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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS-3372-F]

RIN 0938-AT88

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). The Medicare Coverage of Innovative Technology (MCIT) pathway will result in 4 years of national Medicare coverage starting on the date of FDA market authorization or a manufacturer chosen date within 2 years thereafter. This rule also implements regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B.

DATES: This final rule is effective on March 15, 2021.

FOR FURTHER INFORMATION CONTACT: Tamara Syrek Jensen and JoAnna Baldwin, (410) 786-2281 or CAGinquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Department is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. Section 6 of the October 3, 2019 Executive Order 13890 (E.O. 13890) "Executive Order on Protecting and Improving Medicare

for Our Nation's Seniors,"[1] directs the Secretary to "propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients" including by "streamlining the approval, coverage, and coding process".[2] The E.O. 13890 explicitly includes making coverage of breakthrough medical devices "widely available, consistent with the principles of patient safety, market-based policies, and value for patients."[3] The E.O. also directs the Secretary to "clarify the application of coverage standards."[4]

Consistent with these directives, we proposed to create a new coverage pathway for breakthrough devices, which we are calling Medicare Coverage of Innovative Technology (MCIT). This pathway will accelerate the coverage of new, innovative breakthrough devices to Medicare beneficiaries. We also proposed to codify the term "reasonable and necessary" to provide greater certainty to stakeholders seeking coverage for innovative items and services and to ensure that this substantive legal standard is codified.

The MCIT coverage pathway is specifically for Medicare coverage of devices that are designated as part of the Food and Drug Administration's (FDA) Breakthrough Devices Program (hereafter referred to as "breakthrough devices") and are FDA market authorized. FDA's Breakthrough Devices Program is for certain medical devices, device-led combination products, and can include lab tests.[5] The MCIT pathway would be voluntary and device manufacturers would notify CMS if they want to utilize this coverage option.

We proposed that National Medicare coverage under the MCIT pathway could begin immediately upon the date of FDA market authorization (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 or on the date designated by the manufacturer

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[1] Executive Order on Protecting and Improving Medicare for Our Nation's Seniors, *available at* https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/
[2] *Id.*
[3] *Id.*
[4] *Id.*
5 Food and Drug Administration, Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff, *available at*: https://www.fda.gov/media/108135/download

within any point during the four year eligibility period for coverage under MCIT. This coverage can occur unless the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute (that is, the Medicare statute does not allow for coverage of the particular device.) This coverage pathway delivers on the Administration's commitment to give Medicare beneficiaries access to the newest innovations on the market, consistent with the statutory definitions of Medicare benefits. Because Medicare is a defined benefit program, devices that do not fit within the statutory definitions may not be considered for MCIT. As an example, medical equipment for home use by the beneficiary must be durable (that is, withstand repeated use) for it to be coverable by Medicare (as defined in statutes and regulations by the Secretary).

The Secretary has authority to determine whether a particular medical item or service is "reasonable and necessary" under section 1862(a)(1)(A) of the Act. (*See Heckler v. Ringer*, 466 U.S. 602, 617 (1984).) When making coverage determinations, our policies have long considered whether the item or service is safe and effective, not experimental or investigational, and appropriate. (For more information see the January 30, 1989 notice of proposed rulemaking (54 FR 4307)). These factors are found in Chapter 13 of the Medicare Program Integrity Manual (PIM) at section 13.5.4—*Reasonable and Necessary Provisions in LCDs* as instructions for Medicare contractors.[6] We proposed to codify in regulations the Program Integrity Manual definition of "reasonable and necessary" with modifications, including to add a reference to Medicare patients and a reference to commercial health insurer coverage policies. We proposed that an item or service would be considered "reasonable and necessary" if it is--(1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is--

6 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf

- 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.

We also proposed that an item or service would be "appropriate for Medicare patients" under (3) if it is covered in the commercial insurance market, except where evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals. An item or service deemed appropriate for Medicare coverage based on commercial coverage would be covered on that basis without also having to satisfy the previously listed bullets. We believed this definition would be a significant step in meeting the E.O.'s discussion of the need to bring clarity to coverage standards. Stakeholders have expressed interest in codifying a definition of "reasonable and necessary" for many years.

A. Statutory Authority

As stated in the previous section, we proposed to codify the PIM's definition of reasonable and necessary with a modification to the appropriateness factor to allow CMS to refer to commercial coverage. We will finalize in regulation the factors we have historically used in making "reasonable and necessary" determinations under section 1862(a)(1)(A) of the Act, with a modification, discussed below, to factor (3) to determine whether an item or service is appropriate based, in prescribed circumstances, on coverage in the commercial market. In general, this section of the Act permits Medicare payment under part A or part B for any expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Thus, with some exceptions, section 1862(a)(1)(A) of the Act requires that an item or service be "reasonable and necessary" to be covered by Medicare. The courts have recognized that the

