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AdvaMed
Advanced Medical Technology Association

November 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

**RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary;" Proposed Rule (CMS-3372-P)**

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) is pleased to offer comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."[1] AdvaMed has long supported a swift and streamlined approach to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients with debilitating or life-threatening illnesses, and we commend CMS for taking this important step.

AdvaMed's member companies produce the life-saving 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.

In 2016, Congress enacted the 21st Century Cures Act[2], which among other things advanced medical device innovation by creating a new Food and Drug Administrative (FDA) program to expedite the development of diagnostics and devices that represent breakthrough technologies and to promote their use in health care delivery. At that time, Congress did not include provisions that would have created a streamlined approach to coverage, coding and payment for those innovations.

However, in its fiscal year (FY) 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule, CMS provided for an alternative new technology add-on payment (NTAP) pathway for breakthrough technologies, deeming such technologies to meet criteria for newness and substantial clinical improvement and thus to automatically qualify for NTAP if the cost criterion was also

[1] *Federal Register*, Vol. 85, No. 170, pp. 54327-39, September 1, 2020.
[2] P.L. 114-255, December 13, 2016.

met. In the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS provided for an alternative transitional pass-through payment (TPT) for breakthrough technologies, deeming such technologies to meet the substantial clinical improvement and thus to automatically qualify for TPT payment if the newness and cost criteria are also met. Later that year, the October 13, 2019, Executive Order 13890 (E.O. 13890) directed the Secretary to issue proposals that would encourage innovation for patients, including such streamlined approaches.

We applaud these efforts by CMS to recognize the importance of new innovations and the role they play in improving the lives of patients with debilitating illness. The MCIT proposed rule represents CMS's continuing commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve health and outcomes.

***Overarching Recommendations:***

AdvaMed strongly supports the MCIT pathway proposal for FDA-designated breakthrough technologies and urges CMS to finalize the MCIT portion of the proposed rule as quickly as possible. In the final rule, CMS should make clear that the MCIT pathway applies to diagnostic tests. The MCIT provisions are critical for Medicare beneficiary access to breakthrough devices and diagnostics.

Combined with the new breakthrough pathway for inpatient NTAP and outpatient TPT payment, MCIT will help to spur future advancements in patient care because CMS is sending a signal to the entire innovation ecosystem that taking the risk to develop new breakthroughs will be rewarded if those devices receive FDA marketing authorization and improve patient care.

While AdvaMed appreciates CMS's efforts to clarify its definition of "reasonable and necessary" for Medicare beneficiaries, we oppose codification of the proposed definition at this time. Should CMS wish to proceed, it should initiate a more extensive dialogue using an open and transparent process that includes multiple opportunities for stakeholder input and consideration.

Additionally, given key differences between the coverage determination process used by CMS compared to private health plans, AdvaMed opposes and has serious concerns with the proposal to include an analysis of commercial insurance coverage policies as part of the definition of reasonable and necessary when determining Medicare coverage. Commercial insurance coverage decisions lack transparency and processes for stakeholder engagement and are not appropriate for inclusion in Medicare's reasonable and necessary definition.

AdvaMed recommends that CMS move quickly to finalize the MCIT provisions of the rule with the clarifications and refinements below; and we urge CMS to withdraw its proposal to codify the definition of reasonable and necessary.

Again, AdvaMed appreciates CMS's efforts to improve access to new medical technologies in this proposed rule and we offer detailed comments below related to:

I. Proposed MCIT Pathway for Breakthrough Technologies
II. Proposed Definition of "Reasonable and Necessary"

## I. Proposed MCIT Pathway for Breakthrough Technologies

- **Opt-In Approach**

MCIT is a voluntary program. AdvaMed supports an opt-in approach under which a manufacturer would voluntarily notify CMS of its interest in pursuing the MCIT pathway. An opt-in approach will allow manufacturers to pursue their own business judgment rather than rely on an assumption by Medicare about the manufacturer's preference. Further, manufacturers should have the opportunity to opt-in at any point in time, although a delay in notifying CMS of a manufacturer's intention to pursue the MCIT coverage pathway may result in a period of coverage of less than four years, depending on the date of FDA market-authorization or market availability (see below).

