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Client Alert

FDA and Life Sciences

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A Pathway for Medicare Coverage for Breakthrough Devices: Take Two

On June 27, 2023, the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") issued a "Notice with Comment Period" ("Notice") describing a new process for providing expedited Medicare coverage for certain eligible FDA-designated Breakthrough Devices.[1] Named the Transitional Coverage for Emerging Technologies ("TCET") pathway, this effort offers a different approach to Medicare coverage of Breakthrough Devices than the Medicare Coverage for Innovative Technologies ("MCIT") Final Rule issued by the Trump Administration in early 2021 and subsequently rescinded by the Biden Administration before it took effect. Under the TCET pathway, CMS purports to leverage current National Coverage Determination ("NCD") and Coverage with Evidence Development ("CED") processes to "deliver transparent, predictable, and expedited" Medicare coverage of certain emerging technologies.[2] CMS estimates coverage to be temporary—typically lasting between three to five years—to enable manufacturers to generate adequate evidence to meet the reasonable and necessary standard for coverage under Section 1862(a)(1)(A) of the Social Security Act (the "Act").[3] While the pathway may be well-intentioned and offers an alternative procedural option for certain limited technologies, CMS fails to make any significant changes to the current Medicare coverage process to materially facilitate Medicare beneficiary access to Breakthrough Devices. Arguably, CMS does the opposite by effectively committing these technologies to the long and arduous CED pathway. The deadline to submit comments to the Notice is August 28, 2023.

GENERAL PRINCIPLES OF THE TCET PATHWAY

CMS casts the TCET pathway as an opportunity to accelerate Medicare beneficiary access to emerging technologies while generating additional clinical evidence.[4] CMS specifically envisions the TCET pathway to apply to medical devices that are: (i) FDA-designated Breakthrough Devices; (ii) determined to be within a Medicare benefit category; [5] (iii) not already the subject of an existing Medicare NCD; and (iv) not otherwise excluded

from coverage through law or regulation (hereinafter "eligible Breakthrough Devices").[6] CMS explains that, by the time they are introduced to market, most of these eligible Breakthrough Devices are not likely to have sufficient clinical data (*e.g.*, health outcomes data related to the Medicare population) to support broad, national coverage (*i.e.*, they do not meet the reasonable and necessary standard for coverage under Section 1862(a)(1)(A) of the Act).[7] At the same time, CMS appreciates the potential impact of ensuring Medicare beneficiaries have earlier access to such promising technologies.[8] CMS therefore conceives the TCET pathway to enable temporary coverage of eligible Breakthrough Devices while continuing to collect evidence pursuant to an Evidence Development Plan ("EDP") to demonstrate benefit for the Medicare population. With the additional data, CMS hopes that it can make a more informed decision on whether to transition coverage to an NCD without evidence development requirements.[9]

The TCET pathway builds off of prior initiatives including CED. CED is a pathway where CMS uses the NCD process to deny coverage for the item or service *except* for patients using the item or service within a CMS-sanctioned clinical trial. For the TCET pathway, CMS will conduct a literature review of the breakthrough devices' strengths and weaknesses, and develop an EDP to address any gaps necessary for coverage that will become the basis of the post-FDA-approval clinical trial within which CMS will cover the device.

TCET PATHWAY PROCESS

Manufacturers of eligible Breakthrough Devices may voluntarily nominate themselves to participate in the TCET pathway.[10] Manufacturers are advised to submit their nominations approximately 12 months prior to the anticipated FDA decision date by emailing CMS with information about the device, such as its technology and the disease or condition the device is intended to diagnose or treat, the development status of the technology (including FDA's Breakthrough Designation letter), a comprehensive list of peer-reviewed publications that support the Breakthrough device, and information to assist CMS determine the appropriate benefit category and codes.[11] In return, CMS commits to issue a preliminary decision to provisionally accept or decline a nomination within 30 business days from the date CMS confirms receipt of the nomination.[12]

CMS will determine whether a product is an appropriate candidate for the TCET pathway through a review process that includes engaging both the manufacturer and FDA. CMS explains that the review process will consist of: (i) a brief, initial intake meeting with the manufacturer within 20 business days from the date it receives a complete nomination; (ii) discussions with FDA to learn more information about the technology and, potentially, FDA's review timing; and (iii) a benefit category review to assess whether the device is eligible for Medicare coverage through an existing benefit category.[13]

