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AdvaMed
Advanced Medical Technology Association

April 15, 2021

Ms. Elizabeth Richter
Acting 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;" Delay of Effective Date; Public Comment Period (CMS-3372-IFC)

Dear Acting Administrator Richter:

The Advanced Medical Technology Association (AdvaMed) offers the following comments on the Centers for Medicare & Medicaid Services' (CMS) Interim Final Rule (IFC) delaying the effective date and requesting comments on the recent final rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."[1] AdvaMed has long advocated for streamlined approaches to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients who suffer from debilitating or life-threatening illnesses. **AdvaMed urges CMS to implement the MCIT final rule without further delay.**

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

Another division, AdvaMed Accel, represents small and mid-sized companies. Many of these early-stage, start-up, and pre-revenue companies create breakthrough devices that would be directly impacted by the MCIT rule. The coverage certainties offered by the MCIT program are

[1] 86 *Fed Reg* 14542, et seq, March 17, 2021; *see* https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf.

critical to these companies, many of whom devote significant resources to evidence and technology research and development to sustain the continued development of their novel technologies.

Throughout this letter, AdvaMed refers to AdvaMed and its AdvaMedDx and AdvaMed Accel divisions. AdvaMed Accel intends to submit separate comments specifically addressing the importance of coverage through MCIT to the small company ecosystem.

AdvaMed is concerned that additional delay in implementing MCIT could compromise access to breakthrough diagnostic and therapeutic devices for Medicare beneficiaries suffering from debilitating conditions, such as heart disease, diabetes, kidney disease and cancer. We urge CMS to implement the MCIT program expeditiously so that all Medicare beneficiaries, including the most vulnerable patients, beneficiaries with multiple comorbid conditions, and beneficiaries at various points along the social and economic spectrum, can benefit from access to these important breakthroughs. In doing so, MCIT may become one of several different strategies that CMS can use to help address the impact of health inequities and social disparities in health.

CMS also highlighted in the proposed rule concerns from stakeholders that "breakthrough devices are not automatically covered nationally by Medicare once they are FDA market authorized," noting that variation in coverage from one jurisdiction to another is also a concern. The MCIT program would improve this long-standing issue of regional coverage inconsistency by ensuring nationwide access to these new technologies.

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 review of diagnostics and devices that represent breakthrough technologies and to promote their use in health care delivery. The MCIT rule would extend the spirit of 21st Century Cures by accelerating the coverage process, thus expediting access to innovative breakthrough devices for the patients who need them most.

In the fiscal year 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule[3], 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 met. In the calendar year 2020 Hospital Outpatient Prospective Payment System (OPPS) final rule[4], 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, cost, and other criteria are also met.

These actions by CMS demonstrate a recognition of the role breakthrough technologies play in improving the lives of patients with debilitating illness. The MCIT rule that was finalized on January 14, 2021, further advanced CMS' commitment to ensuring that Medicare beneficiaries have access to new and innovative breakthrough technologies that improve health and outcomes.

[2] P.L. 114-255, December 13, 2016.
[3] 84 FR 42047.
[4] 84 FR 61295.

Overarching Recommendations:

AdvaMed strongly supports the MCIT pathway to coverage for FDA-designated breakthrough technologies and urges CMS to implement the final rule as soon as possible. The MCIT program will provide meaningful access to breakthrough devices and diagnostics for Medicare beneficiaries without other options.

Combined with the breakthrough pathway for inpatient NTAP and outpatient TPT payment, MCIT will help to promote future advancements in patient care. Implementation of MCIT signals to the entire innovation ecosystem that taking the risk to develop breakthrough technologies is important to improving patient care and can be rewarded if those devices receive FDA marketing authorization.

While AdvaMed appreciated CMS' efforts to clarify a definition of "reasonable and necessary" for Medicare beneficiaries, we opposed codification of the proposed definition in last year's proposed rule and recommended that CMS proceed thoughtfully and first initiate more dialogue with stakeholders. AdvaMed was primarily concerned with the inclusion of commercial insurance policies as part of the definition of reasonable and necessary when determining Medicare coverage, especially because commercial policies themselves lack transparency and processes for stakeholder engagement. CMS has committed to an additional comment period on sub-regulatory guidance for the use of commercial insurance within one year of issuance of the final rule.