***Recommendation:***

- **AdvaMed supports an opt-in approach under which a manufacturer would voluntarily notify CMS of its interest in pursuing the MCIT pathway.**

- **Posting of Covered MCIT Pathway Devices on CMS Website**

CMS states that it intends to put devices that are covered through the MCIT pathway on the CMS website so that stakeholders can be aware of what is covered through the MCIT pathway. AdvaMed supports efforts by CMS to be transparent about this new program and sharing information with stakeholders regarding MCIT-covered devices, similar to the way CMS posts information about Medicare coverage of Investigational Device Exemption (IDE) studies.

***Recommendation:***

- **AdvaMed supports the proposal to post devices covered through the MCIT pathway on the CMS website.**

- **Four-Year Coverage Period**

AdvaMed supports the proposed four-year MCIT coverage period. We agree with CMS statement that, while MCIT should have some time-limit on how long a breakthrough device can be considered "new" for purposes of MCIT coverage, manufacturers can leverage this period to demonstrate the value of innovative new devices in the marketplace. The proposed four-year period appears adequate to allow for coverage and market access while also allowing manufacturers that choose to do so to further develop clinical evidence.

AdvaMed supports the proposed four-year coverage period, beginning with the date of FDA market authorization as a breakthrough technology, unless there is a documented delay in U.S. market availability, in which case coverage should begin on the date of market availability. This option is consistent with the way CMS determines the start of coverage for new technology add-on payments under the Inpatient Hospital Prospective Payment System (IPPS) or transitional passthrough payments under the Hospital Outpatient Prospective Payment System (OPPS).

Furthermore, it would be meaningful to smaller companies for whom the resources for evidence generation studies is very often prohibitively expensive without a stream of revenue from coverage.

CMS proposes MCIT eligibility for technologies that are FDA market authorized up to two years prior to the effective date of the MCIT final rule. AdvaMed appreciates CMS's recognition of the need for MCIT to cover these breakthrough technologies that have already been approved for marketing authorization. However, for the small handful of FDA-designated breakthrough devices that obtained FDA marketing authorization prior to the effective date of the final MCIT regulation, we believe CMS should provide four years of coverage beginning with the effective date of the final rule, or the date of FDA-market availability, whichever comes second. Those early entrants into the FDA Breakthrough Pathway program should be able to receive the benefit of four full years of coverage. To deny or truncate the coverage period for early entrants would not meet the spirit of the rule nor the Executive Order, which were intended to encourage access to innovative technologies for patients who need them.

***Recommendations:***

- **CMS should finalize the four-year MCIT coverage period.**
- **CMS should begin coverage on the date of FDA market authorization or, in the event of delay, on the date of market availability, as attested by the manufacturer.**
- **For early entrants to the Breakthrough Pathway program that have already received market authorization, CMS should provide the full four years of coverage, beginning on the date the final rule becomes effective, or the date of market availability, whichever comes second.**

- **FDA Labeled Indication for Use**

CMS proposes that under MCIT the device will be covered only for use consistent with its FDA approved or cleared indication but seeks comment on whether and under what circumstances off-label use of breakthrough devices should be covered. While we agree that off-labeled device use should not be part of a national MCIT program, MACs should not be prohibited from using discretion to make coverage determinations regarding off-label uses of a breakthrough technology, consistent with current processes for non-MCIT technologies.

***Recommendation:***

- **MACs should retain discretion to make coverage determinations regarding off-label uses of MCIT-approved technologies.**

- **<u>Four-year Coverage for FDA-Designated Breakthrough Devices and Second-to-Market Breakthrough Devices</u>**

AdvaMed supports coverage under the MCIT pathway for every device that is *designated as a breakthrough device by the FDA*. Notably, the FDA Breakthrough Devices Program is designed to be product-specific, which may conflict with CMS's traditional categorical approach to coverage, under which CMS typically covers and pays for similar products, or procedures in which similar technologies are used, in the same way. In other words, similar technologies manufactured by

different companies may be covered in a procedure under a single NCD, for example, and reported using the same codes. When new but similar products are approved or cleared by the FDA, they may use the available coverage and payment pathway.

AdvaMed believes that the MCIT pathway should be available to any FDA-designated breakthrough device that is authorized for marketing. MCIT should apply to these breakthrough technologies regardless of whether the breakthrough device is the second- or subsequent-to-market of that device type. Each of these breakthrough technologies should be eligible to receive coverage for the full four-year period. Additionally, existing technologies that receive breakthrough designation from the FDA for a novel indication also should be eligible for coverage under the MCIT program for that new indication for the four-year period.

