



October 15, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: Medicare Coverage of Innovative Technology (MCIT) and Definition
of “Reasonable and Necessary” Proposed Rule [CMS–3372–P2]**

Dear Administrator Brooks-LaSure:

The Advanced Medical Technology Association (AdvaMed) offers the following comments on the Centers for Medicare & Medicaid Services’ (CMS) proposal to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” final rule¹ that was published on January 14, 2021. AdvaMed urges CMS not to repeal the final rule but to move forward with an MCIT pathway that will provide access to innovative medical devices and diagnostics to Medicare beneficiaries with life-threatening or irreversibly debilitating diseases or conditions.

AdvaMed’s member companies produce the lifesaving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. AdvaMedDx functions as an association within AdvaMed and its member companies produce advanced *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early disease detection, and often reduce overall health care costs.

Another division, AdvaMed Accel, represents small and mid-sized companies. Many of these early-stage, start-up, and pre-revenue companies create breakthrough devices that would be directly affected by the MCIT rule, which would provide greater predictability regarding coverage of breakthrough technologies.

Throughout this letter, AdvaMed refers to AdvaMed and its AdvaMedDx and AdvaMed Accel divisions.

¹ 86 *Fed Reg* 51326, et seq, September 15, 2021, see <https://www.govinfo.gov/content/pkg/FR-2021-09-15/pdf/2021-20016.pdf>.

We are discouraged that CMS has proposed to repeal the MCIT final rule, which would expedite access to breakthrough diagnostic and therapeutic devices for Medicare beneficiaries suffering from debilitating conditions, such as heart disease, diabetes, kidney disease, acute infections, sepsis, and cancer, which are prevalent in the Medicare population and represent a significant burden of disease, as well as societal cost. We are confident that CMS can implement an MCIT program that would enable all Medicare beneficiaries to benefit from access to important innovations in health care. We have previously stated and still believe that MCIT could become one of several strategies that CMS uses to help address health inequities, particularly for vulnerable patients in underserved communities, by creating an expedited pathway to national coverage for new technologies.

AdvaMed has long advocated for streamlined approaches to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients who suffer from debilitating or life-threatening illnesses. CMS has a critical role in advancing access to innovations that would benefit the Medicare beneficiaries it serves. AdvaMed looks forward to working together with CMS on ways to provide improved and timely access to needed care for these patients.

AdvaMed urges CMS not to repeal the MCIT final rule. AdvaMed is committed to working with CMS to strengthen the MCIT rule to support patient access to new and innovative technologies for Medicare beneficiaries with debilitating or life-threatening conditions.

The MCIT pathway for FDA-designated and approved breakthrough² technologies would have provided a new, expedited path to coverage for these transformational products. Combined with the breakthrough pathways for new technology add-on payments in the FY 2020 Inpatient Prospective Payment System (NTAP) and outpatient transitional pass-through (TPT) payments in the Outpatient Prospective Payment System, MCIT would help to improve patient care for Medicare beneficiaries by providing rapid access to innovative new products and services.

Expedited coverage of new and innovative technologies is needed for many reasons, including to bridge the very real gap that can exist between FDA approval and Medicare coverage, during which time patients with serious medical conditions may not have access to innovations that could be truly life-altering. Without national coverage, health

² See FDA Breakthrough Devices Program, <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s1>, defining breakthrough devices as those that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The device also meets at least one of the following:

- Represents Breakthrough Technology
- No Approved or Cleared Alternatives Exist
- Offers Significant Advantages over Existing Approved or Cleared Alternatives
- Device Availability is in the Best Interest of Patients



care providers and Medicare beneficiaries may experience regional differences in coverage provided by local Medicare Administrative Contractors, or face having no coverage at all. Additionally, while Medicare Advantage plans are required to cover all Part A and Part B covered services, many MA plan policies do not align with traditional Medicare coverage, exacerbating the coverage gap for those beneficiaries enrolled in those plans. Challenges presented by existing Medicare coverage policies can also affect the pipeline of innovation targeting unserved or underserved patient populations, which will suffer from compounding challenges. Finally, expedited Medicare coverage would facilitate the real-world data collection that is so important to continuing to evaluate the use and benefits of these devices and diagnostic tests.