- **AdvaMed recommends that CMS implement the final MCIT rule without further delay.**
- **AdvaMed recommends that any modifications to the definition of "reasonable and necessary" be addressed in a manner that does not delay implementation of MCIT. CMS can address its concerns with the "reasonable and necessary" definition through the subregulatory process it has announced. Alternatively, CMS could sever the "reasonable and necessary" from the MCIT provisions. As "reasonable and necessary" and MCIT are independent and distinct provisions that were adopted via a single rulemaking vehicle, MCIT could be implemented as soon as possible, and CMS could address its "reasonable and necessary" concerns separately.**

Medicare Coverage of Innovative Technology - CMS Concerns

In our November 2, 2020, comment letter on the proposed rule, we provided substantial comments on specifics of the MCIT program. Our comments below focus on the key issue areas raised in the March 17, 2021 IFC.

A. Operational Issues

CMS states in the IFC that the Agency underestimated certain operational challenges for implementation of the MCIT program, including establishing coding and payment amounts, and making benefit category determinations (BCD). However, CMS specifically considered this issue as part of the MCIT notice and comment rulemaking and determined that "a detailed description

of coding and payment is beyond the scope of the MCIT rule and resides in other payment rules."[5] Given that the coding and payment issues were explicitly considered as part of notice and comment rulemaking procedures, the issues do not now warrant further delay of the MCIT rule.

AdvaMed remains confident that existing coding and payment pathways, including provision of instructions necessary for claims processing, could be utilized for MCIT-eligible technologies. CMS has extensive experience with expediting coding and payment for medical devices with and without breakthrough designation through both the inpatient NTAP process and the hospital outpatient TPT process, with TPT allowing for quarterly code creation for select technologies. CMS also is experienced with coding, payment, and benefit categories for breakthrough technologies under investigational device exemption (IDE) studies. CMS can adapt established processes such as these to assign codes and payment for MCIT-covered technologies.

These pathways would be improved through the new Technology, Coding, and Pricing Group CMS established late last year to harmonize coverage, coding, and payment processes for innovative technologies, including breakthroughs. This new group also incorporates a pilot project under which knowledgeable CMS staff will guide innovators through the coverage, coding, and payment processes to assist with the Agency's objective of delivering critical new technologies to Medicare beneficiaries more quickly.

As CMS itself noted, for some devices that receive breakthrough designation from the FDA, the timeframe from the date a device receives the FDA-breakthrough designation to the date of market authorization could be months or potentially even years. As discussed in more detail below, FDA breakthrough designation is only the first step in a long process. An August 2020 study, *Early Experience with the FDA's Breakthrough Devices Program*, found that, even after submission to the FDA for approval, the FDA's review time among publicly disclosed high-risk breakthrough devices ranged from 146 to 301 days, with median review time of 181.5 days.[6]

We believe that the FDA time frame required for the designation/approval process affords both substantial lead-time for manufacturers to engage with CMS on these issues, to pursue necessary coding strategies, and to have discussions with CMS regarding the site of service, appropriate payment system, MS-DRG or APC placement or other issues. Even if there is insufficient time to develop permanent codes and national payment amounts for MCIT-eligible technologies, CMS currently has the processes in place to operationalize coding and payment for these technologies (e.g., assignment of temporary codes, invoice pricing, holding of claims for some time-period, or other processes). Concerns about coding and payment are unwarranted and are not obstacles that should further delay or prevent implementation of this program.

Recommendation:

— **CMS should implement the MCIT final rule. CMS' concerns regarding operational challenges are resolvable and are not obstacles to implementation.**

[5] 86 FR 3002.

[6] Johnston, James L.; Dhruva, Sanket; Ross, Joseph; and Rathl, Vinay; "Early Experience with the FDA's Breakthrough Devices Program," Nature Biotechnology, Vol. 38, August 2020, p. 933-938.