The situation where a subsequent similar technology also receives breakthrough designation should be infrequent, given FDA's narrow definition and the fact that breakthrough-designated devices are designed to meet serious debilitating or life-threatening diseases or conditions. It therefore makes sense to ensure, as CMS has proposed, that each technology should be eligible for four years of coverage under MCIT.

FDA has contemplated situations where multiple devices with the same intended use may be granted breakthrough designation. Under FDA's guidance for breakthrough devices:

> *Breakthrough Device designation may be granted for multiple devices with the same proposed intended use, and a Breakthrough Device designation will not be revoked solely on the basis of another designated device obtaining marketing authorization. As a consequence, multiple Breakthrough Device designations for the same intended use may be granted and have subsequent submissions pending simultaneously. However, when a Breakthrough Device has been approved or cleared or has had a De Novo request granted, no additional devices with the same intended use will be designated as a Breakthrough Device, unless the criteria for designation described above are still met in light of the first Breakthrough Device's market availability.*[3]

While we believe these situations will be rare, CMS ultimately will need to address coverage and payment for second-to-market (or any subsequent) devices that are not designated as breakthroughs by the FDA. While the MCIT pathway would not be available to a non-breakthrough device under the proposed rule, a manufacturer should be able to pursue coverage through existing processes (national or local coverage determination process, claim-by-claim adjudication, etc.).

CMS will certainly encounter implementation issues as this new program develops and new technologies enter the market; and AdvaMed stands ready to work with CMS to address these and other issues that may not have been contemplated in the development of the proposed rule. Patient access to these innovative technologies should serve as an important guiding principle and would support the spirit of the proposed regulation. While these are important issues to resolve over time,

[3] *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program, Guidance Document, FDA Breakthrough Devices Program, December, 2018

contemplation of how all future scenarios can be addressed should not delay issuance of the final rule.

***Recommendations:***

- **AdvaMed supports MCIT coverage for each FDA-designated breakthrough technology for the full four-year coverage period. Second-to-market (or subsequent) devices of the same type, even for the same indication, that are designated as breakthrough devices should be eligible for the full four-year MCIT period.**
- **Similar, subsequent-to-market non-breakthrough devices that fall under the same class or category as the breakthrough device may pursue coverage through existing processes.**

- **Coverage Beyond the MCIT Coverage Period**

CMS states in the preamble that, at the conclusion of the four-year MCIT coverage period, several scenarios are possible, including (1) a CMS National Coverage Determination (NCD); (2) a negative, or non-coverage, CMS NCD; (3) a local coverage determination (LCD) or claim-by-claim adjudication based on the discretion of a local Medicare Administrative Contractor (MAC). CMS specifically solicits feedback on whether CMS should initiate a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within six months of the expiration of the four-year MCIT coverage period.

AdvaMed does not support the automatic initiation of a national coverage analysis if a MAC has not acted by issuing an LCD. We believe the best approach is to allow manufacturers to decide which option to pursue as the four-year MCIT coverage period draws to a close. Because the MCIT pathway is voluntary, and each specific breakthrough device unique, companies should have flexibility to pursue the option for coverage that meets the needs of the population being served. Companies desiring an NCD at the end of the four-year coverage period could apply for that option. On the other hand, companies that prefer a local coverage option should have the flexibility to pursue that option as well. CMS might even consider extending MCIT coverage for some period of time if necessary, on a case-by-case basis, for example, to allow companies that are conducting studies to support coverage beyond the four-year MCIT period to complete those studies. CMS's goal should be to allow for flexibility and to avoid any gap in coverage at the end of the MCIT period that could affect patient access to these innovative technologies.

While nothing in these comments would preclude CMS from acting on its own to open a national coverage analysis, AdvaMed does not support a process where this happens automatically or is triggered by inaction on the part of the MACs. This approach would provide flexibility for manufacturers to pursue a range of options that may be appropriate for the company, the technology, and most importantly for clinicians and patients. A flexible approach would also allow for ongoing discussions between CMS and manufacturers regarding the best approach to take.