If CMS finds that the product is an appropriate candidate, it will initiate an "Evidence Preview," which is a systematic literature review that would provide early feedback on the strengths and weaknesses of the publicly available evidence for the item or service. The Evidence Preview will be conducted by a contractor using an assessment protocol developed by the Agency for Healthcare Research and Quality ("AHRQ"). CMS anticipates that the Evidence Preview will take approximately 12 weeks to complete. Upon completion, CMS will discuss the Evidence Preview in a meeting with the manufacturer. Notably, for manufacturers who seek to withdraw from the TCET pathway following completion of the Evidence Preview, CMS seeks comment on its intention to share the Evidence Preview with Medicare Administrative Contractors to use in their decision-making.[14]

Upon being deemed an appropriate candidate for the TCET pathway, manufacturers must request CMS to open an NCD by submitting: (i) a formal NCD request; and (ii) an EDP that sufficiently addresses evidence gaps identified during the Evidence Preview.[15] Manufacturers may include traditional clinical study designs and/or fit-for-purpose study designs, including those that rely on real-world data, in their EDP.[16] CMS will work with AHRQ to evaluate the EDP for conformance with established standards of scientific integrity and relevance to the Medicare population, and

subsequently with the manufacturer to make necessary adjustments to the EDP.[17] Specifically, CMS notes that manufacturers should plan a "continued access study" that maintains market access between the period when the primary EDP is complete, the evidence review is refreshed, and a decision regarding post-TCET coverage is finalized.[18]

CMS notes that, if it determines that further evidence development is appropriate, it intends to work with manufacturers to "reduce the burden on manufacturers, clinicians and patients while maintaining rigorous evidence requirements" and to ensure that such evidence development requirements do not conflict with or duplicate FDA post-market requirements.[19]

CMS sets its goal to finalize a TCET NCD within six months after FDA market authorization.[20] Thus, CMS recommends that manufacturers should plan to submit their EDP as soon as possible and finalize their EDPs within 90 business days from the date of FDA approval or clearance.[21] However, CMS also indicates that the process of coverage under the TCET pathway will follow the traditional NCD process as set forth in Section 1862(*l*) of the Act. Specifically, CMS will open an NCD by posting a tracking sheet (with a 30-day comment period) following FDA marketing authorization, will publish a proposed NCD and EDP within six months (followed by another 30-day public comment period), and will issue a final NCD within 60 days after that comment period ends.[22] Thus, the entire NCD process could take nine months after FDA market authorization—not six months, as aspired by CMS.

COVERAGE UNDER THE TCET PATHWAY AND TRANSITION TO POST-TCET COVERAGE

CMS envisions that coverage under the TCET pathway would not continue in perpetuity. Rather, the TCET pathway would be tied to the timeframes set forth in the EDP. CMS expects that coverage would be time-limited—generally from three to five years—to allow the manufacturer to generate sufficient evidence to address evidence gaps found during the Evidence Preview and, ultimately, allow CMS to determine whether the item or service is reasonable and necessary and to extend coverage without evidence development requirements.[23] Within six months of the review date specified in the EDP, CMS will review the updated evidence, practice guidelines, and consensus statements by engaging a third-party contractor to conduct a systematic literature review. Based on this review, CMS will open an NCD reconsideration proposing one of the following: (i) an NCD without evidence development requirements; (ii) an NCD with continued evidence development requirements; (iii) a non-coverage NCD; or (iv) local Medicare Administrative Contractor discretion to decide whether to cover the item or service on a claim-by-claim basis for individual patients.[24] Standard NCD processes would apply: Following a 30-day public comment period, CMS would have 60 days to finalize the NCD reconsideration.

THE PATHWAY – GOOD, BAD OR UGLY?

The CMS Notice has already been met with mixed reviews, and for good reason. First, the TCET pathway falls far short of the Trump Administration's MCIT Final Rule, withdrawn by the Biden CMS, that would have provided expedited coverage of all breakthrough devices for up to four years.[25] The Trump rulemaking was founded on the idea that if FDA had accepted a device as "breakthrough," it was incumbent on the Medicare program to ensure that beneficiaries had access to the new technology. The current Administration, however, has not only withdrawn and replaced the MCIT rule, but has also revived it through a fundamentally different CED prism. This approach precludes beneficiaries from earlier access to eligible Breakthrough Devices (or many other items or services such as Accelerated Approval drugs) until the manufacturer can produce additional evidence showing that the device is appropriate and beneficial for the Medicare population—above and beyond what FDA requires for approval or clearance. This new CMS framework fundamentally turns the clinical development process on its head and undermines healthcare for Medicare beneficiaries. Regardless of whether CMS has pivoted to this policy to save money or simply on principle, the outcome is the same: beneficiaries are virtually guaranteed delayed access to potentially life-saving medical innovations.

