MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street, NW
Suite 400W
Washington, DC 20005
Phone (202) 354-7171
Fax (202) 354-7176

November 2, 2020

Via Electronic Submission

Ms. Seema Verma Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
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–P]

Dear Administrator Verma:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, we appreciate the opportunity to provide the following comments to the proposed rule on coverage for breakthrough medical devices and the definition of "reasonable and necessary" for purposes of determining coverage.[1]

As stated in the preamble to the proposed rule, the Administration and Centers for Medicare & Medicaid Services (CMS) are "committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes."[2] Furthermore, CMS is issuing the proposed rule as part of its effort to implement the Administration's policy set forth in Section 6 of the President's Executive Order (E.O.) on Protecting and Improving Medicare for Our Nation's Seniors (E.O. 13890).[3] We enthusiastically support the Administration's objectives as laid out in

[1] 85 Fed. Reg. 54327-54339 (Sep. 1, 2020).
[2] *Id.* at 54328.
[3] E.O. 13890 (Oct. 3, 2019) (https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/) Section 6 of EO provides that "Within 1 year of the date of this order, the Secretary shall propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients by:

> "(a) streamlining the approval, coverage, and coding process so that innovative products are brought to market faster, and so that such products, including breakthrough medical devices and advances in telehealth services and similar technologies, are appropriately reimbursed and widely available, consistent with the principles of patient safety, market-based policies, and value for patients. This process shall include:
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> > "(i) adopting regulations and guidance that minimize and eliminate, as appropriate, the time and steps between approval by the Food and Drug Administration (FDA) and coverage decisions by the Centers for Medicare and Medicaid Services (CMS);
> >
> > "(ii) clarifying the application of coverage standards, including the evidence standards CMS uses in applying its reasonable-and-necessary standard, the standards for deciding appeals of coverage decisions,

Section 6. Minimizing the time between the receipt of marketing authorization from the Food and Drug Administration (FDA) and the completion of the coverage, coding and payment changes needed to effectuate patient access will improve the health of Medicare beneficiaries and encourage investment in more technologies that will drive continued improvements in patient outcomes.

We appreciate the careful work that has gone into developing this proposed rule, as well as the opportunity to provide these comments on behalf of the hundreds of medical technology innovators who are members of MDMA

General Comments

We believe it is important to note up front that the proposed rule includes two separate and distinct proposals—the establishment of a four-year period of automatic coverage for medical devices upon receipt of market authorization from the FDA for any device designated by the FDA as a "breakthrough device"; and, separately, the codification in regulation of a definition of "reasonable and necessary" for purposes of determining Medicare coverage of an item or service. Furthermore, the latter proposal can be further divided into two distinct parts—the codification of the longstanding definition of reasonable and necessary, and the proposed use of coverage policies from insurers in the commercial market as determinative in evaluating whether a particular item or service meets certain requirements set forth in the definition. In developing the final rule, MDMA urges CMS to evaluate each of these distinct proposals independently, and to move forward expeditiously with adopting those parts with broad stakeholder support, while rejecting or allowing for additional consideration of parts for which there is substantial stakeholder opposition or unresolved questions.

In addition, the final rule should be consistent with the intent of E.O. 13890, which is to expand access to innovative medical therapies for Medicare beneficiaries. As will be described below in our detailed comments, we are concerned that certain proposals could actually adversely impact access for Medicare beneficiaries in ways that are both direct (*e.g.,* by imposing coverage limits from the commercial market that otherwise would not have been adopted by CMS for Medicare beneficiaries) and indirect (*e.g.,* by overburdening the coverage determination process in a way that delays the development of local and national coverage policies.)

We appreciate the clarity with which CMS set forth specific requests for comment in the proposed rule, especially with regard to the proposed MCIT coverage pathway. While there is some overlap between some of the requests, to the extent possible we have organized our comments to address each specific question regarding the MCIT pathway in the order they are raised in the proposed rule. With regard to the definition of reasonable and necessary, we have organized our comments around the two general questions that are presented by the proposed rule: the codification of the definition and the use of commercial coverage policies by CMS and Medicare Administrative Contractors (MACs) in making coverage determinations.

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and the prioritization and timeline for each National Coverage Determination process in light of changes made to local coverage determination processes; and

"(iii) identifying challenges to the use of parallel FDA and CMS review and proposing changes to address those challenges[.]"

PART I – MCIT Pathway for Coverage of FDA-Designated Breakthrough Devices

MDMA strongly supports the agency's proposal to create a new MCIT pathway that will provide a temporary period of automatic Medicare coverage of FDA-designated breakthrough devices commencing immediately following issuance of FDA marketing authorization, and urges CMS to move forward with adopting a final rule implementing the proposal at the earliest opportunity, with specific refinements suggested below.

A. MDMA supports the maintenance of the pathways currently available for Medicare coverage, and recommends specific actions that CMS can take to achieve the goals set out by E.O. 13890. MDMA also supports the establishment of a new office at CMS to coordinate coverage, coding and payment described in the CMS press release announcing the proposed rule.