B. Overlapping Rules and Benefit Category Determination

In the IFC, CMS notes an issue regarding benefit category determinations for MCIT technologies that it considers a potential obstacle to implementation. CMS appears concerned that MCIT does not allow for public input on benefit category determinations before there is national coverage. In the IFC, CMS indicates:

> *[I]n order to fully operationalize Medicare coverage for a particular breakthrough device, CMS must make other decisions before it can properly pay claims. Among those are whether the device falls within a Medicare benefit category under Part A (Hospital Insurance Benefits) or Part B (Supplementary Medical Insurance Program). These determinations are often called benefit category determinations or BCDs.*[7]

As part of an NCD, CMS will make a formal benefit category determination. However, most Medicare claims are processed without a formal NCD, and there are other ways CMS makes benefit category determinations that do not require an NCD. As CMS notes in a 2013 *Federal Register* notice:

> *In the absence of an NCD, Medicare contractors may establish a local coverage determination (LCD) (defined in section 1869(f)(2)(B) of the Act) or adjudicate claims on a case-by-case basis. The case-by-case adjudicatory model permits consideration of a beneficiary's particular factual circumstances described in the medical record. The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule.*[8]

In the durable medical equipment (DME) proposed rule published in the *Federal Register* on November 4, 2020, CMS reiterated that benefit category determinations can be made on a case-by-case basis: "In situations where CMS has not established a BCD for an item or service, the BCD is made by the MACs on a case-by-case basis as they adjudicate claims".[9] Later, in the same section of that proposed rule, CMS distinguishes benefit category determinations made by CMS or the Medicare contractors from decisions about coding: "Whether or not an item falls under one of the Medicare benefit categories such as DME is a decision made by CMS or the MACs based on statutory and regulatory definitions, separate from the HCPCS Level II coding system and process for identifying items and services."[10]

MACs also make implicit benefit category determinations as part of LCDs. For example, in its LCD for Benign Skin Lesion Removal L34233, Noridian Healthcare Solutions does not specify a benefit category.[11] In this case, Noridian Healthcare Solutions stated only when removal of benign skin lesions would be considered medically reasonable and necessary and not excluded from

[7] 86 FR 14543.
[8] 78 FR 48165.
[9] 85 FR 70396.
[10] 85 FR 70397.
[11] L34233, Benign Skin Lesion Removal (Excludes Actinic Keratosis, and Mohs) Local Coverage Determination, (noridianmedicare.com).

coverage (e.g., the service is not cosmetic). While a benefit category is not specified, removal of skin lesions clearly has a benefit category ("physician services" under section 1861(s)(1) of the Act), or it would not be relevant to specify when these services are covered. In other words, the Medicare Administrative Contractor (MAC) is implicitly making a benefit category determination, as absent a benefit category, a subsequent determination of Medicare coverage or medical necessity would be moot. In general, whether a service is covered by Medicare, including if the service has a statutory benefit category, is primarily based on information provided to the MAC during processing of the claim, including coding or other information on the claim, or other interaction between the MAC and the provider.

In the DME proposed rule, CMS argues that it has "in effect" established "procedures for obtaining public consultation on BCDs and payment determinations for all items and services"[12] because it has established procedures to obtain public consultation on national payment determinations for new DME in response to section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. In 2005, these procedures were expanded to all items and services.

CMS has procedures for establishing BCDs. As stated earlier, CMS has experience making BCDs under IDE studies that we believe is precedential for meeting the timeframe that would be needed for MCIT. In other contexts, CMS establishes national codes and prices through rulemaking such as the Physician Fee Schedule, IPPS, OPPS, and other rules. Furthermore, in these regulations, there is typically no explicit discussion or determination of benefit category. Benefit category is either implicit in the coding and pricing determination or assumed. It also remains the case that in LCDs or case-by-case payment determinations, there is no national process for obtaining input on benefit category determinations—nor would there be a need for such a process when the benefit category is implicit or assumed when making the payment determination.

