King & Spalding
Client Alert

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For more information, contact:

Preeya Noronha Pinto
+1 202 626 5547
ppinto@kslaw.com

David Farber
+1 202 626 2941
dfarber@kslaw.com

Melissa Monaghan
+1 202 340 4171
mmonaghan@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

Medicare Coverage Breakthrough Delayed

Biden Administration Delays Effective Date and Opens Another Comment Period for New Medicare Coverage Pathway for Breakthrough Medical Devices and Definition of "Reasonable and Necessary"

To the dismay of the medical device industry, in an Interim Final Rule published in the Federal Register on March 17, 2021, CMS delayed the effective date of a groundbreaking Medicare coverage regulation issued in the final days of the Trump Administration. The Final Rule entitled, "Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary'" published in the Federal Register on January 14, 2021 (the "MCIT Final Rule"), would establish a novel coverage pathway for breakthrough devices as well as codify in regulation a definition for the Medicare coverage standard of "reasonable and necessary" that includes reference to commercial insurer coverage decisions as a basis for Medicare coverage. The MCIT Final Rule is now subject to a 30-day public comment period so that CMS can determine whether to revise or rescind the MCIT Final Rule by May 15, 2021, its new, delayed effective date. ***Comments are due to CMS by April 16, 2021.***

THE MCIT PATHWAY

The MCIT Final Rule represents CMS willingness, for the first time, to automatically cover certain products based on FDA approval—something that may seem obvious to most people, but is revolutionary to seasoned reimbursement professionals. The MCIT Final Rule would permit four years of national Medicare coverage for certain new, innovative medical devices designated as breakthrough devices by the FDA beginning immediately upon FDA market authorization (including eligible medical devices authorized by FDA up to two years prior to the effective date of the MCIT Final Rule). Manufacturers would have the option of choosing a start date for coverage within two years after FDA market authorization of

the medical device, but the initial period of Medicare coverage under the MCIT pathway would still end four years after FDA market authorization. Coverage would be limited to on-label indications only. Participation in the MCIT pathway is voluntary; eligible manufacturers must only notify CMS of their desire for breakthrough device coverage under MCIT by email, and then CMS would coordinate with FDA and the manufacturer to facilitate Medicare coverage following FDA marketing authorization. Upon expiration of the initial four-year period of Medicare coverage, the standard Medicare definition of "reasonable and necessary" would apply to determine whether and to what extent continued coverage is appropriate. Manufacturers would need to seek coverage through typical processes, which include a National Coverage Determination, Local Coverage Determinations or claim-by-claim adjudication.

The new Medicare coverage pathway is intended to address administrative obstacles to the availability of innovative technologies in the Medicare patient population, which are often authorized by FDA with minimal clinical trial data. Former CMS Administrator Seema Verma noted that "[f]or new technologies, CMS coverage approval has been a chicken and egg issue. Innovators had to prove their technologies were appropriate for seniors, but that was almost impossible since the technology was not yet covered by Medicare and thus not widely used enough to demonstrate their suitability for Medicare beneficiaries."[1]

The MCIT Final Rule would create a helpful precedent for reimbursement in that the MCIT pathway relies entirely on the FDA's designation of breakthrough status and marketing authorization to approve an initial period of Medicare coverage. The FDA's Breakthrough Devices Program is for medical devices (including lab tests) and device-led combination products that meet two criteria. The first criterion is that the device provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The second criterion is that the device must satisfy one of the following elements: (1) it represents a breakthrough technology; (2) no approved or cleared alternatives exist; (3) it offers significant advantages over existing approved or cleared alternatives; or (4) device availability is in the best interest of patients. Upon FDA approval or clearance of a breakthrough device, FDA determines that the breakthrough device satisfies the FDA's statutory standard of reasonable assurance of safety and effectiveness. In the MCIT Final Rule, CMS explained at length how FDA's determinations would essentially guarantee that the devices are "reasonable and necessary" under the Medicare coverage standard.

Significantly, CMS made clear in the MCIT Final Rule that the new coverage pathway would only enable medical devices to satisfy the "reasonable and necessary" prong of the Medicare coverage standard. It would not affect whether a medical device falls within a statutorily-designated "Medicare benefit category" or whether a medical device is otherwise excluded from coverage by the Medicare statute. CMS recognized that Medicare is a defined benefit program, and devices that do not fit within a Medicare benefit category in the statute would not be eligible for Medicare coverage through the MCIT pathway or any other coverage pathway, as CMS does not have the authority to modify the Medicare statute. Thus, certain medical devices that qualify for breakthrough status and are authorized for marketing by FDA (for example, equipment for home use that is not durable) may not qualify for Medicare coverage because they do not fall within a Medicare benefit category.

DEFINITION OF "REASONABLE AND NECESSARY"

The second part of the MCIT Final Rule is arguably even more significant than the creation of a new coverage pathway for certain medical devices. The MCIT Final Rule would codify a regulatory definition of "reasonable and necessary" under section 1862(a)(1)(A) of the Social Security Act for all items and services furnished under Medicare Parts A and B.