CMS seeks comment regarding if any of the existing coverage pathways should be modified to achieve the goals set out by E.O. 13890.[4]

We believe providing multiple pathways to evaluate and provide coverage for new medical technologies, including through national coverage determinations (NCDs), local coverage determinations (LCDs), claim-by-claim adjudication by MACs, the Investigational Device Exemption (IDE) and Clinical Trial Policies, and FDA-CMS Parallel Review, provides flexibility for both the Medicare program and medical technology manufacturers and, when conducted efficiently and grounded on appropriate clinical criteria, can allow for both timely initial coverage and the evolution of coverage over time.

Most importantly, CMS should increase its focus on ensuring transparency in the coverage process. This includes transparency related to specific technologies, such as the clinical questions relevant to the Medicare population that the agency believes are unresolved by FDA market authorization and the evidence needed to address those questions. It also includes procedural matters, such as the current status of a particular coverage review, the number and subject matter of all NCD and LCD coverage reviews in the queue, and the performance of CMS and each MAC in adhering to review timelines.

We are particularly concerned about what we believe is a hesitancy on the part of CMS to exercise appropriate oversight of the performance of MACs in coverage determinations. Through both claim-by-claim adjudication and the development of LCDs, the MACs play a significant role in determining the extent to which Medicare beneficiaries have access to medical technologies, especially innovative technologies. We appreciate steps that CMS has taken to eliminate inappropriate barriers to access, such as requiring MACs to eliminate policies that categorically define procedures identified by a Category III Current Procedural Terminology (CPT®) code as "experimental and investigational" and, thus, excluded from coverage; however, for technologies other than the relatively small number that receive FDA-designated breakthrough device status, the goals outlined in E.O. 13890 will not be achieved without even greater effort to require local contractors to clarify coverage standards, increase transparency and stakeholder engagement, and

[4] 85 Fed. Reg. at 54330.

devote sufficient resources to efficiently manage coverage determinations. For example, MDMA urges CMS to require MACs to set and publish specific timelines for completing an LCD review at the time a review commences, including requests for reconsideration of an existing LCD. CMS also should undertake a review of inconsistencies between coverage policies established by MACs and coverage of same items or services by Medicare Advantage plans operating in the corresponding MAC jurisdiction.

With regard to specific pathways, there is general acknowledgement that the Parallel Review process has faced challenges, and neither the uptake nor anticipated benefits have been realized. This is reflected in specific direction provided to CMS and FDA in E.O. 13890. We look forward to collaborating with both agencies in evaluating and improving the program to meet the objective of minimizing or eliminating the time between FDA approval and issuance of an NCD for eligible devices.

Finally, MDMA and its members strongly endorse the agency's plan to establish a new office to coordinate coverage, coding and payment. While the current proposed rule deals only with the coverage process, the reality is that providing access to Medicare beneficiaries to new items or services often requires a combination of actions related to coverage, coding and payment, and sometimes all three. For example, MAAA (multianalyte assays with algorithmic analyses) tests require a new code (most commonly a new Proprietary Laboratory Analyses (PLA) code assigned via the American Medical Association (AMA) CPT process), and the length of time from requesting a code to potentially getting coverage for that new test is six quarters at a minimum. Existing mechanisms that separate coverage, coding and payment in siloed decision-making must be better aligned if CMS is to "demolish the existing bureaucratic barriers that have created a valley of death for innovative products, resulting in lag times and lack of access for America's seniors". [5]

We believe this new office could have a significant impact on minimizing the time between FDA market authorization and access for Medicare beneficiaries by (1) evaluating the intersection between coverage, coding and payment decisions, enhancing opportunities for coordination between the relevant CMS departments and stakeholder organizations, and recommending procedural changes aimed at reducing timelines; and (2) by working directly with individual manufacturers to navigate the process in a coordinated and holistic manner for new technologies. We look forward to working with the agency to define the priorities for the new office and ask that CMS include as part of its mandate the collaboration with stakeholders as well as the issuance of reports on its priorities, activities and accomplishments on at least an annual basis

B. MDMA agrees that manufacturers of breakthrough devices should not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway. That said, we ask CMS to provide clear information to manufacturers utilizing the MCIT pathway about the clinical questions relevant to the Medicare population that the agency believes are unresolved by FDA market authorization and the evidence needed to support permanent coverage after the four-year period ends and to be flexible about the type of evidence that is acceptable.

[5] CMS, "CMS Administrator Announces Proposal to Spur Innovation for America's Seniors, Roundtable Discussion Among Health Industry Leaders in Minneapolis", September 1, 2020 (press release).

CMS is proposing that manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway. The agency is requesting comment as to whether it should require or incentivize manufacturers to provide data about outcomes or should be obligated to enter into a clinical study similar to CMS's Coverage with Evidence Development (CED) paradigm.[6]

MDMA agrees that data collection should not be mandated during the initial coverage period for breakthrough devices. We believe the maintenance of coverage beyond the initial period of automatic coverage provides enough motivation for a manufacturer to gather data that might be needed to address questions related to appropriateness of the therapy for the Medicare population during the initial coverage period. We note that not all technologies will raise such questions, so any across-the-board requirement could result in unnecessary data collection requirements. In addition, some manufacturers will be conducting FDA postmarket studies, and we have concerns about CMS mandates for data collection that would be inconsistent or compete for enrollment.

