King & Spalding

Client Alert

FDA and Life Sciences

SEPTEMBER 04, 2024

For more information, contact:

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

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

Sophia Hafley (Sophie)
+1 213 218 4049
shafley@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Suite 900
Washington, D.C. 20006
Tel. +1 202 737 0500

Transitional Coverage for Emerging Technologies: CMS's Latest, But Not Necessarily Greatest, Coverage with Evidence Approach

On August 7, 2024, the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") issued a final procedural notice ("Notice") outlining a new Medicare coverage pathway, aimed at achieving timelier and predictable access to 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for Innovative Technologies ("MCIT") Final Rule issued by the Trump Administration in early 2021 and subsequently rescinded by the Biden Administration before its effective date. The Agency claims that the TCET pathway is intended to increase the number of National Coverage Determinations ("NCDs") CMS conducts each year, "providing a clear, transparent, and consistent coverage process while maintaining robust safeguards for the Medicare population."[2] However, given the Agency's track record of policies which utilize a Coverage with Evidence Development ("CED") process, it remains to be seen whether the Notice will actually result in better access to innovative technologies for Medicare beneficiaries. The Notice became effective August 12, 2024.

THE TCET PATHWAY: HOW IT WORKS

The TCET pathway purports to utilize CMS's existing NCD and CED processes to reduce uncertainty about coverage options for Breakthrough Devices, by providing a pre-market evaluation of "potential harms and benefits of technologies while identifying any important evidence gaps." Consistent with the Agency's July 2023 proposal, appropriate candidates for the TCET pathway would include those devices which are: (i) FDA-designated Breakthrough Devices; (ii) determined to be within a Medicare

benefit category; (iii) not already the subject of an existing Medicare NCD; and (iv) not otherwise excluded from coverage through law or regulation.[3] Manufacturers with eligible devices may self-nominate by submitting a non-binding letter of intent, approximately 18-24 months before anticipated FDA marketing authorization as determined by the manufacturer (note, the TCET proposal did not include the option of submitting a non-binding letter of intent).[4] Then, consistent with the proposal, formal nominations are considered approximately 12 months prior to FDA marketing authorization. According to the Agency, this additional step of allowing the submission of non-binding letters of intent will improve CMS's ability to track potential candidates, coordinate with FDA, and make operational adjustments.[5] CMS anticipates only accepting up to five TCET candidates per year.

To submit a nomination, manufacturers must email CMS with information about the device, including a description of 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 relevant published clinical studies regarding the safety/efficacy of the product. Following the submission of a complete TCET nomination, CMS will offer an initial meeting with the manufacturer to review the nomination within 20 business days of receipt.[6] In this initial meeting, the manufacturer is expected to describe the device, its intended application, place of service, a high-level summary of the evidence supporting its use, and the anticipated timeframe for FDA review. Then, after CMS initiates a review of the formal nomination, the Agency will coordinate with FDA to learn more about the technology "to the extent the Agencies have not already done so."[7] The Notice revised CMS's timeframe for reviewing TCET nominations, which will now be done on a quarterly basis. In the Notice, CMS also expressed an intention to soon release the proposed factors the Agency will use to prioritize TCET nominations, "to provide greater transparency, consistency, and predictability."[8]

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 established review criteria developed in collaboration with the Agency for Healthcare Research and Quality ("AHRQ").[9] CMS anticipates that the Evidence Preview will take approximately 12 weeks to complete once the review is initiated, following acknowledgment of an accepted nomination in the TCET pathway. Upon finalization of the Evidence Preview, the manufacturer may decide to pursue national coverage under the TCET pathway or to withdraw from the pathway.[10] Notably, CMS has changed its position from the proposal, now opting *not* to share Evidence Preview information with the Medicare Administrative Contractors ("MACs") if the manufacturer chooses to withdraw from the TCET pathway.[11]

If the manufacturer decides to continue, the next step will include submitting a formal NCD request cover letter expressing the manufacturer's desire for CMS to open a TCET NCD analysis. If CMS and/or AHRQ identifies evidence gaps during the Evidence Preview, the manufacturer will also need to submit an Evidence Development Plan ("EDP") to CMS that sufficiently addresses the evidence gaps identified in the Evidence Preview.[12] The EDP should be submitted to CMS simultaneously with the formal NCD request cover letter. If a device that is accepted into the TCET pathway receives FDA market authorization, CMS will initiate the NCD process by posting a tracking sheet following FDA market authorization (that is, the date the device receives PMA approval; 510(k) clearance; or the granting of a De Novo request) pending a CMS and AHRQ-approved EDP (as noted in the proposal, CMS emphasizes that the goal is to have a finalized EDP no later than 90 days following FDA approval).[13]