***Recommendations:***

- **The MCIT pathway should allow manufacturers to have flexibility in determining the appropriate approach for continued coverage beyond the four-year MCIT coverage period.**

- **This flexibility includes a company's ability to seek national or local coverage, as appropriate for the technology and the affected patient population, or to not seek a formal coverage determination and rely instead on claim-by-claim adjudication by the MAC.**
- **CMS could consider, on a case-by-case basis, extending MCIT to avoid gaps in coverage at the end of the MCIT period.**

- **Clarify Application to Diagnostic Tests**

CMS states in the preamble to the proposed rule that it is limiting MCIT to medical devices "because that is a category of products explicitly identified in EO 13890, and [CMS] has identified that breakthrough devices can experience variable coverage across the nation shortly after market authorization."[4] In other preamble language, CMS makes contradictory statements about the application of the MCIT to diagnostic technologies. For instance, CMS states that "the MCIT pathway can provide a fast-track to Medicare coverage of innovative devices that may more effectively treat or diagnose life-threatening or irreversibly debilitating human disease or conditions."[5] CMS should clarify in the final rule that FDA-approved breakthrough diagnostic technologies are breakthrough devices and therefore are eligible for the MCIT coverage pathway.

CMS proposes a regulatory definition of "breakthrough device" in a new section 42 CFR 405.601(b) to mean "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-(d)(1))."[6] FDA's Breakthrough Devices Program is for medical devices and device-led combination products that "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."[7] Therefore, CMS's proposed regulatory language would apply the new MCIT coverage pathway to diagnostic technologies that are designated by the FDA as breakthrough devices.

***Recommendation:***

- **CMS should clarify in the final rule that FDA-approved breakthrough diagnostic technologies are breakthrough devices and therefore are eligible for the MCIT coverage pathway.**

- **MCIT Coverage for Humanitarian Use Devices (HUDs) with Humanitarian Device Exemption (HDE) Status**

CMS states that the MCIT coverage pathway shall be available to FDA-designated breakthrough devices that are FDA market authorized (that is, the date the medical device receives Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for the breakthrough device, and that fit within a Medicare benefit category. CMS should clarify that Humanitarian Use Devices intended to benefit patients with rare diseases or conditions should also

[4] 85 F.R., p. 54329.
[5] Ibid. at p. 54333.
[6] Ibid. at p. 54338.
[7] Ibid. at p. 54329.

be eligible for the MCIT pathway. Per the FDA, these devices, by definition, are intended to diagnose or treat very rare diseases that occur in small patient populations where there is an inability to follow the typical clinical pathway.

FDA may grant a Humanitarian Device Exemption (HDE) from certain requirements of the Food, Drug & Cosmetic Act if the device, among other criteria, demonstrates probable benefit that outweighs the risk of injury or illness from its use and would not be available to a person with the disease or condition in question without the HDE, and no comparable device exists to treat or diagnose the rare disease or condition.

***Recommendation:***

- **Given the unique nature of devices with HDEs, CMS should make clear that such devices are eligible for the MCIT pathway.**

- **Clarify that MCIT Eligibility Includes Non-implanted Technologies**

As CMS has described in its preamble, MCIT would apply to all FDA-designated breakthrough technologies. MCIT should not limit coverage under the rule to only implanted devices but should codify that all breakthrough devices are eligible for the MCIT coverage pathway. As drafted, the proposed regulatory text at 405.605(b) could be misinterpreted to suggest that MCIT would only apply to "implanted" technologies. We believe the intent of 405.605(b) is to ensure that the related physician or professional services to implant or "use" the breakthrough device would also be covered which is an important clarification that we support. However, the language only references implanted technologies.

***Recommendation:***

- **In the final rule, CMS should amend the proposed regulatory language at 405.605(b) by adding "or use" after "to implant" to clarify that covered items and services include:**

  **(b) any reasonable and necessary procedures to implant *or use* the breakthrough device**.

- **Medicare Benefit Category**

CMS proposes to automatically cover breakthrough technologies unless CMS determines that a device does not have a Medicare benefit category. The proposed regulation would apply the MCIT pathway to any FDA cleared or approved breakthrough device that is "within a Medicare benefit category" and is not excluded by statute, regulation, or NCD. AdvaMed supports the broad definition of "within a benefit category," as this approach aligns with the purpose of the MCIT to provide an additional pathway to Medicare coverage for innovative breakthrough devices (including diagnostic and screening tests) in order to avoid unnecessary access delays following FDA authorization.