As suggested above, MDMA believes it will be critical for CMS to provide clear information to manufacturers utilizing in the MCIT pathway about the clinical questions relevant to the Medicare population that the agency believes are unresolved by FDA market authorization and the evidence needed to support permanent coverage after four-year period ends. The agency should be flexible in the type of evidence that will be acceptable. In addition, because it is foreseeable that similar devices for the same indications from other manufacturers will follow a breakthrough device to market, CMS should ensure that all manufacturers with products in the breakthrough device's class have the opportunity to participate in collaborative discussions related to evidence requirements to support coverage beyond the MCIT period.

C. MDMA is concerned about abrupt disruption in beneficiary access to breakthrough technologies following the expiration of the MCIT period, and believes that specific criteria that limit coverage should be adopted through the NCD or LCD process. MDMA opposes the automatic triggering of an NCD or LCD review in the absence of specific clinical questions about appropriateness for use in the Medicare population.

CMS is proposing that at the end of the four-year MCIT pathway, coverage of the breakthrough device would be subject to one of these possible outcomes: (1) NCD (affirmative coverage, which may include facility or patient criteria); (2) NCD (non-coverage); or (3) MAC discretion (claim-by-claim adjudication or LCD). The agency has requested comment on whether CMS should open a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within six months of the expiration date of the four-year MCIT period.[7]

MDMA's comments regarding the appropriate length of the initial MCIT coverage period are set forth below in Comment I.G. Regarding the potential outcomes following the MCIT period, MDMA believes that there should be an ongoing presumption of coverage for a device when used in accordance with the FDA-approved indications in the absence of an NCD or LCD.

[6] *Id.* at 54330-54331.
[7] *Id.* at 54331.

We oppose any requirement that would automatically trigger an NCD review upon failure by a MAC to adopt a specific LCD. For many breakthrough technologies, coverage and beneficiary access to the therapy could continue unhindered without the need for adoption of a formal coverage policy. If CMS or a MAC believes that issues related to appropriateness for use in the Medicare population require more specific coverage requirements, the NCD or LCD process provides the appropriate mechanism for evaluating those issues and developing additional clinically-supported coverage criteria transparently and with public input; however, forcing an NCD based upon an arbitrary time metric, and in the absence of questions related to appropriateness, would not be consistent with the goals of the NCD process, and would needlessly divert limited resources to unnecessary administrative activity.

D. MDMA supports the CMS proposal to limit automatic eligibility for coverage to FDA-designated breakthrough devices. In addition, we recommend that the final rule include discretion for CMS to accept into the MCIT pathway devices that have not received a breakthrough designation but for which the agency believes expediting access is in the interest of Medicare beneficiaries.

MDMA supports, in general, CMS's proposal to limit the MCIT pathway to FDA-designated breakthrough devices,[8] at least with regard to automatic eligibility for coverage that would be subject only to the manufacturer's decision to opt-in. We believe this is a significant, initial step forward to achieving the goal of minimizing the time between FDA approval of innovative medical devices and access by Medicare beneficiaries.

We note, however, that there is no indication that E.O. 13890 intended "breakthrough medical devices" to be limited to the definition set forth in the section 515B(d)(1) of the Food, Drug and Cosmetic Act (21 U.S.C. 360e–3(d)(1)). We do believe there are likely to be circumstances where a non-breakthrough designated medical device has the potential to offer clinical benefits for Medicare beneficiaries that are different from or in addition to those offered by existing therapies, and that CMS should have the flexibility to provide coverage, limited to a specific period of time, without the need to undertake a full NCD evaluation and approve a formal CED study. Discretionary MCIT eligibility would be a valuable tool in a situation where the manufacturer of an innovative new technology has engaged in collaborative discussions with CMS during the FDA review process, and CMS wishes to incentivize and support specific data collection activities relevant to the Medicare program following FDA marketing authorization.

MDMA and its members are specifically concerned about decisions by MACs that deny access for Medicare beneficiaries to technologies that have been granted New Technology Add-on Payment (NTAP) or transitional pass-through (TPT) payment. Such coverage decisions undermine purpose of NTAP and TPT, which is to support access to care that represents a substantial clinical improvement relative to existing therapies while collecting data needed to accurately establish permanent payment for the technology. The adoption of the rule as proposed would expand access to NTAP and TPT devices with an FDA-breakthrough designation; however, MDMA believes CMS also should open the MCIT pathway to non-breakthrough devices when CMS determines that the substantial clinical improvement offered by the technology justifies temporary national coverage.

[8] *Id.*

Specifically, we ask CMS to revise the definition of "Breakthrough device" in proposed 42 CFR § 405.601(b) to state:

> *Breakthrough device* means a device that receives such designation by the Food and Drug Administration (FDA) (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) or a device that the Centers for Medicare & Medicaid Services otherwise determines is a breakthrough that has the potential to offer clinical benefits for Medicare beneficiaries that are different from or in addition to those offered by existing therapies.

