Medicare coverage pathway: the MCIT.

Under the MCIT pathway, *national* Medicare coverage for a period of up to four years would begin immediately and upon the date the medical device received Premarket Approval (PMA); 510(k) clearance, or a De Novo classification. In addition, the MCIT pathway only applies to medical devices that fit within statutorily defined benefit categories (e.g., surgical dressings),[1] and the final rule explains that participating manufacturers should submit an NCD request during the third year of MCIT to allow for sufficient time for NCD development. Finally, CMS may terminate MCIT coverage if the FDA issues a medical device safety communication or warning letter, or if the FDA revokes market authorization for a device.

[1] For example, medical equipment for *home use* by the beneficiary must be "durable," that is, able to withstand repeated use.

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C. **The MCIT pathway only applies to "breakthrough" medical devices designated as such under the FDA's Breakthrough Devices Program.**

"Breakthrough" designation by the FDA is set forth under section 3051 of the 21st Century Cures Act (21 U.S.C. § 360e-3), which states that medical devices and device-led combination products must meet two criteria:

1. The device must provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

2. The device must satisfy one of the following elements:

    a. It represents a breakthrough technology;

    b. No approved or cleared alternatives exist;

    c. It offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or

    d. Device availability is in the best interests of patients.

Under the MCIT pathway, the breakthrough device may only be used for the device's FDA-approved or cleared indication(s), that is, the FDA "label" or "indication." So-called "off-label" uses are not coverable through MCIT.

D. **The MCIT pathway is *not* CMS/FDA "parallel review."**

The parallel review process is a program in which FDA and CMS simultaneously review clinical data to help decrease the time between FDA's approval of a premarket application or granting of a de novo classification, and a subsequent NCD. Parallel review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial within the FDA pre-submission process; and (2) FDA and CMS concurrently review ("in parallel") the clinical trial results submitted in the PMA, or de novo request. FDA and CMS then independently review the data to determine whether it meets their respective agency standards and communicate with the manufacturer during their respective reviews. Parallel review is most successful for devices with a significant amount of clinical evidence.

By contrast, breakthrough device manufacturers are not obligated or mandated by CMS to conduct clinical studies during MCIT coverage. Manufacturers are simply encouraged to develop the clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends. Furthermore, the final rule states that candidates for parallel review are not appropriate for simultaneous MCIT consideration.

E. **Coverage for ancillary items and services.**

MCIT would cover both the breakthrough device and the implantation of the device. Other items and services for the diagnosis and treatment of the patient's illness would be recoverable as usual through existing coverage regulations and policies or when determined to be reasonable of the local MACs in the claims appeals process. There are existing Medicare coverage and payment policies that also potentially apply to other items and services that may be used for treatment during hospitalizations and complications arising from the device treatment in subsequent hospitalizations.

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F. **The final rule does *not* establish codes or payment amounts.**

Although the final rule establishes a Medicare coverage pathway, it does not address coding or payment matters. Breakthrough device manufacturers must still obtain the appropriate code(s) for the device and obtain a reimbursement/payment level.

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