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Medicare Expands Coverage of "Breakthrough" Medical Devices and Codifies "Reasonable and Necessary" Standard

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On January 14, 2021, the Centers for Medicare and Medicaid Services ("CMS") published a final rule that significantly alters the Medicare reimbursement landscape for medical devices approved under the Food and Drug Administration's ("FDA") "Breakthrough Devices Program."[1] The rule, which represents the culmination of years of advocacy by the medical device industry and patient and provider interest groups, finalizes a September 1, 2020 proposed rule that aimed to address the substantial time lag between FDA authorization of medical devices and Medicare coverage of the same. Specifically, the rule establishes a Medicare Coverage of Innovative Technology ("MCIT") pathway for Medicare coverage of Breakthrough Devices and related medical procedures during a four-year period that begins immediately upon FDA marketing authorization. The final rule also codifies the definition of the "reasonable and necessary" standard that is used to determine when other items and services (and MCIT devices after the four-year period) may be covered by the Medicare program. The new rule becomes effective March 15, 2021.

This Alert summarizes key provisions of the final rule. Ropes & Gray's analysis of the September 1, 2020 proposed rule can be found here.

Medicare Coverage of Breakthrough Devices under the Final Rule

The FDA's Breakthrough Devices Program is a voluntary program to expedite access to certain medical devices and device-led combination products. To qualify for designation as a Breakthrough Device, a device must provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and (1) represent a "breakthrough technology," (2) have no FDA-approved or cleared alternative, (3) offer "significant advantages over existing approved or cleared alternatives," or (4) be of such a nature that the "availability [of the device] is in the best interest of patients," as determined by FDA.[2] Devices subject to premarket approval applications, premarket notification or requests for De Novo classification are eligible for Breakthrough Device designation so long as they meet these eligibility criteria. Manufacturers of products designated as Breakthrough Devices enjoy certain benefits intended to expedite the development and availability of such products, including "sprint discussions" with FDA to reach agreement on specific product development topics, coordination with FDA on a Data Development Plan to help ensure predictable, transparent, and timely devices assessment and review, interactive Clinical Protocol Agreements with FDA, and regular updates from FDA on product review status.

The Existing Framework for Coverage of Breakthrough Devices

Under the existing framework, FDA Premarket Approval (PMA), 510(k) clearance, or granting of a De Novo classification request ("FDA marketing authorization") of a Breakthrough Device does not automatically lead to Medicare coverage. Rather, after FDA marketing authorization is obtained, medical device manufacturers must separately seek coverage through a National Coverage Determination ("NCD") issued by CMS, or, more commonly, through a Local Coverage Determination ("LCD") by a Medicare Administrative Contractor ("MAC").[3] These determinations are made after a lengthy and thorough evidence-based review process with opportunities for public input, and LCDs can result in varying Medicare coverage in different geographical areas. Citing significant delays in both patient access to devices that have been deemed suitable for marketing by FDA and recoupment of R&D investment by manufacturers, medical device manufacturers and provider and patient interest groups have long sought to find a quicker way to arrive at Medicare coverage.

The New MCIT Pathway

The final rule streamlines Medicare coverage of Breakthrough Devices by establishing a new MCIT pathway for national coverage. Under the MCIT pathway, devices that receive Breakthrough Device designation are presumed to be covered

by Medicare for four years following FDA marketing authorization, unless CMS determines that the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute. Medicare coverage under the MCIT pathway includes both coverage of the device itself and coverage of reasonable and necessary items and services to implant, use, maintain or treat complications arising from use of the device. Manufacturers that wish to receive an NCD after the four-year period of MCIT coverage are encouraged to submit a NCD request during the third year of MCIT coverage eligibility.