Similarly, proposed 42 CFR § 405.603(a) should be revised to state, "That are FDA-designated or CMS-designated breakthrough devices."

E. MDMA supports the inclusion of diagnostic and physiologic monitoring products as eligible for the MCIT pathway. MDMA also requests clarification that for breakthrough combination products for which the medical device approval process is the primary regulatory pathway, coverage will extend to all components of the combination product. Finally, we urge CMS to take the broadest possible view in determining whether a breakthrough device falls within a Medicare benefit category.

CMS has requested comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA.[9]

In the preamble discussion of the proposed rule, CMS indicates that its proposal does not include coverage for diagnostic tests[10]; however, the language proposed to amend the Code of Federal Regulations does not include such a limitation.[11] MDMA believes that the MCIT pathway should be open to all product types regulated by the FDA Center for Devices and Radiological Health (CDRH). This includes diagnostics and monitoring devices. Diagnostics and monitoring devices are defined as medical devices by statute,[12] and they are reviewed for market authorization by FDA using the same systems and classifications as therapeutic devices, including eligibility for designation as a breakthrough device.[13] CMS provides no specific explanation in the preamble for

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[9] *Id.*

[10] *Id.* at 54334 ("Based on the explicit mention of devices in E.O. 13890 and our interaction and feedback from stakeholders who expressed their concern that there is more uncertainty of coverage for devices than for other items and services (for example, diagnostics, drugs and biologics), this proposed policy is for devices only.").

[11] *Id*. at 54338.

[12] "Medical device" is defined in section 201(h) of the Food, Drug and Cosmetic Act (21 U.S.C. §321(h)) as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 360j(*o*) of this title."

[13] *See* https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s3.

the supposed exclusion of diagnostic devices from eligibility for the MCIT pathway. Because such exclusion would be inconsistent with the goals of E.O. 13890, we ask CMS to clarify that diagnostic and physiologic monitoring devices will be eligible for the MCIT pathway on the same basis as other medical devices.

While we do not wish to take a position on non-device products, we do note that most drugs and biologics do not face the same barriers to coverage as medical devices for FDA-approved indications. To the extent that there are concerns that opening up the MCIT pathway to products beyond medical devices could result in an overburdening of the CMS resources available for activities related to MCIT, such as meeting with manufacturers to provide guidance on data requirements to support continued coverage, we ask the agency defer expansion to additional product types until the program is established and operating smoothly.

We also ask that in addition to the acknowledgement in the preamble to the proposed rule that the MCIT pathway is open to combination products regulated by the FDA as medical devices[14]—*i.e.*, in which CDRH has been assigned the primary responsibility for conducting the premarket review—CMS should clarify that coverage will extend to all components of the product.

Finally, we understand that the exclusion from the MCIT pathway of any medical device that does not fall within a Medicare benefit category is intended to reflect statutory limitations on the agency's authority; however, it is well-established that an agency is entitled to make reasonable interpretations of the statute it administers in the absence of clear congressional direction to the contrary.[15] MDMA urges CMS to exercise it authority to interpret statutory limits on Medicare benefits in such a manner as to provide Medicare beneficiaries access to the widest possible range of breakthrough technologies that offer improved clinical outcomes.

F. MDMA supports an "opt-in" approach for breakthrough devices as the best means to limit the burden imposed on either the manufacturer or CMS.

We agree with the agency's belief that manufacturers will welcome this new coverage pathway, and further appreciate the desire by CMS to preserve the manufacturers' business judgment and not assume which Medicare coverage pathway a given manufacturer of a breakthrough device would prefer.[16]

MDMA believes that good arguments can be made for both "opt-in" and the "opt-out" alternative; however, we lean toward support of the agency's opt-in proposal as a means to confirm for the agency the manufacturer's awareness of the MCIT coverage pathway, the temporary nature of MCIT coverage, and the need to adequately plan for any postmarket data collection that might be needed to support long-term coverage. We urge CMS to work with FDA to ensure that a notification to a manufacturer about FDA breakthrough device designation also includes specific information about the MCIT coverage pathway, including the need to opt-in and information on the appropriate CMS staff to contact for assistance. Collaboration between the manufacturer of breakthrough devices and CMS at this stage will also provide the opportunity to evaluate other

[14] 85 Fed. Reg. at 54329.
[15] *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 468 U.S. 837 (1984).
[16] *Id.* at 54331.

reimbursement issues beyond coverage, such as the need for a new code and the possibility or mechanisms to address potential payment shortfalls that could act as barriers to beneficiary access even with mandated national coverage.

The ability to opt-in, as well as the ability to withdraw an opt-in election, should extend up until the date of FDA market authorization. The same timeframes could apply should CMS choose an opt-out system.

MDMA recommends that CMS adopt a specific process for providing notice to the MACs, Medicare Advantage plans, providers, beneficiaries and other stakeholders regarding devices that are covered under the MCIT pathway. This could be done on a dedicated part of the CMS website, through publication in the Federal Register (possibly as part of any relevant rule based upon the benefit category or payment system), or other mechanism.