Secretary has significant authority to determine whether a particular item or service is "reasonable and necessary," and that the statute affords broad discretion to interpret this term (*Heckler v. Ringer*, 466 U.S. 602, 617 (1984). *See also, Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 84 (2d Cir. 2006); *Kort v. Burwell,* 209 F. Supp. 3d 98, 110 (D. D.C. 2016) (The statute vests substantial authority in the Secretary.)) In regard to the MCIT coverage pathway, we proposed national Medicare coverage for breakthrough devices that are FDA market-authorized and used consistent with the FDA approved or cleared indication for use (also referred to as the "FDA-required labeling").[7] This device coverage under the MCIT pathway is reasonable and necessary for a duration of time under section 1862(a)(1)(A) of the Act because the device has met the very unique criteria of the FDA Breakthrough Devices Program.

B. FDA Breakthrough Devices Program

Under the MCIT coverage pathway, CMS will coordinate with FDA and manufacturers as medical devices move through the FDA regulatory processes for breakthrough device designation and market authorization to ensure seamless Medicare coverage after market authorization unless CMS determines those devices do not have a Medicare benefit category. The Breakthrough Devices Program is an evolution of the Expedited Access Pathway Program and the Priority Review Program (section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), 21 U.S.C. 360e-3; see also final guidance for industry entitled, "Breakthrough Devices Program," https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf).

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.

[7] FDA Guidance for Industry, "Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers", *available at* https://www.fda.gov/media/133619/download.

In accordance with section 3051 of the 21st Century Cures Act (21 U.S.C. 360e-3),[8] the Breakthrough Devices Program is for medical devices and device-led combination products that meet two criteria. The first criterion is that the device provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The second criterion is that the device must satisfy one of the following elements: it represents a breakthrough technology; no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or device availability is in the best interest of patients (for more information see 21 U.S.C. 360e-3(b)(2)). These criteria make breakthrough designated devices unique among all other medical devices.[9] The parameters of the breakthrough devices program focus on innovations for patients, in turn, MCIT, focuses on these breakthrough devices consistent with E.O. 13890 and in order to streamline coverage of innovative medical devices. We note that the FDA's guidance stresses the need for breakthrough devices to still meet the statutory standard of reasonable assurance of safety and effectiveness at the time of approval, meaning that a device which receives FDA breakthrough designation automatically satisfies factor (1) of our reasonable and necessary definition.

C. Current Medicare Coverage Pathways

Currently, we utilize several coverage pathways for items and services, which includes medical devices. None of the coverage pathways described in this section offer immediate, predictable coverage concurrently with FDA market authorization like the proposed MCIT pathway would do. We summarize the other coverage pathways here to provide context for MCIT.

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[8] 21st Century Cures Act, *available at* https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf; *see* FDA Guidance for Industry and Food and Drug Administration Staff, Breakthrough Devices Program *available at* https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.

[9] FDA does not publish a list of breakthrough designated or breakthrough designated and subsequently market authorized devices. However if a breakthrough device gains market authorization through a PMA only, then the summary of safety and effectiveness data (SSED) will contain a reference for the breakthrough designation. This is not true for De Novos which have been granted or cleared 510(k)'s. In consideration of that approach, this notice of public rulemaking does not contain such lists.

● National Coverage Determinations (NCDs): Section 1862(l)(6)(A) of the Act defines the term national coverage determination as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title." In general, NCDs are national policy statements published to identify the circumstances under which particular items and services will be considered covered by Medicare. Traditionally, CMS relies heavily on health outcomes data to make NCDs. Most NCDs have involved determinations under section 1862(a)(1)(A) of the Act, but NCDs can be made based on other provisions of the Act, and includes a determination that the item or service under consideration has a Medicare benefit category. The NCD pathway, which has statutorily prescribed timeframes, generally takes 9 to 12 months to complete.[10]

● Local Coverage Determinations (LCDs): Medicare contractors develop LCDs based on section 1862(a)(1)(A) of the Act that apply only within their geographic jurisdictions. (Sections 1862(l)(6)(B) and 1869(f)(2)(B) of the Act.) MACs will not need to develop LCDs for breakthrough devices when they are nationally covered through MCIT. Manufacturers declining to participate in the MCIT pathway may still seek LCDs from the MACs during and after the four year eligibility period, using the current process.

The MACs follow specific guidance for developing LCDs for Medicare coverage in the CMS Program Integrity Manual, and in some instances, an LCD can also take 9 to 12 months to develop (MACs must finalize proposed LCDs within 365 days from opening per Chapter 13-Local Coverage Determinations of the (PIM) 13.5.1). We note that the MCIT pathway does not alter the existing coverage standards in Chapter 13-Local Coverage Determinations of the PIM.[11] That chapter will continue to be used, to the extent consistent with other parts of this final rule, in making determinations under section 1862(a)(1)(A) of the Act. .

