MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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October 15, 2021

Via Electronic Submission

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P2
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' [CMS–3372–P2]

Dear Administrator Brooks-LaSure:

The Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, is submitting this letter in response to the proposal by the Centers for Medicare and Medicaid Services (CMS) to repeal regulations that provide an expedited Medicare coverage pathway for new medical devices and diagnostics designated as breakthrough devices by the U.S. Food and Drug Administration (FDA) and define "reasonable and necessary" for purposes of Medicare coverage.[1]

For nearly 30 years, MDMA has represented the medical device industry in Washington, DC, supporting policies that promote medical innovation and patient access to lifesaving and life-changing medical technologies. MDMA's membership is broad and diverse, ranging from small start-ups to multi-national medical device companies.

I. Comments Regarding the Proposed Repeal of the MCIT Coverage Pathway for Breakthrough Medical Devices

Improving the health of Medicare beneficiaries by reducing the time between the receipt of FDA marketing authorization and the completion of the Medicare coverage, coding and payment changes needed to effectuate patient access is a core part of our mission. Significant progress toward that goal has been made over the past two decades through collaborative, bipartisan efforts with Congress and

[1] 86 Fed. Reg. 51,326 (Sep. 15, 2021).

successive administrations. The creation of a specific coverage pathway for innovative medical device and diagnostic technologies (hereinafter referred to collectively as "devices" or "technologies"), which has been proposed in bipartisan legislation going back to at least 2016,[2] represents another important step forward for Medicare beneficiaries whose medical needs are not well met by currently available technologies. As stated in the comment letter from one of the country's leading organizations promoting medical research, such a pathway "furthers the goals and objectives of the 21st Century Cures Act, a 2016 law that has played a pivotal role in responsibly reducing the time from bench to bedside for patient-critical medical advances."[3]

The "coverage gap"—which describes the significant amount of time that can elapse between FDA marketing authorization of an innovative medical device and the issuance of coverage policies providing access to the device for Medicare beneficiaries—is real, as is the difficulty innovators face in navigating the Medicare coverage process and in ascertaining the evidence that will be required to achieve coverage. The adverse impacts of the delay and uncertainty on beneficiaries and investment in new medical innovations are also real. The currently available pathways for defining Medicare coverage policy—the national coverage determination (NCD) process, the issuance of local coverage determinations (LCDs) by Medicare Administrative Contractors (MACs), and claim-by-claim adjudication by MACs—have proven insufficient to address those adverse impacts, as have other initiatives such as FDA-CMS parallel review. That is why ***an overwhelming majority of comment letters submitted in response to either the original MCIT proposed rule and the subsequent interim final rule—from not just device manufacturers (as highlighted by CMS), but also patients and patient advocates, providers and medical specialty societies, investors, and others—supported creation of an expedited coverage pathway for breakthrough technologies.***

MDMA submitted detailed comments in response to both the MCIT proposed rule and the subsequent interim final rule delaying implementation.[4] In our comment letters and other communications with CMS and the Department of Health and Human Services (HHS), we expressed our strong support for implementation of the MCIT coverage pathway. We also provided recommendations for resolving questions and concerns identified by the agency, along with other possible improvements. ***We are disappointed that CMS does not intend to move forward with implementation at this time, as this means that measures to speed access for Medicare beneficiaries to breakthrough innovations that promise improvement in their care will be delayed.***

Despite our disappointment, we acknowledge the operational challenges and other implementation issues raised by CMS and understand that the agency may be constrained in its ability to resolve those issues within the framework of the existing MCIT rulemaking process. We also are pleased to note that, although the proposed repeal reflects the agency's reconsideration of certain aspects of the final rule, CMS does not appear to be stepping back from the goals that prompted the development of the MCIT rule. Rather, as the agency states in the preamble,

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[2] *See, e.g.,* H.R. 5333, Ensuring Patient Access to Critical Breakthrough Products Act of 2019 (116th Congress); H.R. 5997, Ensuring Patient Access to Critical Breakthrough Products Act of 2019 (115th Congress); and H.R. 5009, Ensuring Patient Access to Critical Breakthrough Products Act of 2016 (114th Congress).

[3] Letter from Research! America to CMS Administrator Seema Verma, Nov. 2, 2020 (Docket No. CMS-3372-P).

[4] Letter from Mark Leahey, CEO of the Medical Device Manufacturers Association, to CMS Administrator Seema Verma, Nov. 2, 2020 (Docket No. CMS-3372-P); Letter from Mark Leahey, CEO of the Medical Device Manufacturers Association, to CMS Acting Administrator Elizabeth Richter, Apr. 16, 2021 (Docket No. CMS-3372-IFC).