In the Notice, CMS again reiterates its goal to finalize a TCET NCD within six months after FDA market authorization. Yet, CMS also still 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 Social Security Act.[14] Such process includes CMS opening an NCD by

posting a tracking sheet (with a 30-day comment period) following FDA marketing authorization, publishing a proposed NCD and EDP within six months (followed by another 30-day public comment period), and issuing a final NCD within 60 days after that comment period ends. Thus, the entire NCD process could in actuality take nine months following FDA market authorization, not six. Further, if approved, the TCET "study" is virtually guaranteed to last for over five years—and if history is any guide, could last for a decade or even longer. Additionally, CMS now plans to add some information on TCET devices to the NCD Dashboard, including the number of devices in the TCET pathway, the date of nomination, the date of acceptance, and the date the NCD process was initiated.[15]

TCET PATHWAY COVERAGE AND POST-TCET COVERAGE

According to CMS, "[c]overage under the TCET NCD will continue only as long as needed to facilitate the timely generation of evidence that can inform patient and clinician decision making," with the duration of coverage being tied to the CMS- and AHRQ-approved EDP.[16] As noted in the proposal, CMS expects that coverage under a TCET NCD may last for approximately five years, while evidence is generated to address the gaps identified in the Evidence Preview (as noted above, CMS precedent suggests that CED studies will last far longer). Then, 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) rescinding the NCD, resulting in coverage decisions being made by MACs on a claim-by-claim basis. Standard NCD processes would apply: Following a 30-day public comment period, CMS would have 60 days to finalize the NCD reconsideration.[17]

DOES THE TCET PATHWAY SIGNAL A FUNDAMENTAL COVERAGE SHIFT?

The final TCET Notice is CMS's latest attempt at instituting a CED approach, which in the past, have been met with criticism due to low rates of success. For example, as noted in the TCET proposal, CMS has initiated 26 CED studies over the past 20 years—begging the question of how CMS would be equipped to handle five TCET candidates per year. In particular, there are two notable aspects of the Notice worth highlighting. First, CMS claims without citation to any meaningful evidence that it cannot grant coverage for Breakthrough Devices because the FDA review of devices does not require a focus specifically on the Medicare population. Implicit (and sometimes explicit) in the Notice is a viewpoint that clinical trials that do not focus on all different types of Medicare beneficiaries receiving care in their normal settings are somehow insufficient evidence to establish whether the product would be effective in treating Medicare populations. This will no doubt be news to Congress, which created the Breakthrough Pathway in the first instance, and to FDA, which has spent decades developing clinical trial protocols to ensure that products are safe and effective. Further, the CMS presumption undermines Congress's intent in creating the Breakthrough Device designation, which only applies to devices in which 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."[18] CMS utterly fails to explain why those findings by FDA would not also apply to the Medicare population writ large. In fact, commenters to the TCET proposal expressed concern that CMS would be undermining FDA's Breakthrough Devices Program by requiring additional evidence through the TCET pathway. CMS disagrees, claiming that the TCET pathway would not undermine FDA's separate statutory authority—and, that there is an opportunity under TCET to leverage an FDA-required post-market study, if any, to address specific evidence gaps for Medicare beneficiaries.[19]

Second, there is a looming question whether the CED process generally, and the new TCET process specifically, are legal. CMS provides a weak legal justification for its Notice, claiming that, because CMS can pay for studies that

Congress has allowed the Agency for Healthcare Research and Quality (AHRQ) to "conduct and support," and since CMS has the "support" of AHRQ for its efforts, it may conduct CED trials. Of course, the law requires AHRQ to not only "support" the research but to "conduct" it as well—a point that CMS simply ignores, even though a prior HHS General Counsel found the CED process to be illegal for precisely these reasons. Time will tell whether litigation challenging the Agency will be brought, but we believe CMS faces an extremely challenging task, particularly after the Supreme Court's *Loper Bright* decision, in justifying the CED process that it has created without statutory authorization.