10 Section 1869(f)(4) of the Act.

[11] CMS Program Integrity Manual, Chapter 13 Local Coverage Determinations, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf

- Claim-by-claim Adjudication: In the absence of an NCD or LCD, MACs would make coverage decisions under section 1862(a)(1)(A) of the Act and may cover or not cover items and services on a claim-by-claim basis. The majority of claims are handled through the claim adjudication process.

- Clinical Trial Policy (CTP) NCD 310.1: The CTP pathway can be used for coverage of routine care items and services (but generally not the technology under investigation) in a clinical study that is supported by certain Federal agencies. The CTP coverage pathway was developed in 2000.[12] This coverage pathway has not generally been utilized by device manufacturers because they usually seek coverage of the device, which is not included in the CTP pathway.

- Parallel Review: Parallel Review is a mechanism for FDA and CMS to simultaneously review the submitted clinical data to help decrease the time between FDA's approval of a premarket application or granting of a de novo classification and the subsequent CMS NCD. Parallel Review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial within the FDA pre-submission process; and (2) FDA and CMS concurrently review ("in parallel") the clinical trial results submitted in the PMA, or De Novo request. FDA and CMS independently review the data to determine whether it meets their respective Agency's standards and communicate with the manufacturer during their respective reviews. This program is most successful for devices that have a significant amount of clinical evidence. (Candidates for parallel review are not be appropriate for simultaneous MCIT consideration.)

In contrast to these other coverage pathways, MCIT is readily available to provide immediate national coverage for new breakthrough devices with a Medicare benefit category as early as the same date as FDA market authorization. The MCIT pathway can support

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[12] CMS, National Coverage Determination for Routine Costs in Clinical Trials *available at* https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true.

manufacturers that are interested in combining coverage with their own clinical study to augment clinical evidence of improved health outcomes, particularly for Medicare patients. .

Comment: Many commenters generally supported the MCIT concept, expressing that it would result in faster and more consistent access to newly authorized technologies for Medicare beneficiaries. Those commenters recognized that immediate coverage of newly FDA market-authorized breakthrough technologies via the pathway would avoid the ambiguity and possible inconsistency of claim-by-claim coverage by the MACs as well as the delays inherent in either the LCD or NCD pathways. Commenters suggested that MCIT will bring closer alignment of FDA and CMS decision-making, and would help to more closely coordinate coverage, coding and payment functions. Those who were supportive also stated their belief that the proposal would promote innovation; decrease uncertainty and delays in coverage; improve FDA – CMS coordination; and improve beneficiary access to cutting-edge treatments. Many commenters expressed support for the MCIT proposal in principle but nonetheless requested important clarifications or expressed significant reservations about specific elements.

Some commenters did not believe that the proposed MCIT pathway was necessary because existing coverage pathways provide a sufficient mechanism for coverage of newly FDA market authorized items and services. One commenter expressed concern that the MCIT pathway may undermine or circumvent existing pathways. A few commenters recommended that coverage for breakthrough technologies should be left to MAC discretion because they retain considerable flexibility to cover new technologies and can adjust coverage policy as new evidence emerges. Other commenters discussed the parallel review and Coverage with Evidence Development (CED) programs (CED is a paradigm whereby CMS issues an NCD to cover items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data). The commenters stated that the parallel review program may shorten the time between FDA market authorization and coverage, but is generally more appropriate for items and services where there is relatively greater clinical evidence than

under the breakthrough device pathway. For topics where there is less evidence on safety and efficacy available, such as newly FDA market authorized breakthrough technologies, they asserted the CED pathway is more appropriate. A few commenters recommended that instead of establishing the MCIT pathway, more resources should be applied to existing pathways to allow CMS to conduct expeditious review of a larger number of topics.

Response: CMS agrees that coverage of breakthrough devices through the MCIT pathway will accelerate access to items and services that address important unmet needs, as well as help CMS work more closely with FDA. We do not believe that simply devoting more resources to the existing coverage pathways will yield the synergy with FDA we anticipate will be created from the MCIT pathway. With the exception of claim-by-claim coverage, both LCDs and NCDs are subject to statutory timeframes and require considerable CMS resources to complete. This includes policy analysts, epidemiologists, physicians, data analysts and additional supporting staff in addition to contract money that is required to host meetings of the Medicare Evidence Development and Coverage Advisory Committee and commission external technical assessments. There are many steps outlined in Chapter 13 of the PIM regarding the process for attaining an LCD, and this process must be repeated in each MAC jurisdiction. The MCIT pathway will increase Medicare beneficiary access to newly FDA market-authorized treatments, for which similar devices may not exist and which improve health outcomes for patients, simplify and accelerate the process to gain coverage, and eliminate geographic variations in coverage that may occur for treatments covered on a claim-by-claim basis. Support for further innovation is a secondary benefit of the MCIT coverage pathway. We also agree with commenters that the parallel review program or CED may not be available to innovators under all circumstances, or may not be the most appropriate pathway for their circumstances, which is in part why we are making the MCIT pathway available as another route to CMS coverage. We remind commenters that coverage under MCIT is provisional, and that once MCIT coverage expires, our standard definition of reasonable and necessary as modified in this rulemaking, will

be applied to determine whether and when to cover these devices.

