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CMS Reverses Course on Medicare Coverage of "Breakthrough" Medical Devices

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On September 15, 2021, the Centers for Medicare and Medicaid Services ("CMS") published a proposed rule[1] that would repeal the Medicare Coverage of Innovative Technology final rule ("MCIT final rule"),[2] which was published on January 14, 2021 and is scheduled to become effective on December 15, 2021. CMS established the MCIT final rule to provide Medicare beneficiaries with faster access to FDA-designated "Breakthrough Devices"—devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Specifically, the MCIT final rule provided national Medicare coverage of Breakthrough Devices for four years starting on the date of FDA marketing authorization or a select date up to two years after the market authorization date as requested by the device manufacturer. Additionally, the MCIT final rule would codify CMS's longstanding interpretation of the "reasonable and necessary" standard used to determine which items and services are covered under Medicare.

The MCIT final rule originally was planned to become effective on March 15, 2021. However, in response to a memorandum from the Assistant to the President and Chief of Staff titled "Regulatory Freeze Pending Review"[3] and concerns raised by public comments, CMS decided it was in the best interest of Medicare beneficiaries to delay the effectiveness of the MCIT final rule until December 15, 2021.[4] The new proposed rule, if finalized, would repeal the MCIT final rule altogether.

This Alert summarizes CMS's rationale for proposing to repeal the MCIT final rule and its future plans for addressing access to innovative medical devices.

Ropes and Gray's analysis of the MCIT final rule can be found here.

Rationale for the Proposed Repeal

CMS has proposed the repeal of the MCIT final rule because, after further consideration of the public comments, it concluded that the rule was not in the best interest of Medicare beneficiaries. CMS now states that the MCIT rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment *for the Medicare patients that have the disease or condition that the device is intended to treat or diagnose*. Thus, CMS does not believe the MCIT final rule is the best method of achieving the rule's intended goals of more precisely meeting the needs of Medicare beneficiaries and other stakeholders in a timely manner. Rather, CMS suggests that better utilizing existing pathways or conducting future rulemaking could be more effective than the MCIT final rule as currently drafted. To explain its acknowledged change of position, CMS offered the following rationale:

1. Differences in CMS and FDA Evidentiary Standards

After considering public comments, CMS no longer agrees that FDA safety and effectiveness standards alone are adequate to support open-ended Medicare coverage because FDA and CMS do not have synonymous standards. CMS concluded that the MCIT final rule would have provided Medicare coverage without sufficient evidence to demonstrate the Breakthrough Device was a "reasonable and necessary" treatment for addressing additional risks often found in Medicare patients. Specifically, FDA may grant a device breakthrough designation when there is a "reasonable expectation" that a device could provide for more effective treatment or diagnosis relative to the current standard of care in the U.S, and that evidence could be "supported by literature or preliminary data (bench, animal, or clinical)."[5] As interpreted by CMS in the proposed rule, this is in contrast to the Medicare statute, under which CMS considers whether a device is reasonable and necessary for the Medicare population specifically. The Medicare population is typically older and often has a higher rate of comorbidities, which generally require more frequent treatment and a higher degree of clinical oversight than the general U.S. population, and these additional considerations are generally not addressed in the early device development process. In particular, CMS states, Medicare beneficiaries are often underrepresented or not

represented in many clinical studies. Accordingly, CMS intends to require manufacturers who wish to participate in future innovative coverage pathways, such as MCIT, to produce evidence that demonstrates the health benefits of the device and related services for patients with demographics similar to that of the Medicare population.

2. Limitations of the MCIT Pathway

CMS also agreed with public commenters that using the MCIT pathway could give specific technologies an unfair advantage that would be unavailable to subsequent market entrants, which would decrease market competition and innovation. To be designated under the FDA Breakthrough Devices Program, a medical device must satisfy one of the following elements:

- It represents a breakthrough technology;
- No approved or cleared alternatives exist;
- It offers significant advantages over existing approved or cleared alternatives; or
- Device availability is in the best interest of patients.[6]

Instead of limiting coverage through the MCIT pathway only to those devices that FDA designates as Breakthrough Devices, CMS would prefer a more flexible coverage pathway that neither creates an unfair disadvantage against subsequent devices nor disincentivizes innovation.