Aside from the conceptual problems in the Notice, there are practical considerations as well. It remains to be seen whether the TCET pathway will result in a faster, more streamlined approach for innovative technologies to obtain coverage—or, whether the requirements under the TCET pathway signify a fundamental shift by the Agency which would result in *less* coverage for Breakthrough Devices. A third option also exists, which is that CMS may not be successful in getting the TCET pathway off the ground. As you may recall, in 2016, CMS and FDA instituted the Parallel Review program, intending to reduce the time between FDA marketing approval and Medicare coverage decisions through the NCD process. As commenters to the TCET proposal pointed out, Parallel Review has yielded very few results over the years (according to some, only one!), and contains many of the same features as the TCET pathway.[20] Thus, it may be the case that the TCET pathway results in neither more nor less coverage for Breakthrough Devices—but rather, signifies another failed attempt by FDA and CMS to conduct a collaborative review. Potentially more threatening, TCET also risks CMS slowing down the FDA approval/clearance process, which would be particularly harmful for manufacturers.

Given CMS's track record with CED processes, as well as collaborative efforts with FDA, manufacturers would be well-advised to think twice before embarking on what may seem like a straightforward pathway from FDA approval to CMS coverage but which may delay both FDA review and CMS coverage.

A WAY FORWARD: ENSURING PATIENT ACCESS TO CRITICAL BREAKTHROUGH PRODUCTS ACT

CMS's issuance of the TCET Notice also heightens the need for Congress to get involved, through the pending Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 1691, 118th Cong.), which, similar to the Trump administration's 2021 MCIT rule, would allow Breakthrough Devices to be temporarily covered by Medicare during a four-year transitional period, and require CMS to assign payment codes for such devices within three months of FDA approval.[21] The bill passed the House Energy and Commerce Subcommittee on Health on November 15, 2023, by a vote of 21 – 6, and recently passed the Committee on Ways and Means in the House on June 27, 2024, by a vote of 36 – 5. Next steps would be passage by the full Energy and Commerce Committee and then a vote by the House (no Senate action has occurred to date). If successful, the bill would be critical in shoring up Congress's original intent in creating the Breakthrough Device Program: access to a greater number of innovative technologies, for a greater number of patients. Given the Agency's unsupported presumptions that clinical trials are not "fit" for the Medicare population, and its adoption of legally suspect procedures that risk patient access to treatment, it would be a welcome development indeed for Congress to pass the bill into law and put a rest to CMS's questionable efforts.

CONCLUSION

Over the history of the Breakthrough Device program, FDA has approved over 930 such devices to meet unmet medical needs or to improve the standard of care. Many of the products have never gone through the NCD or LCD process, or even been subject to CEDs. The new CMS TCET Notice now threatens coverage for all future breakthrough devices, and subjects the "lucky five" that are accepted into the program to an extensive, costly, and uncertain multi-year "study" process, potentially with no end, before the Agency will afford these products coverage. Given TCET's numerous

hurdles and limited scope, it is difficult to see how the new program can ever expand Medicare beneficiary access. In our view, at best this program mirrors "parallel review" and becomes another failed CMS experiment. At worst, however, it is the beginning of Medicare beneficiaries becoming second-class healthcare citizens and being denied access to new and innovative breakthrough treatments. For that reason, we caution manufacturers to think twice about the purported benefits of the program.

***

King & Spalding LLP regularly counsels drug and device manufacturers on strategies for Medicare coverage, coding, and payment for new and existing technologies. Please contact us if you have any questions regarding the TCET pathway or other aspects of Medicare reimbursement.

[1] 89 Fed. Reg 65724 (Aug. 12, 2024).
[2] CMS Press Release, *Final Notice — Transitional Coverage for Emerging Technologies (CMS-3421-FN)*, available at https://www.cms.gov/newsroom/fact-sheets/final-notice-transitional-coverage-emerging-technologies-cms-3421-fn
[3] *Id.* at 65730.
[4] *Id.* at 65746.
[5] *Id.* at 65733.
[6] *Id.* at 65750.
[7] *Id.*
[8] *Id.* at 65754.
[9] *Id.* at 65750.
[10] *Id.* at 65751.
[11] *Id.* at 65746.
[12] *Id.* at 65751.
[13] *Id.* at 65752.
[14] *Id.*
[15] *Id.* at 65754.
[16] *Id.* at 65748.
[17] *Id.* at 65753.
[18] *Id.* at 65726.
[19] *Id.* at 65728.
[20] *Id.* at 65743.
[21] H.R. 1691, 118th Congress.