We do not agree that the MCIT pathway will undermine or circumvent existing pathways. Only breakthrough devices will be eligible for the MCIT pathway. Sec. 515B(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 360e-3(c)) states that a request for a breakthrough device designation may be made at any time prior to the submission of an application for premarket approval, approval under Sec. 510(k) of the FD&C Act (21 USC 360(k)), or approval under a de novo marketing authorization. Because requesting a breakthrough device designation presumes an application for approval under one of these three pathways, the MCIT pathway depends on, and does not undermine, these three avenues for FDA approval. We also do not agree that coverage for breakthrough technologies should be left to MAC discretion. The MCIT pathway will provide innovators greater certainty of initial Medicare coverage.

Comment: We solicited comments in the MCIT proposed rule on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval) or all diagnostics, drugs, and/or biologics. Some commenters expressed support for changing the way innovative technologies without FDA breakthrough device designation are covered by Medicare. These commenters pointed out that there may be innovative technologies which they believe ought to be covered by Medicare that choose not to use FDA's breakthrough device pathway or may be an innovative technology that may not qualify for the designation. One commenter suggested that CMS should preclude MACs from non-covering these technologies. Other commenters suggested non-breakthrough devices, drugs, and biologics should be eligible for an MCIT type of coverage pathway because non-breakthrough items and services also improve patient health outcomes. One commenter recommended that CMS be able to include non-breakthrough devices based on agency discretion as to when beneficiaries should have expedited access to an item or service.

In response to the question CMS posed about whether MCIT should include diagnostics, drugs, and biologics that use the breakthrough or other expedited FDA pathways, commenters provided varied suggestions. Some commenters offering general support of the MCIT program stated that the MCIT program should be limited, as we proposed, to technologies that are designated by the FDA as breakthrough devices. Some of these commenters supported their position by suggesting that device coverage lags further behind that of drugs and biologics and; therefore, devices are more in need of a program like MCIT. There were specific requests for CMS to include humanitarian use devices. Other commenters suggested that innovative devices using FDA Investigational Device Exemption (IDE) Category B designation should be eligible for MCIT.

Response: We appreciate that commenters shared their interest in CMS providing a pathway for non-breakthrough designated devices, and we share their interest in furthering innovation. Noting that, as stated in our proposed rule, E.O. 13890 makes explicit mention of medical devices in its directive, we have heard concerns from stakeholders that there is more uncertainty surrounding coverage of devices than for other items and services, such as drugs and biologics. For this reason, our proposal centered on breakthrough designated devices, since we believed that this was the area with the most immediate need, particularly in light of the unique FDA criteria for breakthrough designation status. We agree with commenters that we should undertake efforts to promote innovation across all items and services which could potentially be covered under Medicare. However, because we have consistently heard from stakeholders about the need for more rapid approval of breakthrough devices in particular, E.O. 13890 explicitly mentions devices, and because the immediate opportunity is to align with the FDA's breakthrough device designation, we are not expanding beyond breakthrough devices for the final rule. As the MCIT pathway develops and proves successful, we may consider expanding its application to other items and services, including Category B IDE and HUD devices in future rulemaking.

Comment: Some commenters asserted that FDA market authorization of breakthrough devices should suffice to establish that they are safe and effective. Other commenters argued further that establishment of safety and effectiveness is within the exclusive purview of the FDA, and no additional evidence should be required to meet the CMS reasonable and necessary evidence standard.

Response: We agree that establishment of safety and effectiveness is generally within the purview of the FDA under its statute, but not all items and services that may be covered under Medicare are regulated by the FDA.

Comment: A significant number of commenters noted that some breakthrough devices have no clinical data at the time of FDA market authorization, and many breakthrough devices lack data on patients older than 65, patients with disabilities, and patients with end stage renal disease, which poses some uncertainty about the FDA's ability to gauge safety and efficacy in the context of the Medicare population. There was also concern expressed about how the Medicare population is often excluded from clinical trials due to age and health status. Numerous commenters noted that the FDA frequently extends market authorization after reviewing short-term clinical studies with the proviso that ongoing data collection in the post-market authorization period is required to establish long-term durability of treatment effect. Furthermore, commenters cited evidence that FDA mandated post-market studies are not reliably completed and asserted that explicit assessment of safety and effectiveness in Medicare beneficiaries is essential. Several commenters provided specific examples of FDA market authorized devices that failed to demonstrate benefit when subjected to post-market clinical study.

Response: FDA assessments of safety and efficacy are general characterizations of a product. It is always up to an individual, in consultation with their physician, to determine whether an item or service is best applied to their individual health circumstances. Given this fact, we 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.