Effect of the Repeal: Maintaining the Status Quo

Because the effective date of the MCIT final rule had already been postponed until December 2021, if the proposal to repeal is finalized before that date (or if CMS postpones the effective date still further), the rule's revisions to part 405 of Title 42 of the Code of Federal Regulations would not take effect and the current text would remain unchanged. Specifically, a definition of "reasonable and necessary" would not be included among the defined terms, and Subpart F, which wholly consisted of the MCIT program provisions, would not be added.

Status Quo: MCIT pathway

If the MCIT Final Rule does not become effective, the current framework would continue. Under the current framework, FDA Premarket Approval, 510(k) clearance, or granting of a De Novo classification request for a Breakthrough Device does not automatically lead to Medicare coverage. Instead, after FDA marketing authorization is obtained, providers seeking Medicare reimbursement for use of the device in patient diagnosis or treatment must still show the device is "reasonable and necessary" for the diagnosis or treatment of an illness or injury by seeking coverage through either a National Coverage Determination ("NCD") issued by CMS or through a Local Coverage Determination ("LCD") by a Medicare Administrative Contractor.[7] These determinations are made after a thorough evidence-based review process with opportunities for public input, and it is therefore often quite some time after FDA authorization that Medicare coverage of Breakthrough Devices becomes available.

As a result, unless the relatively uncommon NCD route is followed, LCDs may result in varying Medicare coverage in different geographical areas. In addition, the lengthy process prevents Medicare beneficiaries from quickly accessing breakthrough devices, and slows the process by which medical device manufacturers can recover their development costs through sale of the device.

Current Standard: Reasonable & Necessary

As mentioned above, Section 1862(a)(1)(A) of the Social Security Act excludes items and services from Medicare coverage that 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.[8] However, neither the Act nor CMS regulations officially define the phrase. The MCIT final rule intended to formally codify the long-used definition found in Chapter 13 of the Medicare Program Integrity Manual. Under the Manual, an item or service is reasonable and necessary if it is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - 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;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.[9]

Although the proposal to repeal the MCIT final rule also entails removing the codification of the standard, CMS is actively inviting comments for how the term should be codified in the future.

Invitation to Comment on the Proposed Rule

CMS seeks comment on a number of issues, including, among others, on:

- The proposal to repeal the MCIT final rule generally.
- Whether the proposal should fully repeal the reasonable and necessary term or only modify it.
- Which criteria should be considered if reasonable and necessary were defined in a future rule.

In addition, CMS states that it is considering future policies and potential rulemaking to provide improved access to innovative and beneficial technologies and is "committed to exploring other policy options and statutory authorities" to achieve these goals. Consequently, the comment period on the proposed rule may represent a useful opportunity to propose policy options to the agency.

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Comments on the Proposed rule must be submitted by October 15, 2021. If you have any questions, please contact one of the authors or your usual Ropes & Gray advisor.

1. 86 Fed. Reg. 51326 (Sep. 15, 2021).
2. 86 Fed. Reg. 2987 (Jan. 14, 2021).
3. 86 Fed. Reg. 7424 (Jan. 28, 2021).
4. 86 Fed. Reg. 26849 (May 18, 2021).
5. *Breakthrough Devices Program*, U.S. Food & Drug Admin. (Jan. 5, 2021), *accessible at* https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.
6. *Id.*
7. *Medicare Coverage Determination Process,* CMS.gov (Feb. 23, 2021), *accessible at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess.
8. 42 U.S.C. § 1395u(a)(1)(A).
9. Medicare Program Integrity Manual Chapter 13 – Local Coverage Determinations, U.S. Dept. of Health and Human Services (Jul. 8, 2020), *accessible at* https://www.hhs.gov/guidance/document/medicare-program-integrity-manual-chapter-13-local-coverage-determinations-0.