AdvaMed is committed to working with CMS to achieve our mutually-shared goal of timely access of new innovations in health care diagnosis and treatment to patients.

A Path Forward

AdvaMed believes it is critical for CMS to find a path forward that can promote patient access to technologies that have the potential to improve and, in some cases, extend the lives of Medicare patients. AdvaMed is committed to working with CMS toward this result. CMS has expressed concerns regarding the MCIT rule as finalized,³ but these concerns could be addressed with modifications to MCIT that would lead to faster coverage of new technologies while at the same time prioritizing patient health and outcomes, as referenced in the September 15, 2021, proposed rule.

CMS' stated concerns regarding evidence gaps and the development of additional clinical evidence could be minimized through the establishment of a process that would expedite coverage of innovative technologies, building on successful elements of existing CMS processes, and providing the Agency with assurances that clinical evidence supports improved outcomes for Medicare beneficiaries.

A modified CMS MCIT process could include elements like the following:

Make MCIT A Voluntary Participation Program with Opt-In for MCIT Coverage Based on Eligibility Criteria

While not every breakthrough technology is intended for use in the Medicare population, those breakthroughs that are intended for Medicare patients should have access to an expedited pathway to coverage. For example, CMS could create an opt-in process for breakthrough technologies that builds on elements of existing CMS programs, like CMS' process for reviewing and covering technologies that are used in Investigational Device Exemption (IDE) clinical trials.

³ 86 FR 2987-3010.



The process could be limited to breakthrough technologies that are approved by the FDA, or it could potentially be broader and provide a mechanism for other new, non-breakthrough technologies. In the proposed rule, CMS discusses the need for a flexible coverage pathway that could provide faster coverage of new technologies that could include breakthrough devices as well as some non-breakthrough-designated or second to market devices or subsequent technologies of the same type and still prioritize patient health and outcomes.⁴ CMS could outline eligibility criteria, including:

- Technology is designated as a breakthrough technology by the FDA (if limited to breakthrough);
- Technology is approved or cleared by the FDA;
- Technology is relevant to the needs of the Medicare population;
- Additional criteria as determined by CMS.

This approach could include an opportunity for companies to opt-in to the program to seek Medicare coverage, and for CMS to be engaged with companies earlier in the process about their technologies. As part of the process, a company could present the relevant evidence developed to date and identify and discuss with CMS any known evidence gaps. CMS would have the opportunity to learn about the technology, its intended use and benefits to the Medicare population. Early engagement would also allow CMS to ask questions or provide feedback on the evidence that would support Medicare coverage, both immediately and in the long term.

An opt-in and early engagement process would ease CMS concerns regarding the number of devices that may seek coverage, as devices that are not Medicare-relevant or that pursue other existing coverage pathways would not be participants in an MCIT program. This approach would facilitate access to those breakthrough technologies that are approved for patients who have very limited disease monitoring and treatment options.

Feedback Process Between Breakthrough Technology Developers and CMS to Identify CMS Issues

Companies are eager to assist CMS in understanding their breakthrough devices, and an established communication pathway can help all parties convey critical information efficiently and streamline efforts proactively to address post-MCIT coverage issues, including ongoing evidence development. Companies could submit information to help CMS better understand the breakthrough technology, such as:

- General Information regarding the technology’s intended use, the targeted patient population, clinical workflow, therapeutic research value, and other information.
- Information on Medicare Relevance or Appropriateness and Impact. Company can explain/demonstrate how the technology improves outcomes for the Medicare population or is generalizable to the Medicare population.

⁴ 86 FR 51330



- Disparities/Health Equity Information. The company may highlight any known disparities in access to treatment for the condition addressed by the technology and suggest ways of addressing such disparities with the breakthrough-designated and approved device during the MCIT period.
- Other information as necessary to respond to CMS’ evidentiary questions.