Additionally, in our proposed rule, we recognized that breakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. We believe that a device meeting these criteria, once also FDA market authorized, is ‘‘reasonable and necessary’’ for purposes of Medicare coverage. The MCIT pathway establishes rapid coverage of breakthrough devices because existing coverage pathways do not provide immediate, national Medicare coverage. We believe this 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. We do not agree that automatic coverage for other FDA approved products under section 1862(a)(1)(A) is warranted because by definition, breakthrough devices are those for which no approved alternative exists or that offer significant advantages over existing approved or cleared alternatives (21 USC 360e-3(b)(2)). Because other alternatives exist for conditions that can be treated with non-breakthrough devices, the urgency to provide coverage for these items and services on a provisional basis is not as great. In addition, we believe other avenues exist for non MICT eligible items and services to expeditiously gain coverage. For example, FDA has special procedures in place to grant fast track designation for certain new drugs, and other types of new drugs are eligible for a separate breakthrough therapy designation (not to be confused with the breakthrough device designation for which this rule makes MCIT coverage available). Furthermore, the need for certainty in this regard is not as high as compared to breakthrough devices because, the FDA only grants

breakthrough designation to devices where no approved or cleared alternatives exist and device availability is in the best interests of patients.

D. MCIT Pathway

We proposed that the MCIT pathway would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to 4 years, unless we determine the device does not have a Medicare benefit category as determined by us as part of the MCIT pathway process. The MCIT pathway is voluntary (that is, manufacturers would affirmatively opt-in), and would be initiated when a manufacturer notifies CMS of its intention to utilize the MCIT pathway. (This notification process is described further in section III. of this final rule). We would subsequently coordinate with the manufacturer regarding steps that need to be taken for MCIT implementation purposes. The frequency of subsequent engagement will be largely driven by whether the manufacturer has questions for CMS, or CMS and FDA. The timing of coverage will be left to the manufacturer's discretion provided they request to enter the MCIT pathway within the four year timeframe for which they would be eligible to participate. Engagements can take place in the form of in-person meetings, phone calls, emails, etc. We intend to put devices that are covered through the MCIT pathway on the CMS website so that all stakeholders will be aware of what is covered through the MCIT pathway. This measure was completely supported by the public comments. Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway. However, we sought comment as to whether CMS 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.[13] We are aware some manufacturers may be required by the FDA to conduct post market data collection as a condition of market authorization, and nothing

[13] CMS, *Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development*, *available at* https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.

in this proposed rule would alter that FDA requirement. Manufacturers are encouraged to develop the clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends. This evidence is encouraged not only for CMS and commercial health insurer coverage policies but also to better inform the clinical community and the public generally about the risks and benefits of treatment. CMS encourages early manufacturer engagement, both before and after FDA market authorization, for manufacturers to receive feedback from CMS on potential clinical study designs and clinical endpoints that may produce the evidence needed for a definitive coverage determination after MCIT. This feedback would not involve CMS predicting specific coverage or non-coverage.

In order to further the goals of E.O. 13890, CMS proposed to rely on FDA's breakthrough device designation and market authorization of those devices to define the universe of devices eligible for MCIT, except for those particular devices CMS determines do not have a Medicare benefit category or are statutorily excluded from coverage under Part A or Part B. We proposed to establish a four year time limit on how long a breakthrough device can be eligible for MCIT (that is, considered a breakthrough device for coverage purposes). The 4 year coverage period is particularly important for manufacturers of breakthrough devices that choose to further develop the clinical evidence basis on which the FDA granted marketing authorization. From our experience with clinical studies conducted as part of an NCD, 4 years is approximately the amount of time it takes to complete a study.

At the end of the 4-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). Manufacturers that are interested in a NCD are encouraged to submit a NCD request during the third year of MCIT to allow for sufficient time for NCD development. We sought public comment on whether CMS should open a national coverage analysis if a MAC

has not issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period.

We sought public comment on the proposed MCIT pathway, the considerations described, whether any of the existing coverage pathways should be modified to achieve the goals set out by the E.O., and solicited alternatives to these proposals. We specifically sought public comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval[14]) or all diagnostics, drugs and/or biologics. We sought data to support including these additional item categories in the MCIT pathway. Also, we specifically sought manufacturer input on whether an opt-in or opt-out approach would work best for utilizing the MCIT pathway. We believe manufactures will welcome this new coverage pathway. We want to preserve manufacturers' business judgment and not assume which Medicare coverage pathway a given manufacturer of a breakthrough device would prefer (if any). Therefore, we proposed an opt-in approach with an email to CMS to indicate affirmative interest in coverage. We expressed interest in whether an opt-out approach would be less burdensome for stakeholders. We encouraged public comment on a process for stakeholders to opt-out of MCIT that would not be burdensome. Also, we sought public comment on whether, once a manufacturer has opted-out of coverage, it can subsequently opt-in to MCIT.