AdvaMed has supported legislation that would cover technologies that do not fall within an existing benefit category. We urge CMS to support this legislation. But recognizing that CMS does not on its own have authority to include technologies that do not fit within a benefit category,

we urge CMS to work with industry and other stakeholders to review and consider changes to existing regulatory policies that lack clarity or specification and actually create unnecessary barriers to coverage of some breakthrough technologies.

One area where review and consideration of changes to regulations can create opportunities for coverage within Medicare's current benefit category structure is the area of digital health technologies, for example those using apps, algorithms, augmented or artificial intelligence, and software as a medical device. Many FDA-designated breakthrough technologies use digital technologies or have components that are digital technologies that define their uniqueness among those technologies used in health care delivery. We believe that many of these technologies could be covered under Medicare's existing benefit categories if a clearer pathway were established through regulation for their coverage.

For example, the FDA has approved a technology that would function as an artificial pancreas for persons with diabetes and FDA has defined the technology as having three components: a continuous glucose monitor (CGM), an insulin pump, and an algorithm. The algorithm allows the CGM and insulin pump to talk to each other and automatically adjust the patient's glucose levels. Medicare now covers and pays for each of the first two components as durable medical equipment, but regulations do not provide clarity or specification for how the algorithm could be covered and paid for separately.

We believe that the algorithm could be covered and paid for separately as a supply necessary for the functioning of the technologies that qualify for coverage under the Medicare DME benefit category—in the same way Medicare now covers non-durable test strips used with durable blood glucose monitors and oxygen used in durable oxygen canisters. This example and many others are offered as pathways to coverage for digital technologies in a recently released AdvaMed-CapView study, *Modernizing Medicare Coverage of Digital Health Technologies*. The study examines each of Medicare's major benefit categories to illustrate how coverage and payment for digital technologies can be accommodated through review and changes to existing Medicare regulations, rather than through changes to Medicare statute.[8]

***Recommendations:***

- **CMS should use its existing regulatory authority to ensure AI, virtual, app-based and other digital technologies will be eligible for the MCIT coverage pathway.**
- **CMS should apply its discretion to determine the appropriate benefit category to cover certain breakthrough technologies, such as diagnostic testing, cancer screening or devices used in asymptomatic and/or at-risk and high-risk populations, given breakthrough technologies likely will not have NCCN, USPSTF or other relevant coverage guidelines at the time of FDA market authorization that support a benefit category.**

[8] For a deeper discussion on this topic focusing on the growth of digital technologies and their implications for the Medicare Program, see AdvaMed-CapView September 2020 report entitled, "Modernizing Medicare Coverage of Digital Health Technologies," https://www.advamed.org/sites/default/files/resource/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf

- **Ensure a Process for MCIT Covered Technologies to Receive Appropriate Coding and Payment**

CMS states that once a manufacturer has notified CMS of its intention to utilize the MCIT pathway, CMS proposes to subsequently coordinate with the manufacturer regarding steps that need to be taken for "MCIT implementation purposes."[9] The Agency further states that the frequency of engagement will be driven largely by whether the manufacturer has questions for CMS. AdvaMed has long advocated for, and strongly supports, true engagement and dialogue between device companies and CMS.

When CMS issued the proposed rule for MCIT, the Agency also announced that it had reorganized by establishing a new Technology, Coding and Pricing Group that could better coordinate and manage policies related to new technology innovations in care. CMS also announced that it was creating a new pilot program to help medical technology companies "navigate" the complex process of ensuring coverage, coding and payment. We applaud CMS for taking these steps and we urge CMS to engage with companies that have breakthrough products as early in the process as possible – even before the product is granted market authorization – to ensure that MCIT technologies can receive coding and payment as quickly as they receive Medicare coverage.

Clear processes should be articulated to allow manufacturers to pursue appropriate coding, appropriate placement in payment system categories or establishment of new payment categories, and adequate reimbursement to support new breakthrough innovations. Without coding and clearly designated payment categories established at the beginning of the four-year automatic coverage period, manufacturers will be challenged to generate the evidence CMS expects for continuation of coverage beyond that period. Because of the need to have a code as soon as a device is approved for MCIT, AdvaMed also recommends that CMS create a process that allows for assignment of a specific code to each MCIT approved technology that needs it for use, if only temporarily, immediately upon approval for coverage.

