September 15, 2020

CMS Proposes Significant Rule Change that Would Expedite Medicare Coverage of Breakthrough Medical Devices

On September 1, 2020, the Centers for Medicare and Medicaid Services ("CMS") published a proposed rule that would dramatically change Medicare coverage policy for certain medical devices approved under the Food and Drug Administration's ("FDA") "Breakthrough Devices Program." The change would be significant because for qualifying devices, there would no longer be a need to seek a separate coverage determination from Medicare: upon FDA marking authorization as a Breakthrough Device, coverage would follow nearly automatically. Specifically, the proposed rule would establish a Medicare Coverage of Innovative Technology ("MCIT") pathway by which medical devices with FDA Breakthrough Device designation could obtain immediate Medicare coverage. Relatedly, the proposed rule also would codify the definition of what is "reasonable and necessary," the standard otherwise used to determine whether Medicare will cover an item or service (though it is a bit unclear whether the revised definition is intended to apply outside the MCIT context). Although President Trump's October 3, 2019 *Executive Order on Protecting and Improving Medicare for Our Nation's Seniors*[1] included a general admonition in the direction of improving access for innovative products, the proposed rule really represents the triumph of years of advocacy by the medical device industry, and patient and provider groups.

This Alert summarizes key provisions of the proposed rule.

The Existing Framework: Hurry Up and Wait

The FDA's Breakthrough Devices Program is an expedited review process available to medical devices and device-led combination products that FDA determines provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.[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 the eligibility criteria.[3]

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, providers seeking Medicare reimbursement for use of the device in patient diagnosis or treatment must still navigate the usual Medicare pathway to establish that, although deemed safe and effective by FDA, the device is also "reasonable and necessary" for the diagnosis or treatment of an illness or injury.[4] This determination is made either at the national level through a National Coverage Determination ("NCD") issued by CMS, or more commonly through a Local Coverage Determination ("LCD") by a Medicare Administrative Contractor ("MAC"). These determinations are made after a thorough evidence-based review process with opportunities for public input, and LCDs can result in varying Medicare coverage in different geographical areas.[5] The lengthy process not only prevents Medicare beneficiaries from quickly accessing breakthrough devices, but also slows the process by which medical device manufacturers may begin to recover their development costs through sale of the device. Manufacturers, providers and patient groups have sought for years to find a quicker way to arrive at Medicare coverage.

The Proposed Rule: Good Enough for FDA, Good Enough for Medicare

The proposed rule seeks to streamline Medicare coverage of breakthrough devices by establishing a new MCIT pathway, a four-year period in which a Breakthrough Device would be reimbursable by Medicare following FDA marketing authorization. Towards the end of the four-year period, manufacturers may request an NCD or LCD. The proposed rule also expands and codifies the definition of "reasonable and necessary" as used in the Medicare Program Integrity Manual.

The MCIT

Upon receiving FDA marketing authorization, the MCIT would provide national coverage of Breakthrough Devices for four years, unless CMS determines that the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute. Device manufacturers would need to opt in to participate in the MCIT pathway.

The proposed rule contemplates that manufacturers would notify CMS ideally within two weeks of receiving Breakthrough Device designation from FDA via email or letter. However, manufacturers may provide notice shortly before, upon, or after the date of FDA marketing submission. The four-year window for the MCIT pathway would begin on the date of the FDA marketing authorization, regardless of when the manufacturer notifies CMS. Once a manufacturer has indicated its desire to utilize the MCIT pathway, CMS would coordinate with FDA and the manufacturer regarding the necessary steps for MCIT implementation. The MCIT pathway would only cover use consistent with its FDA-approved or -cleared indication for use (i.e., no coverage for "off-label" use), as other indications or conditions for use would not have been reviewed by FDA and there is unlikely to be data available to support extending beyond the FDA required labeling for Breakthrough Devices on the date of FDA marketing authorization. CMS seeks comment on whether off-label use of Breakthrough Devices should be covered and, if so, under what specific circumstances or with what evidentiary support.

During the four years, manufacturers would be encouraged, but not required, to further develop the clinical evidence basis on which FDA granted the marketing authorization. The proposed rule does not impose any obligation on manufacturers to conduct clinical studies, though they may be required to collect data as a condition of FDA marketing authorization. CMS seeks comment on whether it should mandate or incentivize manufacturers to provide data about outcomes or to enter into clinical studies, so this may change.