Comment: The majority of comments generated by our questions concern issuing an NCD at the end of the four year period did not support CMS automatically opening an NCD if MACs had not issued an LCD after 6 months. One commenter stated that the 6 month timing was arbitrary with another stated that 6 months would not be enough time for MACs to perform a comprehensive analysis as data may not be fully available or there may be LCDs in-process at

[14] Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, *available at* https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

the 6 month mark. Many manufacturers cited the desire for flexibility in the timing of requesting an NCD and some specifically cited support for claim by claim adjudication by the MACs and believe that FDA approved or cleared indications will be covered by MACs on a claim by claim basis. Some commenters did not want automatic LCDs or NCDs but wanted assurance that absent those mechanisms the MACs would, on a claim by claim basis, cover MCIT graduated technologies consistent with their FDA approved or cleared indications. A few commenters supported some version of a process by which an NCD would automatically be triggered including that the manufacturer would be required to submit an NCD request during year 3 of MCIT coverage and requiring the NCD to be complete by the end of year 4. A few commenters expressed general concern for potential uncertainty among patients and providers regarding whether MCIT coverage of a device would continue past year 4. One commenter noted that submission of requests for NCDs and LCDs are not restricted to manufacturers, anyone can submit a request.

Response: We appreciate commenters' input. We agree that manufacturers should have flexibility in timing their request for an NCD under MCIT so that they can adequately prepare to market the device and satisfy consumer expectations. We further believe that flexibility in the case of timing for the development of LCDs and NCDs would be in the best interest of beneficiaries, manufacturers and providers. We believe that there will be situations in which not enough evidence will be available on which an LCD or NCD can be made and claim by claim adjudication is most appropriate, if even temporarily while the data continues to be developed. A 6-month timeframe may not be appropriate in all situations so this one size fits all approach to trigger an NCD at 6 months after the close of the 4 year MCIT coverage period is not flexible enough to account for the various levels of evidence that may be available. We are not able to require MACs to adjudicate claims for a particular result, this merely sidesteps the NCD process. However, we note that manufacturers and providers can discuss technologies with the clinical staff and medical directors working for each MAC. We also appreciate and are sensitive to the

concern over the continuity of care for patients who are using breakthrough devices and find it important to state that beneficiaries with a device covered under MCIT will continue coverage of any routine services or complications related to that device beyond the 4-year period of MCIT coverage. After considering the comments, we are not making any changes in the final rule with respect to the possible outcomes at the end of the 4-year MCIT pathway, which are: (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). Manufacturers that are interested in a NCD are encouraged to submit a NCD request during the third year of MCIT to allow for sufficient time for NCD development. CMS will not automatically open a national coverage analysis within six months of the expiration four year MCIT period.

Comment: CMS received overwhelming support from commenters in favor of the voluntary, opt-in model of MCIT as proposed because it allows manufacturers to use their judgment in determining whether to participate. Some of the commenters who supported opting-in also added that communicating with CMS for entry into the MCIT program would be beneficial for both parties by encouraging discussion about the technology, coding, payment, and the evidentiary expectations after 4 years of coverage under MCIT. Another commenter indicated that opting-in would not be burdensome and would not likely be a deterrent to MCIT participation. A small number of commenters were in favor of automatic participation in MCIT unless a manufacturer chose to opt-out. One of these commenters cited the likelihood of administrative errors that could occur which could delay opting-in and would inadvertently exclude a manufacturer from MCIT.

Response: We agree with commenters that supported the voluntary, opt-in model for the MCIT program. Of the commenters that had concerns, we believe their concerns will be addressed by finalizing that manufacturers may opt-into MCIT using no more than an email from the manufacturer to CMS indicating a desire to opt-in and the requested start date of MCIT coverage. We believe that this should ensure a simple engagement with CMS to opt and will

limit burden and improve collaboration with CMS. Commenters who expressed support for the opt-in model spoke to increased collaboration with CMS. Commenters who supported the opt-out method in order to limit administrative burden and confusion will be pleased by the simplicity of and public information available for the process of opt-in. Manufacturers may request to opt-in any time during the first 2 years in which they are eligible to participate in MCIT, however, the four year coverage period begins the day the breakthrough devices receives FDA authorization. A more complete discussion including summary of comments and responses on the four-year coverage period and when it begins appears later in this rule.

II. Provisions of Proposed Regulations and Analysis of and Responses to Public Comments

A. Defining "Reasonable and Necessary"

As described in section I. of this final rule, the Secretary has authority to determine the meaning of "reasonable and necessary" under section 1862(a)(1)(A) of the Act. We proposed to codify the longstanding Program Integrity Manual definition of "reasonable and necessary" into our regulations at 42 CFR 405.201(b), with modification. Under the current definition, an item or service is considered "reasonable and necessary" if it 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.