These coordination issues are important and will require the work of multiple groups within CMS. While it may take time to resolve all of these coordination issues, CMS can manage these issues through subregulatory guidance and payment regulations and should not delay issuance of the final MCIT rule.

***Recommendations*:**

- **CMS should ensure there are appropriate processes in place to facilitate engagement with CMS (even before FDA market authorization) to make certain timely coding and payment are available for new technologies in the MCIT pathway. AdvaMed looks forward to working with CMS on implementation of the MCIT pathway.**
- **CMS should clearly articulate the process for code assignment or acquisition for breakthrough technologies that qualify for MCIT.**

[9] 85 F.R., p. 54330.

- **CMS should create a process for assigning a specific code, if needed, to MCIT-approved technologies immediately upon approval for coverage, so that codes are available for use at the start of the MCIT coverage period.**
- **Similarly, CMS should establish payment mechanisms immediately upon coverage of a breakthrough technology.**

- **NTAP and Outpatient Passthrough Approval and Medicare Coverage of Approved Technologies by Medicare Administrative Contractors (MACs)**

CMS solicits comments from the public regarding whether existing pathways should be modified. While we recognize that the approval process for new technology add-on payment (NTAP), outpatient transitional pass-through payment (TPT) and new technology Ambulatory Payment Classification (NT APC) differs from Medicare coverage policies are different, CMS should develop policies that would require MACs to recognize and cover these special payment approvals and associated services (e.g., physician services to implant or provide the technology), and the extra payment that approved technologies are eligible to receive. MACs have issued local non-coverage determinations for technologies that CMS had approved for NTAP, effectively denying beneficiaries in many States access to a new technology. Often, companies with new technologies have limited resources. Thus, when faced with MAC non-coverage determinations, despite showing substantial clinical improvement and having been approved for NTAP/TPT/NT APC, the prospect of pursuing a MAC-by-MAC strategy for coverage can be challenging. Additionally, this problem raises an inconsistency between the purpose of NTAP/TPT/NT APC to provide beneficiaries access to innovative technologies and procedures, on the one hand, and local Medicare coverage policies, on the other. Further, the MCIT regulation should not limit coverage under the MCIT pathway to only implanted devices but should codify that all breakthrough devices are eligible for the MCIT coverage pathway.

This is an important and timely issue to address in the MCIT final rule. Just last year, in the FY 2020 final IPPS and OPPS rules, CMS deemed FDA-approved breakthrough technologies to have met the criteria for newness (in the case of NTAP) and substantial clinical improvement criteria. However, MACs still can determine coverage, and in fact deny coverage, for these technologies and procedures because NTAP/TPT/NT APC are not coverage decisions. While the MCIT proposal will prevent this from happening for FDA-designated breakthrough products, other products that receive NTAP/TPT/NT APC will not have the same protection. MACs should be prohibited from questioning CMS's decisions on these technologies and from denying coverage for *any* NTAP/TPT/NT APC product (though this would not preclude the CMS Coverage and Analysis Group from making a national coverage decision).

***Recommendations:***

- **MACs should be prohibited from denying coverage and add-on payments for medical services or technologies approved for NTAP or pass-through status, or NT APC, by the Secretary. Coverage should also extend to the associated service codes that are required to utilize the device or procedure.**

- **Clinical Study Requirements**

Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during the proposed four-year coverage period under the MCIT program. However, CMS solicits comments on whether the Agency should require or otherwise incentivize manufacturers to collect and provide additional data to track clinical outcomes for the patients that receive these breakthrough devices. CMS recognizes in the preamble that some manufacturers may be required by the FDA to conduct post-market data collection as a condition of market authorization, and notes that the proposed rule would not alter such requirements.

AdvaMed supports CMS's proposal not to require additional evidence development during the MCIT period as a condition for coverage. However, AdvaMed also agrees with CMS's statements that evidence may be needed for continued coverage beyond the four-year MCIT period, which could serve as an incentive to collect and provide additional data. CMS further encourages early manufacturer engagement with CMS to discuss and receive feedback on potential clinical study designs and clinical endpoints that can produce such evidence. It is important that companies understand CMS's expectations regarding the evidence necessary to support coverage beyond the MCIT period and that those companies are able to work together with CMS in an open and transparent manner.