In its IFC, CMS presented concerns that the DME rule's determination of benefit category overlapped with implicit benefit category determinations made as part of the MCIT rule. The DME rule applies *only* to specific benefit categories (generally, DME, prosthetics and orthotics, surgical dressing, splints casts and other devices used to treat fractures) while the MCIT rule would apply more broadly. CMS should consider that DME represents a special case where public input may be needed to determine whether an item meets the statutory or regulation definition of DME, surgical dressings, splints casts or other devices used to treat fractures and dislocations, prosthetic or orthotic devices, leg, arm, back, and neck braces. The unique nature of these products compared to other Medicare benefit categories (e.g., physicians' services, inpatient hospital services, etc.) involves determining whether the precise and detailed regulatory criteria that describe the benefit are met.

The DME rule sought input on procedures for determining benefit category for only these few classifications of items (that is, CMS proposed to set forth regulations for BCD and payment determinations for items and services described in section 1861(n) and (s)(6) of the Act as well as section 1861(s)(5), (8), (9) and (12) of the Act (85 FR 70397). There are special issues associated with whether an item meets the statutory or regulatory definition of these benefit categories, and

[12] 85 FR 70397.

this does not change the fact that benefit category is either implied or assumed obvious for many other benefit categories (e.g., physicians' service, inpatient hospital services, hospital services incident to physicians' service rendered to outpatient, etc.). In short, ongoing rulemaking regarding determination of DME benefit category is not a reason to delay the MCIT rule that has broader application to other items and services where benefit category is not in question, as it is implied or assumed, and determinations are not explicitly made in the large majority of circumstances. Further, CMS can provide subregulatory guidance about benefit category determinations for the DMEPOS devices that meet the MCIT eligibility requirements.

Without a negative coverage determination, or an otherwise limiting NCD or LCD for a given item or service, CMS should default to coverage for medically necessary services that have a benefit category (explicit or implicit and obvious). The MCIT final rule made clear that Medicare will establish coverage only for items and services that fall within the scope of Part A or Part B benefits.[13] Under MCIT, if CMS determines the technology would not be covered under Part A or B of Medicare, then the device would not be eligible for MCIT.

Finally, it is possible that CMS' concern flows from the 2019 Allina Supreme Court decision[14], which has been interpreted by CMS to require a notice and comment process for substantive Agency decisions. AdvaMed notes that the *Allina* decision faulted CMS for not following notice and comment rulemaking procedures under section 1871 of the Social Security Act (the Act). However, CMS did use notice and comment rulemaking to establish how national coverage would be established for breakthrough technologies under MCIT. Subsequent decisions regarding specific items and services should not warrant additional notice and comment rulemaking.

Recommendation:

— **CMS' issuance of the DMEPOS proposed rule does not raise policy or procedural issues warranting further delay in implementing the MCIT final rule. AdvaMed urges CMS to implement the MCIT final rule, and to finalize the DMEPOS rule without further delay.**

C. **Breakthrough Pathway Device Volume**

In the IFC, CMS cited "new information" from the FDA, which reported that more than 400 devices have been designated as breakthroughs to date. However, FDA recently announced that the Agency has approved only 23 breakthrough technologies since 2015 that would potentially be MCIT eligible (this includes expedited review programs that pre-dated the Breakthrough Device program).[15] Over the 6-year period, this equates to about four devices approved per year. This

[13] 78 FR 48165.
[14] Azar v. Allina Health Services, 139 S.Ct. 1804 (2019).
[15] "The FDA has now approved, authorized, or cleared 23 breakthrough devices through the PMA, De Novo or 510(k) pathways. Programs like these facilitate more rapid progress of innovative devices through the regulatory process, advancing CDRH's vision that patients in the U.S. will have access to high-quality, safe, and effective medical devices of public health importance first in the world." See https://www.fda.gov/news-events/fda-voices/reflections-record-year-novel-device-innovation-despite-covid-19-challenges.

important distinction between breakthrough designation and marketing approval must be considered when estimating the impact of the MCIT on CMS resources.