At the end of the four-year MCIT pathway, the breakthrough device would receive (1) NCD (affirmative coverage), (2) NCD (non-coverage), or (3) MAC discretion (claim-by-claim adjudication or LCD). The proposed rule contemplates that manufacturers would submit an NCD request during the third year of the device's MCIT Pathway to allow sufficient time for review.

Breakthrough Devices that obtained FDA marketing authorization during the two calendar years prior to the effective date of the final rule would also be eligible for the MCIT pathway. However, claims with dates of service that occurred prior to the effective date would not be eligible for coverage.

CMS proposes to 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.

Notably, the MCIT coverage pathway is available only for devices where the manufacturer petitions for coverage. The proposed rule does not yet have a mechanism for providers to seek coverage of a device. Since it is obviously in the interests of the device maker to pursue the MCIT pathway, this deficiency may not matter much, although CMS is seeking comment on whether stakeholders should be able to request Medicare coverage.

Defining "Reasonable and Necessary"

As mentioned above, Section 1862(a)(1)(A) of the Social Security Act limits Medicare coverage to items and services that are "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.[6] Neither the Act nor CMS regulations officially define the phrase. The proposed rule codifies the definition of "reasonable and necessary" currently used in Chapter 13 of the Medicare Program Integrity Manual, with only a slight expansion as described below. Because of its location in the regulations, this definition on its face would seemingly apply only to FDA-categorized devices discussed in Part 405, Subpart B of the Medicare regulations and, as such, would be relevant only to devices that have not opted into the MCIT. Since this seems a narrow interpretation, it may be instead that CMS intends for the codified definition to apply more broadly, as it has suggested in certain public statements.[7] This certainly seems worthy of mention in the notice and comment process.

Under the *current* definition, 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 addition to codifying the above standard, the proposed rule would establish an alternative to the appropriateness criteria enumerated in (3). If an item or service does not meet the appropriateness criteria enumerated in (3), CMS would look to whether commercial health insurers cover the device, unless evidence supports that there is a clinically relevant difference between Medicare beneficiaries and commercially insured individuals. The proposed rule also clarifies that Breakthrough Devices in the MCIT pathway would be considered "reasonable and necessary" by virtue of meeting the unique criteria of the FDA Breakthrough Devices Program.

Invitation to Comment on the Proposed Rule

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

- The proposed MCIT pathway generally.
- The proposed definition of "reasonable and necessary."
- The four-year period, as of the date of the FDA marketing authorization, as well as the two-year lookback from the publication of the final rule.
- The best way to determine which commercial plans CMS would rely on to compare for Medicare coverage and whether to make that information public.
- Whether beneficiaries, providers, and others wishing to gain coverage for an item or service may demonstrate that it is covered by at least one commercial plan.
- Whether off-label use of a Breakthrough Device through the MCIT pathway should be covered.

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Comments on the proposed rule must be submitted by 5:00 PM ET on November 2, 2020. If you have any questions, please contact your usual Ropes & Gray advisor.

1. E.O. 13890, accessible at https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/. The Order explicitly requires the Secretary of Health and Human Services to propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients by "streamlining the approval, coverage, and coding process so that innovative products are brought to market faster, and . . . are appropriately reimbursed and widely available." It also calls on the Secretary to clarify the application of coverage standards, including the reasonable and necessary standard.
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. *Id*. As of May 27, 2020, FDA had already granted a total of 298 breakthrough device designations.
4. *Medicare Coverage Determination Process*, CMS.gov (March 27, 2020), *accessible at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess.
5. *Id*.
6. 42 U.S.C. § 1395u(a)(1)(A).
7. *See, e.g.*, Fact Sheet, *Proposed Medicare Coverage of Innovative Technology*, CMS.gov (August 31, 2020), *accessible at* https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p ("Codifying a definition of 'reasonable and necessary' will bring clarity and consistency to the existing coverage determination processes for items and services under Part A and Part B . . . . This definition applies more broadly than MCIT, and will be used for NCDs and other coverage decisions.").