The feedback process would allow CMS opportunity to ask questions and/or provide feedback to the manufacturer on clinical trial design, endpoints, expected outcomes in FDA clinical trials, and planned post-approval studies and registries that would provide CMS with assurance that the clinical evidence is relevant to or supports use in the Medicare population. During this process, CMS would identify any outstanding issues related to Medicare coverage.

Collaboration With Breakthrough Device Companies on Ongoing Evidence Development During the MCIT Coverage Period to Support Long-Term/Permanent Coverage Post-MCIT Period

Companies that would be eligible to utilize a new MCIT pathway for innovative/breakthrough technologies seek coverage in the short-term as well as permanent coverage beyond the MCIT period. Coverage provided soon after FDA clearance or approval, with extension beyond the initial MCIT period, incentivizes companies to develop and continue to collect additional Medicare-specific data during the MCIT coverage period which can better demonstrate benefit of new technologies for the Medicare population for the many years the product may be on the market.

Again, a process could include an opportunity for CMS to review and evaluate the evidence developed to date for its appropriateness for the Medicare population. The process also would allow companies and CMS to coordinate regarding identification of any evidence gaps and determine the best way to develop evidence to fill those gaps. Agreement on an evidence development plan for the MCIT period would provide CMS with a level of confidence that the necessary evidence is being developed. The process could include regular “check-ins” with CMS to ensure proper evidence development, as well as review and evaluation of results.

MCIT coverage should include all the safeguards that CMS currently uses for removing or modifying coverage. CMS could issue a non-coverage NCD, for example, if the Agency learned that a particular device may be harmful to Medicare beneficiaries, but CMS believes a more expeditious process allowing for other, case-specific, determinations is needed. Any revised process that would allow CMS to withdraw or remove coverage, either during or at the conclusion of the MCIT period, should be open and transparent, and provide for stakeholder input, particularly regarding whether a device is reasonable and necessary, or potentially harmful, based on clinical evidence.



CMS has an important role in determining coverage of breakthrough technologies. We understand that CMS may wish to see additional clinical data developed that is relevant to the Medicare population and we will continue to support evidence generation needed to close any evidence gaps for new technologies. However, it is also important to recognize that FDA approval or clearance does take into account the patient population for which a device is indicated, with approval labeling that could include Medicare patients.

Further evidence regarding the Medicare population could be collected during the four-year MCIT coverage period. It is critical to note that swift coverage of these new technologies will enable this evidence collection, in FDA-required post-approval studies and other real world evidence studies, which will be instrumental in achieving those goals and will help build a bridge to long-term coverage beyond the MCIT period.

Existing CMS Coverage Pathways

CMS requested feedback in the proposed rule on the existing coverage pathways. While there are existing coverage pathways for new technologies, including the National Coverage Determination (NCD) process, Local Coverage Determination (LCD) process, Coverage with Evidence Development (CED), Parallel Review, and claim-by-claim adjudication, many of these pathways are insufficient to address the variety of new technologies coming to market.

NCDs, and NCDs with CED, represent less than 10 percent of all Medicare coverage policy and are developed only for technologies that could have a large impact on Medicare, leaving out technologies that may better address health disparities or provide a significant benefit to a smaller patient population, including minority and underserved populations where no, or limited, alternatives exist. Often, these existing mechanisms for establishing coverage are time and resource intensive, for both companies and CMS, and the coverage, even when positive, can take years to put in place. For example, CED has provided some coverage contingent on additional data collection, but the relevant studies or registries can take months or years to implement, and the data collection often continues for years after the relevant clinical questions have been answered for coverage purposes. Additionally, with an increasing share of Medicare-eligible patients enrolling in MA plans, these existing processes can leave MA plan participants with uncertain coverage, which they likely were not aware of when they enrolled and which further inhibits collection of real-world evidence in the Medicare-eligible population.

We strongly believe that for devices and diagnostics that have been designated as breakthrough technologies, and that have completed rigorous FDA review, a new paradigm should be established that would provide expedited coverage. These devices are, by definition, meeting currently unmet needs for patients with severe illness that have no, or limited, alternatives for treatment.