For innovative devices, obtaining the breakthrough designation from the FDA is merely the first step in a long process before ultimate FDA approval or clearance. The device manufacturer still needs to conduct analytical and clinical studies and produce substantial data on safety and efficacy to provide to the FDA. Once submitted to the FDA, there is additional review time before approval or clearance by the FDA. Many breakthrough-designated devices will not be approved or cleared, due to attrition or other reasons, such as lack of funding to complete clinical studies, which will reduce the number of approved/cleared breakthrough technologies to a much smaller number. Of those, a portion will not be applicable to the Medicare population. CMS acknowledges in the IFC that not all breakthrough-designated devices will be market-authorized, nor can CMS know the precise timing of those market authorizations, which will vary.[16]

Additionally, some of those approved breakthrough technologies received coverage through an NCD, while others did not have an existing Medicare benefit category (e.g., a prescription digital therapeutic delivering behavioral therapy for patients with an opioid disorder). Critics of the MCIT program, such as the authors of the recent *New England Journal of Medicine* article cited in the IFC, are overemphasizing the volume of FDA-designations, and underemphasizing the number of breakthrough-designated devices that ultimately are cleared or approved by the FDA, as well as discounting the rigorous process and lengthy timeline to get from designation to approval.
Of the more than 400 BTP designations:

- Many will take time to get through the process from designation as a breakthrough to approval or clearance by the FDA (e.g., 2-5 years).
- Some will not get through the process, either through attrition or failure ultimately to be cleared or approved by the FDA.
- Others will already be covered by an existing NCD (e.g., diagnostic testing for advanced cancer using next-generation sequencing).
- Still others will not be relevant to a Medicare population (e.g., innovative pediatric devices, or devices that do not fall within a Medicare benefit category).

As CMS discusses in the final rule, a majority of those breakthrough technologies that are relevant to Medicare likely would be covered without the MCIT program (covered via an LCD or NCD[17], or paid for by the MAC without an explicit LCD or NCD when medically necessary). MCIT would merely expedite coverage for those breakthrough technologies that are within an existing Medicare benefit category. Where there is no benefit category, there would be no Medicare coverage and payment. As noted above, we are aware of one such breakthrough technology that was cleared by FDA in December 2018 and has not been able to secure coverage because it has not been determined to fit into any existing benefit category.

[16] 86 FR 14544.
[17] Foundation Medicine's breakthrough CDx test was covered under the NCD for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N); https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290.

Ultimately, a relatively small percentage of the number of breakthrough-designated technologies each year will achieve FDA approval or clearance and be eligible for MCIT. The 23 devices approved or cleared since 2015 represent approximately four per year, though we anticipate this number could increase over time, bringing important breakthrough devices and diagnostics to Medicare beneficiaries who need them.

Further, CMS questions in the IFC whether the public had adequate opportunity to consider the potential growth in breakthrough device volume. But CMS did discuss in the MCIT proposed rule that the Agency's assumptions about MCIT utilization reflected its *"*impression from the FDA that the number of devices granted breakthrough status is increasing," and that "more manufacturers could potentially elect coverage under MCIT," although CMS also assumed that "the majority of devices would have been covered under a different coverage pathway. *"*[18] We believe the public was sufficiently notified and that commenters had adequate opportunity to respond meaningfully to these assumptions during the comment period, and we disagree that CMS' assertions about the potential volume were flawed.

Regarding other potential concerns with the regulatory impact analysis, CMS stated in the MCIT final rule that the FDA's Breakthrough Devices Program is not for all new medical devices; rather, it is only for those that the FDA determines meet the standards for breakthrough device designation. The criteria for breakthrough designation make these devices unique among all other medical devices. CMS also stated that, in general, the Agency believes that the MCIT coverage pathway would range in impact from having no impact on Medicare spending to a temporary cost for innovations that are adopted under an accelerated basis. CMS also noted in the final rule that "new technology may also mitigate ongoing chronic health issues or improve efficiency of services thereby reducing some costs for Medicare.[19]

In addition, CMS said in the final rule's impact statement that the anticipated impacts discussed did not reflect any "offsets for the costs of these technologies that would be utilized through existing authorities nor the cost of other treatments (except as noted)" but noted that such offsetting costs could "substantially reduce or eliminate the net program cost." Further, CMS contemplated the voluntary nature of the MCIT program and acknowledged that while manufacturers may choose to opt-in to the program, the "majority of devices would have been covered under a different coverage pathway," and therefore a substantial portion of the offsetting costs were implicitly reflected in its analysis.[20]

Recommendation:

- **The volume of potential MCIT-eligible devices cited by CMS in the IFC overemphasizes the number of breakthrough-designated devices and fails to consider the number of devices that will likely be approved or cleared by the FDA annually. This information should not impact CMS' decision to implement the final MCIT rule without further delay.**

[18] 85 FR 54337
[19] 86 FR 3007.
[20] Id.