G. MDMA supports the proposed four-year initial coverage period for devices covered through the MCIT pathway, and we believe early termination of MCIT coverage pursuant to the adoption of an NCD should only occur if the NCD review is initiated by the manufacturer. In addition, MDMA believes that CMS should have the discretion to extend the four-year period when warranted, especially if related to the ongoing collection of data to support subsequent development of an NCD or when necessary to maintain equitable coverage treatment of devices in the same class with the same indication. We support use of the date of FDA marketing authorization as the start of the four-year period, but consistent with agency practice related to NTAP and TPT device payment programs, we ask that CMS use the date of market availability in situations where the manufacturer provides documentation that justifies using the later date. Finally, we support the inclusion of all devices that have received a breakthrough device designation from FDA, and believe all devices should be granted MCIT coverage for four years from either the date of marketing authorization/market availability or the effective date of the final rule, whichever comes later.

CMS is proposing that coverage under the MCIT pathway for breakthrough devices will end four years from the date the device received FDA market authorization, provided that the period could end earlier if the device becomes subject to an NCD, regulation, statute, or if the device can no longer be lawfully marketed.[17] MDMA supports the four-year period as a general rule, but also supports providing the agency with discretion to extend the period when doing so would be in the best interest of beneficiary access. We believe certainty regarding ongoing coverage would be particularly important in situations where the manufacturer has undertaken data collection on a technology that is of significant relevance to the Medicare population, and that data collection is specifically intended to support the adoption of an NCD defining long term coverage criteria. Four years may or may not be enough time to collect data based on the type and design of the evidence collection and the size of the target population. For technologies addressing procedures of very high volume, substantial data may be collected in two years, whereas for others, it could take six.

[17] *Id.* at 54334.

MDMA also anticipates that multiple devices that utilize similar technology with the same proposed intended use could be moving through the FDA review process at or about the same time, with some or all receiving breakthrough designation, but ultimately receiving final FDA approval or clearance on different dates. To maintain equitable coverage treatment, CMS should provide MCIT coverage to all devices within a class (as determined by technology and intended use) and maintain MCIT coverage for all until at least four years after the date of market authorization for the last breakthrough-designated device.

With regard to the date upon which the four-year period will start, CMS has recognized in the NTAP and transitional device pass-through programs that sometimes there is a lag between FDA market authorization and commercial launch (*i.e.,* market availability.) This is especially true for small, start-up companies that have limited resources to manufacture and build inventory, establish distribution, hire sales and technical support staff, conduct surgeon training, etc. We ask that CMS adopt a policy similar to that used for the NTAP and transitional device pass-through programs and allow manufacturers to submit documentation supporting use of the date of market availability when it more accurately reflects when Medicare beneficiaries first have access to the technology and to change the date upon which the four-year coverage period starts accordingly.

Finally in relation to the coverage period, we are unclear as to the situations in which CMS would anticipate adopting an NCD for a breakthrough device that would have the effect of terminating the MCIT coverage policy before the end of the four-year period. We believe the initiation of an NCD coverage review during the MCIT period should only be undertaken at the request of the manufacturer, and adoption of an NCD prior to the end of the four-year MCIT period should not reduce access to the technology for Medicare beneficiaries.

CMS has also proposed that the MCIT pathway will be available for breakthrough devices that received FDA market authorization no more than two calendar years prior to the effective date of the final rule, and that the four-year coverage period for breakthrough devices market authorized prior to the effective date of this rule will be measured from the date of market authorization.[18] MDMA believes that there are only a limited number of breakthrough devices that fall outside the two-year window. In addition, patient access to many breakthrough devices has been hindered by omnibus coverage policies that deny coverage of technologies described by a Category III CPT code as "experimental or investigational." In light of the limited number of affected devices and the impact of omnibus experimental or investigational non-coverage policies, MDMA asks CMS to ensure all devices covered under the MCIT pathway receive a minimum of four years of coverage, as measured from the date of marketing authorization/market availability or the effective date of coverage under the final rule, whichever is later, to ensure adequate opportunity for discussions with CMS regarding evidentiary requirements and subsequent data collection. Without a reasonable period of eligibility, we believe there will be limited interest in the program from manufacturers of existing breakthrough devices, resulting in continued barriers to access for Medicare beneficiaries and a lost opportunity for the collection of data that could support long term coverage policy.

H. MDMA supports limiting automatic national coverage under the MCIT pathway to the FDA-approved indication, but believes that coverage under the MCIT pathway

[18] *Id.*

should not be interpreted to preclude coverage of off-label uses under other coverage pathways.

CMS is proposing that to be part of the MCIT pathway, the device must be used according to its FDA approved or cleared indications for use, and is requesting comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support.[19]

MDMA supports limiting coverage under the MCIT pathway to the FDA-approved indication. However, we ask that CMS explicitly provide within the rule that the limitation of MCIT coverage to the FDA-approved indication should not be interpreted as non-coverage for any off-label use, unless coverage of such off-label use is specifically denied in an applicable NCD or LCD. Beneficiaries should retain access to off label therapies recommended by their physician when approved by CMS or a MAC. We recommend that CMS add the following statement at the end of proposed section 405.603:

> "Coverage of medical devices for the FDA approved or cleared indications for use under the MCIT pathway shall not preclude coverage for other indications for use under other available coverage pathways."