CMS had already defined the "reasonable and necessary" standard in its Program Integrity Manual, but motivated by a recent Supreme Court holding,[2] decided to codify the Manual definition into regulation through the MCIT Final Rule. The Manual definition provides 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, including the duration and frequency that is considered

appropriate for the item or service, in terms of whether it is—(i) 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; (ii) furnished in a setting appropriate to the patient's medical needs and condition; (iii) ordered and furnished by qualified personnel; (iv) one that meets, but does not exceed, the patient's medical need; and (v) at least as beneficial as an existing and available medically appropriate alternative.

CMS had initially proposed to modify the Manual definition of "reasonable and necessary" by including a separate basis under which an item or service would be "appropriate" that is based on commercial insurer coverage policies. However, following negative stakeholder response to the proposal, including a January 5, 2021 meeting with representatives of America's Health Insurance Plans ("AHIP"), CMS decided to punt on the commercial insurance provision in the definition of "reasonable and necessary" in the MCIT Final Rule. Specifically, within 12 months of the effective date of the MCIT Final Rule, CMS would issue subregulatory guidance on the methodology by which commercial insurers are relevant to Medicare coverage based on the measurement of majority of covered lives. Instead, recognizing that the Medicare program already informally references commercial insurer coverage in its coverage decisions, CMS decided to provide more transparency around these considerations. The MCIT Final Rule would codify regulatory language that would give CMS clear authority to review the majority of commercial insurers, in the context of National Coverage Determinations and Local Coverage Determinations, if an item or service does not otherwise meet the "appropriateness" criteria in the "reasonable and necessary" definition. If Medicare coverage is different than the majority of commercial insurers, CMS would need to include in the National Coverage Determination or Local Coverage Determination its reasoning for different coverage.

CMS DELAY AND REQUEST FOR COMMENTS ON THE MCIT FINAL RULE

The Biden Administration delayed the effective date of the MCIT Final Rule pursuant to a January 20, 2021 memorandum entitled, "Regulatory Freeze Pending Review," issued by the Assistant to the President and Chief of Staff. The memorandum directs Executive Branch Departments and Agencies to consider delaying the effective date of rules published in the Federal Register that have not yet become effective in order to conduct additional review.

CMS invited public comments in several areas:

- CMS noted that it "underestimated the operations challenges" in implementing the new Medicare coverage pathway for breakthrough devices. CMS would need to ensure that the device falls within a defined Medicare benefit category prior to approval of Medicare coverage, which could be challenging since CMS cannot be certain of the precise timing of FDA market authorizations and indications for use until devices are authorized. CMS must also consider the setting of care, whether there is an existing payment methodology that applies, and whether there is an appropriate billing code for the device to support the submission of claims.
- CMS expressed concern about the impact of the timing of the initial comment period for the MCIT Final Rule on a November 2020 Proposed Rule that addressed Medicare benefit category determinations for durable medical equipment. (See Client Alert here.) That Proposed Rule was published in the Federal Register after the public comment period that led to the MCIT Final Rule closed, which may not have allowed stakeholders to adequately comment on the integration of the two policies, at least with respect to durable medical equipment.
- CMS noted that the MCIT Final Rule was based on the expectation that the FDA's Breakthrough Devices Program would initially apply to a relatively small number of devices, which contributed to the regulatory impact analysis for the MCIT Final Rule. Recent data reflects that a significantly higher number of medical devices have been designated breakthrough status by FDA.

- There is potential lack of clinical evidence regarding how breakthrough devices specifically affect the Medicare beneficiary population, which is characterized by numerous co-morbidities and treatments for multiple conditions. These issues were raised in articles published in the New York Times, Health Affairs and New England Journal of Medicine after the MCIT Final Rule initial comment period closed. Moreover, the MCIT Final Rule would permit CMS to remove a breakthrough device from the MCIT coverage pathway if a warning letter is issued by the FDA, or if the FDA revokes market authorization for a device. CMS seeks comment on whether the MCIT pathway and its safeguards adequately address the public's concern that breakthrough devices may not provide clinical benefit to the Medicare population.
- CMS did not include sufficient detail in the proposed revised definition of "reasonable and necessary" about the impact of commercial insurance coverage on Medicare coverage decisions, which prevented the public from providing adequate or meaningful comment. CMS is also generally concerned with whether the rulemaking process was procedurally adequate and whether interested parties had a fair opportunity to present contrary facts and arguments.

THE FUTURE OF THE MCIT FINAL RULE

It would be surprising if a new Medicare coverage pathway for breakthrough devices is not implemented in some form in the future. The policy enjoys broad support from virtually all stakeholder groups, and the Biden Administration favors expansion of access to innovative medical care for all patient populations. Although complex, CMS should be able to find ways to address the operational issues and streamline implementation of a new coverage pathway. The codification of the definition of "reasonable and necessary" that would incorporate commercial insurer coverage as an independent basis for Medicare coverage was not received as enthusiastically, however, and even the Trump Administration decided to delay implementing that policy. Given the widespread concern in taking this approach, it is unclear whether the Biden Administration will re-engage on the issue. Whatever the final policy decisions, it is almost certain that the MCIT Final Rule will not take effect on its delayed effective date of May 15, 2021 without some modifications, if nothing else, to clarify a number of drafting errors in the document, which were likely the result of the rush of regulations and policies issued during the final days of the Trump Administration.

[1] CMS Press Release, CMS Acts to Spur Innovation for America's Seniors (Aug. 31, 2020).
[2] *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).