D. **Medicare Patient Benefits/Protection**

In the IFC, CMS expresses concerns regarding the evidence basis for outcomes in older populations and seeks comment on whether the MCIT final rule addresses concerns regarding the clinical benefit of breakthrough devices for the Medicare population.

Regarding the evidence base, manufacturers are required to perform rigorous analytical and clinical studies to obtain marketing authorization from the FDA. The FDA is the global gold standard in terms of medical regulatory agencies around the world. Device labelling, including indications for use and risks outlined in the summary of safety and effectiveness (SSED), appropriately address device risks. For many technologies, the clinical evidence generated as part of FDA approval should be generalizable to the Medicare patient population. In many cases, the clinical evidence will be specific to Medicare beneficiaries (*e.g.*, medical devices intended for the treatment of heart failure) or include studies with some Medicare patients.

In the MCIT final rule, CMS encouraged engagement on evidence development during the MCIT period, to continue to build the evidence base to support long-term coverage of breakthrough devices. CMS also encouraged engagement with the Agency both before and after market authorization, to obtain feedback from CMS. Many of our member companies have engaged with CMS, in an informal parallel review type of process, when seeking coverage under existing, pre-MCIT coverage pathways. This engagement has resulted in feedback on clinical study design and clinical endpoints, and better understanding by both parties of the type of data CMS would like to be assured that medical technologies will improve outcomes for seniors. We believe that similar informal discussions, as CMS recommends in the MCIT final rule, could be utilized by MCIT-eligible devices to allow a more regular and systematic feedback loop, particularly on the evidence base, and provide CMS the assurance it seeks.

We urge CMS to work with AdvaMed and device manufactures to ensure these engagements are fruitful and result in the type of evidence CMS needs to have confidence that the breakthrough technologies that hold such promise for Medicare beneficiaries with debilitating and life-threatening illness actually do provide clinical benefit for those patients. Further, we believe the timeframe between breakthrough designation and FDA marketing authorization can be utilized to allow for these types of conversations in a manner sufficient to satisfy CMS.

Manufacturers also will have significant incentives to continue to develop strong evidence for long-term CMS coverage after the MCIT period, as well as to obtain commercial insurer coverage, and to inform the clinical community and patients about the risks and benefits of the new technology.

We emphasize that while coverage would be immediate for breakthrough technologies that opt in to the MCIT program, dissemination and clinician adoption is not immediate, as it can take time to educate the clinical community and clinicians and hospitals will not automatically utilize a newly available device. Such uptake generally evolves over time, particularly as additional evidence is generated and collected and as relevant association guidelines and recommendations emerge, including the potential for improved outcomes in the elderly, Medicare population. Ultimately, physicians and patients will continue to make decisions regarding which treatments are most

appropriate, in terms of available data demonstrating safety and efficacy, as well as the availability of other treatment options. MCIT would merely eliminate barriers coverage for breakthrough devices without reducing compelling incentives for manufacturers to continue developing evidence supporting long-term coverage.

We agree with CMS' statements in the final rule that the MCIT policy "will provide a balance of ensuring rapid adoption of breakthrough devices, which by definition provide more effective treatment or diagnosis for life threatening or debilitating conditions, while benefitting beneficiaries."[21]

CMS outlined the protections afforded by *both* FDA and *within MCIT* as follows:

> [W]e believe that current FDA requirements for demonstrating safety and efficacy are sufficient in determining whether to grant coverage to a breakthrough device under MCIT. We also note that our rule provides for the termination of MCIT coverage in instances where a medical device safety communication or warning letter is issued by the FDA, or if the FDA revokes market authorization for a device. We believe that these provisions will help protect beneficiary safety while ensuring that beneficiaries have more rapid access to new and innovative technology.[22]

CMS also noted in the final rule several process steps it intended to use to address the important balance of access and safety for breakthrough devices, such as the inclusion of transparency, pointing to publicly available evidence/clinical studies for clinician/patient review, engaging relevant stakeholders, including clinicians and specialty societies, and receiving regular feedback from FDA on important safety signals and concerns.[23] Furthermore, to the extent CMS determines it is appropriate to establish limitations on coverage for a specific breakthrough device, the final rule maintains CMS' authority to issue an NCD for that device as an alternative to coverage under MCIT. AdvaMed agrees that these provisions will protect beneficiaries and believes the regulation struck the right balance between early access and patient protections.