We also believe automatic national coverage under the MCIT pathway should extend to expanded indications approved by FDA during the MCIT period. In the event that a new indication receives its own breakthrough designation, the new indication would be entitled to a full four years of coverage under the MCIT pathway.

I. MDMA believes that the automatic exclusion of devices that are subject to a current NCD is unwarranted.

In proposed 42 CFR § 405.603(e), CMS excludes from eligibility for MCIT any breakthrough device that is the subject of a current NCD.[20] We do not understand the need for this provision, and while CMS states that such a situation might happen rarely because breakthrough devices are new technologies that are not likely to have been previously reviewed through the NCD process, we are concerned about the potential unintended consequences. We are particularly concerned about a medical device that has potential application for a variety of different disease conditions. It is foreseeable that CMS could adopt an NCD providing coverage for an early FDA-approved indication; yet as potential applications of the therapy evolve and expand, the rule, as proposed, would prohibit coverage of future indications through the MCIT pathway simply due to the existence of an NCD applicable to the device, even without an explicit statement of noncoverage for other indications. We urge CMS to eliminate this provision of the proposed regulation or, at a minimum, apply it only when a previously adopted NCD allows for coverage of the FDA-authorized breakthrough device under criteria that are consistent with the labeled indications for use.

PART II – Reasonable and Necessary/Use of Commercial Insurer Coverage Policies

[19] *Id.*
[20] *Id.*

MDMA generally supports the longstanding definition of "reasonable and necessary" as set forth Chapter 13 of the Medicare Program Integrity Manual (PIM). That said, we do not believe CMS has stated a clear rationale for why codification of the definition in regulation is necessary or beneficial. Codification of the definition is not required in order to achieve the goals set forth in E.O. 13890, which contemplates the use of both "regulatory and sub-regulatory changes"[21] and both "regulations and guidance."[22] Though we are not opposed to codification, it would be helpful for the agency to articulate more clearly the potential benefits and drawbacks associated with codification as compared to the status quo. More importantly, regardless of whether the agency moves forward with codification, we believe CMS should clearly establish that FDA market authorization is sufficient to demonstrate that a technology is "safe and effective" and "not experimental or investigational" when used in accordance with its labeled indications. We believe doing so will substantially reduce the time between FDA marketing authorization and access for Medicare beneficiaries.

MDMA strongly opposes the proposal to use coverage policies from insurers operating in the commercial market as a basis for Medicare coverage. We believe it would be 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. We also believe the proposal as set forth would create insurmountable operational challenges for CMS and the MACs. Finally, we believe that while the intent of the proposal is to achieve the goals set forth in E.O. 13890, it could ultimately have the opposite effect—undermining and distracting the agency from efforts to improve transparency and timeliness in the LCD and NCD processes.

Given the need for more detailed explanation and consideration of the rationale and effect of codifying the definition of "reasonable and necessary" in regulation, significant opposition among stakeholders to the proposed use of commercial coverage policies as determinative to set Medicare coverage policy, and significant unanswered questions regarding how reviews of commercial coverage policies would work and the effect it would have on beneficiary access to items and services, ***MDMA believes the agency should not move forward with promulgation of a final rule revising section 405.201 without additional notice and comment rulemaking.*** And as indicated in our introductory comments, ***CMS should decouple the proposed creation of the MCIT pathway from the proposals related to the definition of "reasonable and necessary," and move forward expeditiously with promulgation of a final rule creating the MCIT pathway, which we believe enjoys broad stakeholder support.***

Our comments are further detailed below.

A. MDMA generally supports the longstanding definition of "reasonable and necessary" as set forth in Chapter 13 of the Program Integrity Manual (PIM); however, we are concerned that the requirement that an item or service be "one that meets, but that does not exceed, the patient's medical need", if stringently interpreted, could limit

[21] E.O. 13890 sec. 6.
[22] *Id.* at sec. 6(a)(i).

beneficiary access to some important breakthrough technologies. We also believe CMS should clearly state in guidance or regulation that medical devices authorized for marketing by FDA are "safe and effective" and "not experimental or investigational" for their labeled use.

MDMA recommends that CMS strike "but that does not exceed" from the definition of reasonable and necessary. The language suggests the ability to define an individual patient's medical need with a level of precision that may not be possible, and we are concerned that overly stringent interpretation of this limitation can hinder beneficiary access to therapy which the treating physician believes necessary for the patient's care. For example, innovations in cancer diagnostic technology, such as liquid biopsy, promise to provide comprehensive information for early stage cancer that will allow providers and patients to make more informed decisions with better health outcomes; but, as written, this could be interpreted as a barrier to providing critical information at an early stage in a patient's cancer diagnosis.

MDMA also believes determinations that FDA-approved devices are "not safe and effective" or "experimental or investigational" even when used in accordance with their labeled indications for use are a significant factor in the lag between the issuance of FDA marketing authorization for a new technology and access for Medicare beneficiaries. To further the goals set forth in E.O. 13890, MDMA recommends that CMS insert the following statement at the end of the proposed addition to section 405.201(b) or, if the agency does not move forward with codification, add the same language to the PIM definition:

> "Medical devices that have been approved for marketing by FDA on the basis of a premarket approval application, a section 510(k) premarket notification, or a De Novo classification are considered safe and effective and not experimental or investigational for Medicare purposes when used for the conditions prescribed, recommended, or suggested in the labeling of the devices."