The MCIT pathway will be available to medical devices that receive or have received Breakthrough Device designation from FDA on or after March 15, 2019. Participation in the MCIT pathway is voluntary—medical device manufacturers may opt into the MCIT pathway at any time within two years following the date of FDA marketing authorization, with coverage beginning on the date of opt-in.[4] Coverage under the MCIT pathway is available for a maximum of four years beginning on the date of FDA marketing authorization. For example, a manufacturer opting into MCIT coverage one year after marketing authorization would enjoy MCIT coverage for three years. MCIT-eligible devices that received Breakthrough Device designation before the effective date of the final rule (March 15, 2021) will be eligible for Medicare reimbursement only for dates of service on or after the effective date of the rule. Recognizing that FDA will not have reviewed any potential off-label uses of a Breakthrough Device, Medicare coverage of Breakthrough Devices under the MCIT pathway only extends to uses that are consistent with a device's FDA-approved or -cleared indication for use.

In order to receive reimbursement under the MCIT pathway, medical device manufacturers must notify CMS of such participation. Manufacturers should attempt to notify CMS via email within two weeks of receiving Breakthrough Device designation from FDA, but manufacturers may provide notice shortly before, upon, or after the date of FDA marketing submission. Once a manufacturer has indicated its desire to utilize the MCIT pathway, CMS will coordinate with FDA and the manufacturer regarding the necessary steps for MCIT participation. During a device's four years of MCIT coverage, manufacturers are encouraged, but not required, to further develop the clinical evidence basis on which FDA granted the marketing authorization. While the final rule does not impose any obligation on manufacturers to conduct post-market clinical studies, manufacturers may be required to collect additional data as a condition of continued FDA marketing authorization.

CMS will publish the devices approved for the MCIT pathway on the CMS website so that all patients, providers, and other stakeholders may be aware of what devices are covered through the MCIT pathway.

Defining "Reasonable and Necessary"

Apart from the new MCIT pathway, the Final Rule also codifies long-standing sub-regulatory guidance as to when items and services that are not covered during the 4-year MCIT approval period will be deemed eligible for Medicare coverage. One of the Medicare coverage limitations imposed under Section 1862(a) of the Social Security Act (the "Act") is that items and services may not be covered if they are not "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.[5] Historically, neither the Act nor CMS regulations officially defined the phrase. Rather, "reasonable and necessary" was defined in Chapter 13 of the Medicare Program Integrity Manual. The final rule codifies the long-standing definition of "reasonable and necessary" articulated in the Manual.

Under the final rule, an item or service is "reasonable and necessary" if it is:

1. Safe and effective;

2. Not experimental or investigational; and

3. Appropriate, 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 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.

In the September 1, 2020 proposed rule, CMS proposed to establish an alternative to the appropriateness criteria enumerated in (3), whereby an item or service that did not otherwise meet the appropriateness criteria enumerated in (3) would, nonetheless, be covered if commercial health insurers commonly covered the device. In the final rule, CMS declined to codify this proposal and instead committed to explaining in national or local coverage determinations the reason for any coverage denials that deviate from what is commonly covered by commercial insurers.[6] CMS stated that coverage of an item or service by a majority of commercial insurers would be relevant to assessment of the item's or service's appropriateness under the "reasonable and necessary" standards, and that CMS will promulgate sub-regulatory guidance within the next 12 months that details how coverage of an item or service by commercial insurers may influence Medicare coverage determinations. CMS also clarified that Breakthrough Devices are considered "reasonable and necessary" during the four-year period of MCIT eligibility by virtue of meeting the unique criteria of FDA Breakthrough Devices Program.[7]

If you have any questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. 86 Fed. Reg. 2987 (Jan. 14, 2021). The new rule will be codified at 42 C.F.R. Part 405.
2. *Breakthrough Devices Program*, U.S. Food & Drug Admin. (May 16, 2019), *accessible at* https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.
3. *Medicare Coverage Determination Process*, CMS.gov (March 27, 2020), *accessible at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess.
4. Note that the rule does not contain a mechanism for providers to petition for coverage under the MCIT pathway. Given the strong incentive for medical device manufacturers to utilize the pathway, however, this detail may not be of practical consequence.
5. 42 U.S.C. § 1395u(a)(1)(A).
6. 86 Fed. Reg. 2987, 2995 (Jan. 14, 2021).
7. 86 Fed. Reg. 2987, 2997 (Jan. 14, 2021).