> we do not believe that the final rule as currently drafted, is the best way to achieve the goals of MCIT as outlined in the MCIT/R&N final rule, in particular, to more precisely meet the needs of Medicare beneficiaries and other stakeholders in a timely fashion. We believe that there are other ways to achieve our stated goals.[5]

Finally, we appreciate the agency's statement that it will explore future rulemaking aimed at reducing the time between FDA market authorization of innovative medical technologies and coverage of those new diagnostics and therapies for Medicare beneficiaries.[6] As a result, MDMA has chosen to focus on working with CMS and other stakeholders on a new rule.

Recognizing the overwhelming support from stakeholders that is evident in the MCIT rulemaking record, MDMA urges CMS to move forward quickly to develop, propose and finalize a new rule to create an expedited coverage pathway for innovative new technologies that can improve care for Medicare beneficiaries. Creating an expedited coverage pathway for important and innovative new medical technologies will expand treatment choices for beneficiaries and physicians, support the collection of additional clinical evidence that can further improve care, and foster investment in the next generation of life-saving and life-improving innovations. CMS should not forgo the opportunity to leverage the stakeholder engagement prompted by the MCIT rulemaking to improve the Medicare coverage process and should begin work on a new proposed rule without further delay. Because of this engagement and the significant amount of substantive public input gathered over the course of three open comment periods, ***we believe that CMS should set a goal of completing the new rulemaking and implementing the coverage pathway no later than June 30, 2022.***

The concerns raised by a small minority of public comments about the design of the MCIT coverage pathway should be weighed in light of the benefit of providing earlier access to new therapies for patients covered by Medicare. We believe any material concerns can be addressed and resolved through a new proposed rule. These may include matters such as:

- more refined criteria for determining eligibility for the expedited pathway,
- a process for the manufacturer of an eligible device to engage with CMS prior to FDA market authorization, facilitating timely implementation of coverage upon or closely following market introduction,
- a framework for data collection during the transitional coverage period focused on developing additional evidence generalizable to the Medicare population and relevant to the refinement of coverage policy, especially with regard to appropriateness, and
- criteria and procedures for CMS to withdraw coverage prior to the expiration of the transitional period.

II. Comments Regarding the Definition of "Reasonable and Necessary"

As discussed in our previous comment letters, MDMA believes that the portion of the final rule related to the definition of "reasonable and necessary" for purposes of determining Medicare coverage of an item or service, as set forth in 42 C.F.R. section 405.201, can be divided into two distinct parts—the codification of the longstanding definition of "reasonable and necessary" and the proposed use of

[5] 86 Fed. Reg. at 51,327.

[6] *Id.* at 51,330.

coverage policies from insurers in the commercial market in some instances as determinative in evaluating whether a particular item or service meets certain requirements set forth in the definition.

CMS has not provided a clear rationale for why codification of the definition of "reasonable and necessary" in regulation is necessary or beneficial. Though we are not opposed to the definition, we believe that in order for stakeholders to fully consider the potential impact and provide comment, CMS should articulate more clearly the potential benefits and drawbacks associated with codification as compared to the status quo.

We oppose the use of coverage policies from insurers operating in the commercial market as a determinative basis for Medicare coverage. We believe it is inappropriate to make access to new medical technologies for Medicare beneficiaries contingent on—or at a minimum subject to—decisions by non-governmental entities driven by factors and motivations that are unrelated, and potentially contrary to, the interests of the Medicare program and beneficiaries. Moreover, medical technology manufacturers, physician specialty societies, beneficiary advocates and others have been working with CMS for more than two decades to improve the Medicare coverage determination process, especially with regard to transparency, timeliness, and opportunity for stakeholder input. Very few of those improvements exist in the commercial payer coverage process. There is little transparency regarding criteria or process; there is typically no right or even opportunity for stakeholders to provide input and, in fact, many insurers outright refuse to meet with medical device manufacturers or outside clinical experts; and there is no appeals process.

For these reasons, which are discussed in greater detail in our previous comment letters, we support the repeal of the provisions of the final rule related to the definition of "reasonable and necessary" and in particular to the development of guidance on the use of commercial coverage policies in Medicare coverage determinations.

Conclusion

We appreciate every opportunity to work with CMS to improve access for Medicare beneficiaries to new medical technologies, providing more therapeutic options for patients and providers and improving outcomes, and to bring greater certainty and transparency to the coverage process.

MDMA looks forward to working with CMS on development of a new accelerated coverage pathway for innovative devices. If we can be of any further assistance, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President and CEO
Medical Device Manufacturers Association