AdvaMed has long-supported such an approach, under which CMS can create opportunities for dialogue and feedback, which will go a long way toward achieving greater transparency in the coverage process long term, will facilitate better understanding by both parties of the evidence expectations over time, and will assist manufacturers in planning and development as these new innovations become more widely accepted by clinicians and patients alike, and their uses potentially expand. We therefore support CMS's encouragement of continued evidence generation that may inform future Agency decision-making about permanent coverage of a breakthrough medical device or diagnostic technology near the end of the four-year MCIT coverage period.

AdvaMed has previously commented, and maintains, that where additional clinical or scientific evidence is needed (beyond FDA requirements for safety and effectiveness), CMS should:

1) collaborate with stakeholders to clearly identify the data collection objectives;
2) consider the minimum data necessary to achieve those objectives;
3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance (including clear stopping rules for data collection, and
4) identify appropriate mechanisms to ensure continuous coverage of an item or service after a study (or other evidence collection) ends, to avoid disruption in coverage and continue to allow Medicare beneficiaries to benefit from important FDA-approved technologies and services until a new or revised coverage determination is issued.

As evidence is generated to support the use of a new innovation or service, AdvaMed believes that Medicare's coverage policies should reflect these outcomes and minimize additional requirements.

***Recommendations:***

- **AdvaMed supports CMS proposal not to require additional evidence development during the MCIT period.**
- **AdvaMed agrees that evidence may be needed for continued coverage beyond the four-year MCIT coverage period and supports early manufacturer engagement with CMS to discuss and receive feedback on potential clinical study designs and clinical endpoints that can produce such evidence.**

## II. Definition of Reasonable and Necessary

CMS proposes to codify in regulation a definition of what it means to be "reasonable and necessary" under §1862(a)(1)(A) of the Social Security Act. CMS proposes to codify existing language found in Chapter 13 of the Medicare Program Integrity Manual (PIM), but with modifications, including a reference to commercial insurers' coverage policies. While AdvaMed commends CMS's efforts to attempt to bring clarity to the interpretation of the term "reasonable and necessary," we are concerned that codifying the proposed definition is not appropriate. We therefore oppose codification of the language, for the reasons articulated below. Should CMS decide to elevate existing language in the PIM to regulatory status, the agency should proceed thoughtfully and engage stakeholders in an open and transparent process, with multiple opportunities for input from stakeholders, including industry.

Under its proposal, CMS would codify the language below in its regulations at 42 CFR §405.201(b) to define reasonable and necessary to mean an item or service is:

*(1) safe and effective;*
*(2) not experimental or investigational; and*
*(3) appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of 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, or*
- *covered by commercial insurers unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.*

Again, AdvaMed opposes CMS's proposal to codify this language in the Code of Federal Regulations. There is a long history behind the meaning of the term reasonable and necessary in the Medicare statute, and previous attempts to define the term in regulation have failed. Codifying the language contained in Medicare's subregulatory guidance is not needed to achieve the result CMS seeks. The longstanding language in Medicare's PIM is well-known by stakeholders

including CMS and industry and retaining this language in sub-regulatory guidance allows CMS to have greater flexibility in interpreting whether an item or service is reasonable and necessary for Medicare beneficiaries. We oppose elevating these guideposts from manual provisions that may offer flexibility to expand patient access to strictly enforceable regulations that could potentially restrict or limit access without extensive stakeholder engagement.

Should CMS choose to codify any portion of the proposed definition of reasonable and necessary, CMS should clarify that medical devices and diagnostics that are authorized by the FDA for marketing (received Premarket Approval (PMA); 510(k) clearance; or granted a De Novo classification request) are "safe and effective" and "not experimental or investigational" and need only be determined "appropriate" for Medicare beneficiaries in order to be considered reasonable and necessary under the proposed regulation. CMS should also clarify that Humanitarian Use Devices with HDEs are considered safe and have probable benefit for the population they serve when used appropriately. A determination by CMS or a MAC that a device with FDA market authorization is not safe and effective, or that such device is experimental or investigational is inappropriate and encroaches on the FDA's authority. CMS and the MAC 's only determination should be whether the FDA-approved medical device is appropriate, i.e., improves health outcomes, for Medicare beneficiaries.