In addition to codifying the previously discussed criteria, we proposed to include a separate basis under which an item or service would be appropriate under (previously stated) (3) that is based on commercial health insurers' coverage policies (that is, non-governmental entities that sponsor

health insurance plans). We proposed the commercial market analysis would be initiated if an item/service fails to fulfill the existing factor (3) criteria defining appropriate for Medicare patients but fulfills (1) safe and effective and (2) not experimental or investigational. We believed that this approach would be in line with E.O. 13890 that directs us to make technologies "widely available, consistent with the principles of patient safety, market-based policies, and value for patients." Under this separate basis, we proposed that an item or service would satisfy factor (3) if it is covered under a plan(s) coverage policy if offered in the commercial insurance market, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant. Under our proposal, we would exclude Medicaid managed care, Medicare Advantage, and other government administered healthcare coverage programs from the types of coverage CMS would consider, as these enrollees are not in the commercial market. In the following paragraphs, we sought comment on this proposal and on how best to implement this mechanism.

We solicited comments on the following:

- Sources of data that could be used to implement this policy, and whether CMS should make this information public and transparent.
- Appropriate source(s) for these coverage policies and the best way to determine which commercial plan(s) we would rely on for Medicare coverage.
- Whether beneficiaries, providers, innovators, or others wishing to gain coverage for an item or service should demonstrate that the item or service is covered by at least one commercial insurance plan policy. If they could provide CMS with evidence of commercial coverage or if CMS or its MACs identify such coverage from its review of compilations of health insurance offerings or data from other sources, CMS would consider factor (3) to be satisfied.
- Whether we should limit our consideration of commercial plan offerings or covered lives to a subset of the commercial market in the interest of simplicity, including looking at

geographic subsets, subsets based on number of enrollees, subsets based on plan type (HMO, PPO, etc.), or other subsets of plans – including utilizing a singular plan.

- Whether, given considerations such the variation and distribution of coverage policies and access to innovations, we should 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. (A plan offering is a contract an insurer offers to its enrollees, and a single insurance company may provide many different offerings).

We recognized that plan offerings may impose certain coverage restrictions on an item or service, e.g. related to clinical criteria, disease stage, or number and frequency of treatment. We proposed, when coverage is afforded on the basis of commercial coverage, we would adopt the least restrictive coverage policy for the item or service amongst the offerings we examine. However, given potential unreasonable or unnecessary utilization, we also solicited comment on whether we should instead adopt the most restrictive coverage policy. We further considered a variation whereby, if coverage restrictions are largely similar and present across the majority of offerings, CMS would adopt these in its coverage policies. We sought comment on whether, if we were to take this approach, we should instead use a proportion other than a majority, as low as any offering and as high as all offerings, as a sufficient threshold. As a final variation, we proposed we could defer, in the absence of an NCD or national policy, to the MACs to tailor the restrictions on coverage based on what they observe in the commercial market, just as we rely on MACs with regards to the current definition.

We further solicited comment on whether to grant coverage for an item or service to the extent it meets the first and second factors and the commercial coverage basis for the third factor. Under this approach, we would only use the current definition of "appropriate" from the current PIM when the exception for clinically relevant differences between Medicare beneficiaries and commercially insured individuals applies (or if the commercial coverage basis is determined by a

proportion like a majority and there is insufficient commercial coverage information available). We noted that referring to commercial coverage in this way may expand or narrow the circumstances under which we would cover a particular item or service and; therefore, solicited comment on whether, under such an approach, we should grandfather our current coverage policies for items and services. We also emphasized that the MACs would continue to make judgements in evaluating individual claims for reimbursement, such that a decision by CMS that an item or service is reasonable and necessary in general does not mean that it is reasonable and necessary in all circumstances with respect to individual claims for reimbursement.

We sought public comment on the most appropriate source(s) for these coverage policies. Further, we proposed 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. We proposed that we may also allow the MACs to develop approaches to address any or all of the considerations as previously outlined, parallel to their current practice of making coverage decisions in the absence of an NCD or national policy. We solicited comment on the best role of the MACs, along these lines or otherwise. We also solicited comment on whether the discretion to use the current criteria in the PIM when there is evidence to believe Medicare beneficiaries have different clinical needs should be exercised through the NCD process or in other ways, as well as what quantum of evidence should be sufficient.

In sum, we proposed to define the term "reasonable and necessary" based on the factors currently found in the PIM, plus an alternative basis for meeting factor (3) based on any coverage in the commercial market. We also solicited comment on an alternative under whether an item or service satisfies the commercial coverage basis for factor (3) is determined by how it is treated across a majority of covered lives amongst commercial plan offerings, as well as an alternative whereby an item or service would be appropriate for Medicare patients to the extent it is covered in the commercial market. When evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant, we proposed

we would rely on the criteria in the current PIM. In the proposed, we stated we would continue relying on local administration of the program by MACs (including coverage on a claim by claim basis and LCDs) and maintain our discretion to issue NCDs based on the final rule.

We solicited comment on the proposed definition of reasonable and necessary, and the previously outlined alternatives, as well as other mechanisms or definitions we could establish for the term "reasonable and necessary", and the merits and drawbacks associated with each, including the potential impact on Medicare program expenses or complexity. We proposed to finalize any variation or outgrowth of the policies described in the proposal, or some combination of these options in lieu of or in conjunction with the proposed definition.