FDA regulation of medical devices, including the process of premarket review and issuance of marketing authorization, is designed to provide a reasonable assurance that devices are safe and effective for their intended use.[23] A determination by CMS or a MAC that a device that has been authorized for marketing by the FDA is "not safe or effective" or "experimental or investigational" when used in accordance with its FDA-authorized label is inappropriate and is inconsistent with the role and function of FDA. Moreover, because the authority of the FDA to regulate medical devices and the authority of CMS to determine whether items and service are "reasonable and necessary" both result from the delegation of authority conferred upon the Secretary of Health and Human Services by statute, such a determination could be viewed as the issuance of two conflicting decisions by the Secretary on the same matter.

MDMA does not believe recognizing FDA marketing authorization as dispositive on the first two criteria in the PIM definition would prevent CMS or MACs from limiting or even denying coverage of an FDA-authorized technology for Medicare beneficiaries. As stated in the proposed rule, the longstanding definition of reasonable and necessary includes a third criterion—that the

[23] See 21 CFR § 860.7.

item is "appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service," which includes whether it is:

- "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;
- "Furnished in a setting appropriate to the patient's medical needs and condition;
- "Ordered and furnished by qualified personnel;
- "One that meets, but does not exceed, the patient's medical need; and
- "At least as beneficial as an existing and available medically appropriate alternative."[24]

The third criterion recognizes that there can be legitimate clinical questions relevant to the Medicare population that are not resolved by FDA market authorization, and resolving those questions could require a manufacturer to provide additional evidence beyond that which was part of the FDA review.

Again, MDMA requests that CMS explicitly provide as part of the definition of reasonable and necessary, in guidance or in regulation should CMS choose to move forward with codification, that medical devices that have been authorized for marketing by the FDA are deemed to be "safe and effective" and "not experimental or investigational" when used in accordance with the FDA-authorized label.

B. MDMA strongly opposes the use of commercial coverage policies as determinative in setting coverage policy. Further, we believe the use of commercial coverage policies to inform coverage decision-making by CMS and MACs should only be done under clear criteria that will ensure that such coverage policies are developed in a transparent process providing adequate opportunity for stakeholder participation and a robust review of clinical evidence.

CMS is proposing to deem an item or service to meet the "appropriate for Medicare patients" criteria described above if they are "covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant."[25] The agency notes in its explanation that the use of commercial coverage policies to determine Medicare coverage policy "may expand or narrow the circumstances under which [Medicare] will cover a particular item or service."[26]

MDMA believes that this proposal is well-intentioned and is aimed at achieving the goals set forth in E.O. 13890. Unfortunately, we believe moving forward with the proposal would actually have the opposite effect, creating uncertainty in Medicare coverage policy and adversely affecting beneficiary access. In part, this would result from the operational challenges it would entail for CMS and MACs, which likely would be insurmountable and, in any case, would be disruptive to efforts that are more likely to improve the timeliness and transparency of coverage decision-making.

[24] 85 Fed. Reg. at 54328.
[25] *Id.* at 54338.
[26] *Id.* at 54332.

We are particularly concerned with the request for comment as to whether a manufacturer, beneficiary, provider or other proponent demonstrate coverage in the commercial market before Medicare beneficiaries have access to a medical technology,[27] and the suggestion that Medicare might only cover an item or service if it is covered for a majority, or a different proportion such as a plurality, of covered lives amongst plans or a majority, plurality, or some other proportion of plan offerings in the commercial market.[28] We acknowledge that these statements are requests for comment, and that the language of the proposed regulation need not be read to require coverage in the commercial market. However, when read as a whole, we believe the proposal represents an unwise and inappropriate delegation of the agency's responsibility for determining whether items or services are "reasonable and necessary" for the treatment of beneficiaries.

As stated above, MDMA strongly opposes making access to new medical technologies for Medicare beneficiaries contingent on—or even subject to—decisions by non-governmental entities driven by factors and motivations that are unrelated to the needs of beneficiaries or the historical social compact upon which the Medicare program rests, including the motivation to NOT cover new technologies as a means to control costs. Moreover, as you are well aware, medical technology manufacturers, physician specialty societies, beneficiary advocates and others have been working with CMS for more than a decade 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.

The lack of transparency and stakeholder participation can result in erroneous conclusions by commercial payers, even on objective factual matters. For example, recently, a large national payer wrote a policy related to an MDMA member company's technology that implied its seminal trial was still enrolling patients and that the technology had not received FDA approval, despite the fact that a quick check of ClinicalTrials.gov and FDA's database would have told them the trial was complete and the technology had received FDA approval 18 months ago. The policy also mischaracterized the patient indications and contraindications in the FDA-approved labeling, and cited small case study reports (5 patients or fewer) in obscure journals while overlooking citations in major, academic journals from the same period of time.

