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CLIENT ALERT

CMS Proposes to Expand the Scope of Medicare Coverage Determinations

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On September 1, 2020, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule that would, for the first time, establish formal criteria to define the "reasonable and necessary" standard for Medicare coverage, and would make Medicare coverage available immediately for medical devices deemed to be breakthrough devices by the Food and Drug Administration ("FDA").[1] If the proposed rule becomes final, it would be a significant expansion of the scope of Medicare coverage. CMS has solicited comments on several important aspects of the proposal, and interested parties should submit comments to CMS by **November 2, 2020.**

Defining the "Reasonable and Necessary" Standard for Medicare Coverage

Since its inception in 1965, the Medicare program has covered those items and services deemed to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[2] However, that phrase was never defined in any statute or regulation; this gave CMS and Medicare Administrative Contractors ("MACs") wide discretion, but often left health care providers, suppliers, and manufacturers to guess about the availability of Medicare coverage. The proposed rule would not establish a bright-line test for Medicare coverage; instead, it would adopt the criteria currently in the Medicare Program Integrity Manual, which is an interpretive guideline for MACs.[3] While this provides a degree of clarity, CMS and the MACs retain a large measure of discretion. In order to meet the "reasonable and necessary" threshold, an item or service must meet the following three criteria:

- It must be safe and effective.
- It cannot be considered experimental or investigational, except for those medical devices for which Medicare coverage is currently available.

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[1] 85 Fed. Reg. 54327 (Sept. 1, 2020).
[2] 42 U.S.C. § 1395y(a)(1)(A).
[3] Medicare Program Integrity Manual, § 13.5.4, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

- It is appropriate for Medicare patients, which requires satisfying five factors:
    - It is furnished in accordance with accepted standards of medical practice.
    - It is furnished in an appropriate setting.
    - It is ordered and furnished by qualified medical personnel.
    - It meets and does not exceed the patient's medical needs.
    - It is "at least as beneficial as an existing and available medically appropriate alternative."

The proposed rule would add an alternate to the third criterion that is entirely new. Instead of demonstrating the five appropriateness factors, Medicare coverage would be available if the item or service is "covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant." This new criterion could make it easier for manufacturers and other stakeholders to obtain Medicare coverage; in the past, CMS and MACs have been reluctant to give significant weight to coverage decisions and medical policies adopted by commercial health plans.

CMS has solicited comments on several aspects of this proposal to determine how broad a final rule may be. For example, CMS noted that coverage might be possible based on a single commercial policy, but also indicated that it was considering a final rule that would require a showing that more plans covered the item or service. Similarly, CMS solicited comments on whether the Medicare program should incorporate limitations on coverage adopted by commercial plans.

A potential significant flaw in the proposed criteria that should provoke comments is the requirement that an item be "safe and effective." It is unclear if CMS intended to require that the item be determined "safe and effective" under the FDA's standards. This would be problematic for those items and services that are outside of the FDA's jurisdiction or are authorized for use by the FDA under an alternative standard, such as through the emergency use authorization process or its expanded access program. In addition, any final rule that incorporates the FDA standard as a prerequisite to coverage may conflict with the current Medicare regulations that cover certain medical devices used in investigational device trials that are intended to evaluate safety and efficacy.[4]

Another important aspect of this proposal are material terms that are left undefined or not clarified and that can be addressed through the comment process. CMS failed to address the requirement that the item or service not be "experimental or investigational"; this phrase was not defined or explained any further, even though there are instances in which a claim is denied on that ground even when the item or service is not furnished as part of a formal clinical trial. Similarly, CMS offered no clarification of

[4] 42 C.F.R. §§ 405.201 – 405.215.

the standard(s) it might use to determine that there is sufficient clinical evidence to conclude that the Medicare population is distinct from the population covered by a commercial plan (or plans) that might warrant disregarding the plan's (or plans') medical policies.

Expediting Medicare Coverage for Breakthrough Devices

The 21st Century Cures Act ("Act")**,** which was signed into law in December 2016**,** authorized the FDA to expedite the marketing approval for innovative medical devices that are unique and that "offer significant advantages over existing approved or cleared alternatives."[5] To date, approximately 300 devices have received marketing approval under this program. Although the FDA was granted this authority to accelerate the authorization process, the Act did not include a companion provision for Medicare coverage. This created a problem for Medicare beneficiaries and clinicians who wanted access to these new technologies: although the FDA might complete its review quickly, access would be delayed because either CMS or a MAC would still follow its procedures for making coverage determinations, which could take up to a year or more.

The proposed rule would align Medicare coverage with the FDA's designation of a medical device as a breakthrough device, and would make coverage effective with the date of the FDA's market authorization.[6] The proposed rule establishes a new voluntary program called the Medicare Coverage of Innovative Technology ("MCIT") program. This program applies only to medical devices that (1) have been designated by the FDA as "breakthrough devices," as defined in the Food, Drug, and Cosmetic Act; (2) fit within an existing Medicare benefit category; (3) are not addressed in a Medicare national coverage determination; and (4) are not excluded from Medicare coverage in a regulation or statute. The available coverage would include the device and any procedures or services needed to implant the device, related maintenance costs and services, and the cost of treating any complications arising from the use of the device.

The MCIT program would allow for rapid access but would create a potential pitfall as well. The benefit is that CMS would accept the FDA's determination that a device has "significant advantages over existing approved or cleared alternatives" and deem a breakthrough device to meet the "reasonable and necessary" test for Medicare coverage. The potential pitfall is that Medicare coverage under the MCIT program is limited to four years from the date of the FDA's market authorization. CMS explained that the four-year period should be sufficient to complete any post-approval clinical studies.

At the end of the MCIT program period, continued Medicare coverage is not guaranteed; CMS can employ its usual coverage determination process that can result in one of several outcomes: (1) a Medicare national coverage determination, which may be favorable or unfavorable; (2) a Medicare local coverage determination developed by one or more MACs; or (3) no determination, which would result in case-by-case

[5] 21 U.S.C. § 360e-3(b).
[6] This includes premarket approval, Section 510(k) designated devices, and De Novo classification.

decisions to evaluate whether or not the reasonable and necessary standard was met.[7] As a result, CMS is encouraging manufacturers to be prepared to provide outcomes data as the MCIT program ends for a device, and has solicited comments on this issue.

As with the expansion of the reasonable and necessary standard, CMS has requested comments on a range of issues affecting the final scope of the MCIT program. Although this proposal is linked to the FDA's designation of breakthrough devices, CMS is interested in a potential expansion of the proposed MCIT program to include diagnostics, drugs, and biologics that qualify for expedited review or breakthrough designation by the FDA.

Interested stakeholders should continue to monitor CMS developments related to Medicare coverage determinations.

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This Client Alert was authored by **Robert E. Wanerman.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[7] If, in the interim, there is legislation or a Medicare national coverage determination denying coverage for the device, then the device would no longer be eligible for coverage.