CMS further stated that it recognized that breakthrough devices are those that the FDA has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. That is why CMS previously adopted policies specifying that breakthrough technologies are deemed to provide substantial clinical improvement for purposes of NTAP payment under the IPPS and TPT under the OPPS. As "substantial clinical improvement" is a higher standard than "reasonable and necessary," it would be incongruous for Medicare to automatically consider a device as eligible for additional NTAP or TPT payment but not eligible for Medicare coverage. As CMS stated in the MCIT final rule:

> [B]reakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or

[21] 86 FR 2991.
[22] 86 FR 2991 and 3010.
[23] 86 FR 3003-4.

> conditions. We believe that a device meeting these criteria, once also FDA market authorized, is ‘‘reasonable and necessary’’ for purposes of Medicare coverage.[24]

The MCIT policy provides a balance of promoting rapid adoption of breakthrough devices, "which by definition provide more effective treatment or diagnosis for life threatening or debilitating condition, while benefitting beneficiaries."[25]

Recommendations:

- **AdvaMed agrees that the MCIT final rule adequately addresses concerns regarding the clinical benefits of MCIT-eligible breakthrough devices and provides for sufficient safeguards to protect beneficiaries.**

E. Adequacy of Rulemaking Process

CMS solicits comments on whether there are other procedural issues pertaining to the MCIT rulemaking process, and if so, how those could be remedied. CMS followed standard procedure under the Administrative Procedures Act with respect to the proposed MCIT rule and provided the typical 60-day comment period, during which the public had opportunity to provide feedback on the policies contained in the rule. CMS received and reviewed more than 300 comments from the public.

Given these processes were followed, consistent with the APA, we do not believe there was inadequacy in the rulemaking process that would provide a reasonable rationale for further delaying the final rule.

Regarding codifying the definition of "reasonable and necessary" in regulation. AdvaMed made recommendations in its November 2, 2020, comment letter opposing codification of a definition of "reasonable and necessary" and urging CMS to proceed thoughtfully and provide additional opportunity for stakeholder input. We recommended that CMS finalize the MCIT provisions in the rule but that the Agency withdraw its proposal to codify a definition of reasonable and necessary.

CMS responded by finalizing a revised version of its proposal, noting it would issue subregulatory guidance within one year regarding the use of commercial insurance in the definition of "reasonable and necessary," and obtain stakeholder input for developing the methodology for evaluating commercial insurance. AdvaMed remains concerned that codifying the long-time definition of reasonable and necessary is problematic and confusing, particularly since being combined with the completely distinct MCIT rule has resulted in many assuming the codified and revised definition of "reasonable and necessary" applies only to breakthrough devices.

Recommendation:

- **CMS should proceed with implementation of the final MCIT rule without further delay.**

[24] Id.
[25] Id.

— **If CMS believes it requires additional feedback with respect to the definition of reasonable and necessary, beyond the additional comment period provided in the IFC, CMS should sever this distinct section of the final rule and address the definition of reasonable and necessary separately.**

There is precedent for such action and CMS should strongly consider proceeding in this manner regarding the "reasonable and necessary" definition. For instance, CMS included its price transparency policy in the 2020 OPPS proposed rule[26] but used a separate final rule to finalize that policy.[27]

In summary, AdvaMed urges CMS to make the MCIT provisions of the final rule effective without further delay.

We greatly appreciate the opportunity to comment on the MCIT IFC. We also appreciate CMS' commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve the lives of patients with debilitating conditions.

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,

Andrew C. Fish
Chief Strategy Officer, AdvaMed
Acting Head, Payment & Health Care Delivery Policy Department

[26] 84 FR 39571.
[27] 84 FR 65524.