There are many additional actions that CMS could take to further improve the coverage process—especially with regard to LCDs—and we urge the agency to focus its efforts toward those as the best means for achieving the goals of E.O. 13890.
We also note that while the proposal would add only 21 words to the longstanding definition of "reasonable and necessary," there are many, many unanswered questions related to how the proposed rule would actually work that argue against moving forward. For example:

- How would CMS or the MACs identify and access private commercial payer policies? Specific coverage policies from commercial insurers are generally not easily accessible,

[27] *Id.*
[28] *Id.*

and creating and maintaining a system to identify new or revised commercial insurer coverage policies would require substantial resources. Moreover, commercial insurers often provide limited if any information regarding the review process or evidentiary basis for a specific policy. Will insurers make their policies readily available to CMS and Medicare stakeholders, and provide transparency with regard to the evidentiary basis they relied upon in developing the policies? Would insurers be "selectively transparent" in order to shape Medicare coverage to support their commercial objectives?

- How would CMS or the MACs determine the scope of what qualifies as a "coverage policy?" Does the exclusion of a particular item or service (*e.g.*, bariatric surgery) from the scope of contracted medical benefits for a particular offering equal non-coverage? How would CMS interpret the absence of a policy? How would CMS view policies that classify a new technology as "experimental or investigational," often based on a Category III CPT code without a substantive review of clinical evidence, especially in light of the agency's efforts to eliminate similar policies issued by MACs?
- How would CMS or the MACs define the scope of "commercial insurers?" Significant changes are happening in the commercial insurance market, and the Administration has actively supported and promoted public policies—including providing more flexibility in regulatory requirements applicable to commercial insurance market—intended to ensure consumers have access to a wide variety of coverage to meet their specific needs and desires. New types of companies, business models and offerings will likely involve different strategies for managing utilization, including differences in how coverage determinations are developed and implemented.
- Without the ability to determine the denominator (*i.e.*, the total number, and type, of commercial coverage policies related to an item or service), how would CMS or a MAC determine a "majority of offerings" or any other proportion necessary to operationalize the policy? The use of the phrase "amongst the offerings we examine" suggests that there could be a significant degree of variation among MACs and the Central Office in how commercial coverage policies would influence Medicare coverage.
- Building commercial coverage for many new technologies is an evolutionary process, especially early in the product lifecycle. A Medicare coverage determination based upon coverage in the commercial market would represent only a snapshot in time, especially with regard to objective measures (*e.g.*, the proportion of policies imposing a specific condition on coverage, such as a requirement that a patient fail to respond to an alternative therapy first). Whether CMS chose to follow the least restrictive or most restrictive policy, at what point would the Medicare policy be open to amendment based upon changes in commercial coverage? How would CMS and the MACs manage that update process? Is it administratively feasible for the agency or the MACs coverage policies to manage a process that requires constant monitoring of and responsiveness to the commercial market?[29]

We note that CMS and the MACs already appear to be looking at the commercial insurance market when conducting coverage reviews, at least in some situations.[30] What is not clear, however, is

[29] According to the proposal, "each MAC would be responsible for reviewing commercial offerings to inform their LCDs or claim by claim decisions, which would include individual medical necessity decisions." *Id.* at 54332.

[30] *See e.g.*, CMS Coverage and Analysis Group, Proposed Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests (CAG-00454N) (October 16, 2020) ("We assessed the commercial market for

what criteria is being used to determine when such assessments should be conducted, how they should be conducted, or how the results should be used to determining Medicare coverage. MDMA believes there are circumstances where the commercial coverage environment could inform coverage review. For example, widespread coverage of an item or service in the commercial market accompanied by limited or no coverage in the Medicare market, in the absence of clinically relevant differences between the two covered populations, suggests the need for a review and update to Medicare coverage policy. But even the use of commercial policies as *informative*, as opposed to determinative, in coverage decision-making should be guided by appropriate substantive and procedural standards, *e.g.*, a requirement that Medicare only review commercial policies that are developed in a transparent process that includes stakeholder participation. MDMA would welcome the opportunity to work with the agency on bringing more clarity to this area.

Conclusion

Thank you for your leadership on this important issue as well as for the opportunity to provide comments on this important proposal. We appreciate the efforts of the Administration and CMS to enhance access to new medical technologies, providing more therapeutic options for Medicare beneficiaries and providers and improving outcomes. MDMA looks forward to working with CMS as it develops the final rule. 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

coverage of blood based biomarker CRC screening tests As of July 9, 2020, none of the commercial payors that we searched on cover the Septin 9 test. Humana states on their medical coverage policy website for CRC screening tests, with effective date February 23, 2017, that Humana members are not eligible for Septin 9 (SEPT9) DNA methylation assay (e.g., ColoVantage, Epi proColon®) (Humana, 2017). Aetna explicitly states that they non cover the Septin 9 (Epi proColon® and ColoVantage) test. While we are still conducting our assessment, the other private payors that we have looked at so far do not make a statement on the Septin 9 screening test in their medical coverage policy. In our ongoing search of CRC screening tests to date, none of the commercial payors cover the Septin 9 test.")