Second, it is far from clear that the TCET process will work as drafted. The pathway, with its evidence review during the FDA approval (or clearance) process, harkens back to CMS's "parallel review" process which itself failed (reports indicate that only two devices ever made it through parallel review). Manufacturers will need to seriously evaluate whether engaging in the TCET pathway risks delays in the regulatory process, as there is a material risk that engaging in a three-way discussion with CMS and FDA may delay FDA marketing authorization in addition to CMS coverage.

Third, CMS continues to contend with a variety of resource challenges. Unlike FDA and its hundreds of career medical professionals, CMS has only a handful of doctors or scientists to perform medical evidence reviews. Neither does CMS have the resources to advance multiple NCDs for eligible Breakthrough Devices. The Agency is already an estimated four to five years behind in addressing the numerous other NCD requests pending before it. Moreover, CMS does not have the staff to manage the TCET process. It is thus of little surprise that CMS admits it needs to engage third-party contractors for evidence reviews and will only be able to accept and manage five applications per year.[26] This will leave all the other Breakthrough Device manufacturers scratching their heads over how they may secure coverage for their innovative products, and poses yet another reason that investors and innovators will think twice before pursuing development of their next medical discovery.

Even if CMS had the resources to pull off the TCET pathway, history leaves much doubt. CMS has a well-documented, poor track record of managing CED studies. As the Agency acknowledges, it has initiated 26 CED studies over the past 20 years—begging the question how it will launch five (or more) a year for the TCET program alone—and, in that time, has only terminated three of the studies. While CMS claims to have "approved" 109 CED studies and five national registries, only 42 have generated evidence and many others never got off the ground (meaning no patients ever received access). This abysmal track record calls into question whether CMS has the capability, even after all this time, to actually develop and manage realistic studies and goals for the studies.

Given the complexities of the new TCET pathway, the challenges that CMS will have in managing even five new technologies through the process, and the potential implications on FDA approval or clearance, manufacturers would be well-advised to think twice before embarking on what seems to be a lovely one-stop-shop, but in reality, can be years of entanglement in delay and uncertainty.

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King & Spalding LLP regularly counsels drug and device manufacturers on the submission of marketing applications to FDA, and strategies for Medicare coverage, coding, and payment for new and existing technologies. Comments on the Notice are due on August 28, 2023. Please let us know if you have any questions regarding this Notice or if you would like to consider submitting a comment.

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[1] 88 Fed. Reg. 41633, 41633 (June 27, 2023).
[2] *Id.* at 41634.
[3] *Id.* at 41642.
[4] *Id.* at 41637, 41642.
[5] Medicare does not cover all items and services, but instead is limited by law to only cover specific items and services included on a list of "defined benefit categories." Such benefit categories include durable medical equipment, certain diagnostic tests, FDA-approved drugs, and items incident to a physician's services, among others. Only breakthrough devices falling within a benefit category and otherwise not excluded from coverage are eligible for TCET. A current example of an item or service that does not have a defined benefit category are prescription digital therapeutics.
[6] *Id.* at 41639.
[7] *Id.*
[8] *Id.*
[9] *Id.* at 41643.
[10] *Id.* at 41638.
[11] *Id.* at 41639.
[12] *Id.* at 41640.
[13] *Id.*
[14] *Id.* at 41640–41.
[15] *Id.* at 41641.
[16] *Id.*
[17] *Id.* at 41641–42.
[18] *Id.* at 41641.
[19] *Id.* at 41639.
[20] *Id.* at 41641.
[21] *Id.*
[22] *Id.* at 41642.
[23] *Id.* at 41639.
[24] *Id.* at 41642–43.
[25] Ctrs. for Medicare & Medicaid Servs., Press Release, *CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices* (Nov. 12, 2021), https://www.cms.gov/newsroom/press-releases/cms-repeals-mcitrn-rule-will-consider-other-coverage-pathways-enhance-access-innovative-medical.
[26] 88 Fed. Reg. at 41644.