However, that said, AdvaMed firmly believes that CMS should proceed slowly and with the utmost diligence. As stated above, previous attempts to define the term have not succeeded. CMS should proceed only with thoughtful input from the range of stakeholders that would be impacted by such a permanent change. CMS should convene listening sessions, Town Hall style meetings or other opportunities to discuss and solicit feedback from stakeholders before finalizing such an important and permanent change in regulatory language.

Further, CMS should <u>not</u> consider including any language that would allow Medicare to make decisions about appropriateness of coverage based on commercial insurer policies.

AdvaMed has many serious concerns with the inclusion of a commercial payer analysis to determine if coverage is "appropriate" for Medicare beneficiaries, which could be used to restrict or limit access to care for Medicare beneficiaries.

Our key concerns include:

- *Lack of transparency* – There is no transparency into the evidence reviewed by commercial insurers in reaching their determinations about coverage. Many commercial payers use external Health Technology Assessment (HTA) organizations' recommendations to develop their coverage policies. These reviews are often "black boxes" with no public process for input or transparency of the evidence or reason for the assessment findings. Even if CMS included a public comment process for a coverage determination (e.g., NCD or LCD) that was based in part on the existence of one or more commercial policies, it is not possible for stakeholders to understand how those policies were derived, what evidence was considered and what rationale was used to reach the findings that determined the proposed coverage or lack thereof. Further, these policies are not consistently available to the public as there is no publicly accessible database.

- *Limited MAC Resources*–AdvaMed is not convinced that the MACs have the resources to conduct a thorough and appropriate analysis of coverage policies.

- *No Independent Review* – Many commercial insurers simply adopt the coverage policies of other commercial payers or HTA organizations, without performing an independent review of the evidence and arriving at their own conclusions.

- *Coverage without a formal policy* – As with Medicare, many devices and diagnostic tests are covered by commercial payers without formal, written coverage/medical policies in place. Further, there is a great deal of heterogeneity in commercial payer coverage/medical policies. Policies can be incredibly diverse, in terms of process, character and content. There is simply not one standard for commercial payer coverage policy, which could create significant challenges in applying a commercial payer analysis to an item or service to determine coverage.

- *Cost-Effectiveness Analyses* – Finally, many commercial insurers consider cost-effectiveness in making their coverage determinations, where CMS is statutorily prohibited from considering cost-effectiveness in Medicare coverage determinations.

CMS recognizes in the preamble of the proposed rule that commercial insurers may impose restrictions on coverage of certain items or services, and clearly states that the Agency's intention is to adopt the least restrictive coverage policy for the item or service being considered. From AdvaMed's perspective, any consideration of commercial payer policies to influence Medicare coverage should be used only to expand access for Medicare beneficiaries. However, our significant concerns with transparency, heterogeneity in commercial payer policies and lack of opportunities for stakeholder input into the process lead us to the conclusion that Medicare coverage based on an analysis of commercial coverage is not appropriate, and that such a policy should not be pursued by CMS at this time.

***Recommendations:***

- **AdvaMed opposes CMS's proposal to codify in regulation a definition of the term "reasonable and necessary." CMS should proceed diligently and thoughtfully and offer multiple opportunities for stakeholder input.**
- **AdvaMed opposes CMS's proposal to determine coverage based on an analysis of coverage of an item or service in the commercial market. Any consideration of commercial payer policies to influence Medicare coverage should be used only to expand access for Medicare beneficiaries.**
- **CMS should clarify that devices and diagnostics that are authorized by the FDA for marketing are "safe and effective" and "not experimental or investigational" and need only be determined "appropriate" for Medicare beneficiaries in order to be considered reasonable and necessary under the proposed regulation.**

As stated above, AdvaMed applauds CMS's commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve the lives of patients with debilitating conditions.

**In summary, AdvaMed urges CMS to quickly to finalize the MCIT provisions of this proposed rule; however, we strongly advise that CMS withdraw its proposal to codify in regulation any definition of reasonable and necessary at this time.**

We greatly appreciate the opportunity to comment on the MCIT proposed rule. If you have questions regarding these comments or if you require additional information, please contact me or Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at cbranham@AdvaMed.org.

Sincerely,

Donald L. May
Executive Vice President
Payment & Health Care Delivery Policy