CMS plays an important role in supporting the types of medical innovations that are changing patients’ lives. For this reason, CMS should look to new approaches that promote patient access and foster innovation by speeding coverage decision-making and improving health care outcomes.

Operational Issues

CMS has continued to reference certain operational challenges to implementing the MCIT program, including establishing coding and payment amounts, and making benefit category determinations (BCD). BCDs are often made implicitly through LCDs or claim-by-claim adjudication. Only through NCDs are BCDs made explicitly. Under the opt-in process described above, AdvaMed believes an applicant for coverage under MCIT could specify or suggest a potential benefit category as part of its application for MCIT eligibility. CMS could indicate if a technology does not qualify for MCIT because the product does not fit into a Medicare benefit category.

AdvaMed remains confident that existing coding and payment pathways, including provision of instructions necessary for claims processing, could be utilized for MCIT-eligible technologies as occurs today subsequent to NCDs and LCDs. Additionally, early engagement between manufacturers and CMS, as discussed above, would facilitate the necessary discussions that would lead to appropriate coding and payment assessments.

Further CMS has extensive experience with expediting coding and payment for medical devices with and without breakthrough designation through both the inpatient new technology add-on payment (NTAP) process and the hospital outpatient transitional passthrough (TPT) process, with TPT allowing for quarterly code creation for select technologies. CMS also is experienced with coding, payment, and benefit categories for breakthrough technologies under IDE studies. CMS can adapt established processes such as these to assign codes and payment for MCIT-covered technologies.

As CMS itself noted, for some devices that receive breakthrough designation from the FDA, the timeframe from the date a device receives the FDA-breakthrough designation to the date of market authorization could be months or potentially even years. We pointed out in our April 14, 2021, comment letter to CMS that FDA breakthrough designation is only the first step in a long process to ultimate FDA approval.

That time frame affords substantial lead-time for manufacturers to engage with CMS on these issues, to pursue necessary coding strategies, and to have discussions with CMS regarding the site of service, appropriate payment system, MS-DRG or APC placement, or other issues. Even if there is insufficient time to develop permanent codes and national payment amounts for MCIT-eligible technologies, CMS currently has the processes in place to operationalize coding and payment for these technologies (e.g., assignment of temporary codes, invoice pricing, holding of claims for some time-period, or other processes). As these issues are not unique to MCIT and arise with every type of coverage



determination, whether local or national, we do not believe they are sufficient to warrant withdrawing the MCIT program in its entirety. Further we believe these concerns are addressable in a modified MCIT program as they are currently under other coverage pathways.

Definition of “Reasonable and Necessary”

AdvaMed did not support and continues to oppose codification of the proposed definition of “reasonable and necessary.” In previous comments to CMS, AdvaMed expressed concerns about the inclusion of commercial insurance policies as part of the definition of reasonable and necessary when determining Medicare coverage, especially because commercial policies themselves lack transparency and processes for stakeholder engagement. As the “reasonable and necessary” definition and the MCIT rule are distinct from each other, we believe these policies can and should be considered separately in the future.

Conclusion

In summary, AdvaMed is disappointed that CMS has proposed to repeal the MCIT final rule, rather than propose reasonable modifications to address the Agency’s stated concerns. We urge CMS not to repeal the final rule, but to move forward expeditiously with a process that will accomplish the important goal of swiftly bringing life-changing medical innovations to Medicare beneficiaries. If CMS does repeal the MCIT final rule, we appeal to CMS to demonstrate its commitment to future rulemaking by December 15, 2021, and to provide a timeline for proposing a new rule. An MCIT program that provides Medicare coverage predictability and expedites patient access to new technologies is supported by an overwhelming majority of stakeholders, including AdvaMed.

We look forward to working together with CMS to advance our shared goal of expediting access to important health care innovations for the patients we serve. Please do not hesitate to reach out to Chandra Branham at cbranham@advamed.org if you have questions or need additional information.

Sincerely,



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Acting Head, Payment & Health Care Delivery Policy Department