"Reasonable and Necessary" Definition

Comment: CMS received many comments requesting that the agency not finalize the reasonable and necessary definition in regulation. These commenters point out the Medicare has not codified the definition since the program was established. Some commenters recognized that the longstanding reasonable and necessary definition in the Program Integrity Manual is understood by stakeholders, including CMS, however, they believed that retaining this definition only in sub-regulatory guidance will allow for greater flexibility.

Response: We disagree with those commenters that opposed the agency issuing a final rule codifying long -standing agency policies with modifications. When we establish substantive legal standards governing the scope of benefits, payment for services, or the eligibility of individuals, entities, or organizations definition that is currently in CMS manuals will not change how CMS is implementing reasonable and necessary currently. Adding it to furnish or receive services, the Medicare statute generally requires that the Secretary establish those policies by regulation. Although it is true that regulations cannot be changed as quickly as other policies, the public benefits by having the opportunity to participate in the rulemaking and the resulting policies will have the force of law and provide greater stability. In addition, issuing regulations in these circumstances is consistent with the Supreme Court's decision in *Azar v. Allina Health*

Services, 139 S. Ct. 1804 (2019). Thus, we believe it is appropriate to establish the reasonable and necessary criteria in regulations, and will not adopt the commenters' suggestion.

Comment: Commenters questioned whether the reasonable and necessary definition would apply to items and services beyond devices.

Response: Yes, the reasonable and necessary definition applies to all items and services Medicare covers under Part A and Part B. This includes, but may not be limited to, drugs, devices and biologics. Medicare Advantage plans are required to offer coverage of these items and services on terms at least as permissive as those adopted by fee for service Medicare under this policy.

Comment: CMS received a few comments regarding broadening the definition of reasonable and necessary to include prevention and screening items and services.

Response: We are not adopting this suggestion because Congress has made express exceptions to 1862(a)(1)(A) in order to provide Medicare coverage for covers. Because those services are based on statutory authorities. CMS has already issue specific regulations for those services, it is not necessary or appropriate to amend the regulations defining reasonable and necessary to include preventive measures

Safe and Effective

Comment: Several comments stated that CMS should further define what it means by "safe and effective." For example, one commenter recommend that evidence-based guidelines that should be considered for meeting the safe and effective criteria. In addition, we had other comments state that FDA market authorization should meet the safe and effective criterion. However, other commenters state that there are items and services not regulated by the FDA; therefore, CMS should not further define this criterion to FDA-market authorization/approval.

Response: The requirement of safe and effective is a long-standing part of the definition of reasonable and necessary. CMS believes the long-standing factor is an appropriate starting point for a definition, with minor technical changes as proposed and then finalized in this rule.

Comment: CMS should establish its own stand-alone criteria that allows for "investigational and experimental" treatment to be deemed to be reasonable and necessary.

Response: CMS has stand-alone criteria that allows for coverage of certain investigational and experimental items and services. CMS covers certain Investigational Device Exemptions (IDE) devices under 42 CFR § 405 Subpart B). In addition, CMS also covers certain investigational items under the Clinical Trial Policy (see https://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=186&bc=AAgAAAAAAAAA&).

Appropriate for Medicare Patients

Comment: Commenters requested more clarification on how the appropriateness criteria may be applied. For example, one commenter requested CMS further explain "at least as beneficial." Another commenter requested clarification regarding appropriate setting.

Response: Because this is a long-standing definition and we are not making significant changes, we believe implementation will have no effect on its application to claim-by-claim adjudication, LCDs or NCDs. We also note that all NCDs and LCDs must go through a transparent process that includes opportunities for full stakeholder engagement when applying the reasonable and necessary definition criteria, including "at least as beneficial."

Comment: A few commenters requested that CMS update the appropriateness standard that states, " . . . 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" to include additional criteria such as improve, maintain, or prevent.

Response: This long-standing definition allows flexibility and consistency to Medicare coverage process. By continuing to use the long-standing definition, there should not be any changes to its applicability when making coverage determinations. We note that prevention is addressed in statute and regulation elsewhere (see 1861(ddd) and 42 CFR 410.64). Further, under 1862(a)(1)(A), the statute states "diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The long-standing definition, while not a direct

quote, uses the same terms in the statute.

Comment: Some public commenters suggested that MACs must maintain flexibility for determining what is appropriate on case-by-case basis, because this factor turns on particular medical facts. They suggested that finalizing the regulatory proposal could mean patients with rare conditions are overlooked because "appropriate for Medicare patients" means decisions are not individualized.

Response: We appreciate commenters' feedback. We agree that the appropriate factor is made based on the consideration of specific facts and that MACs should continue to adjudicate individual claims to ensure that they are reasonable and necessary, in the absence of a NCD. We also agree that it is important to consider whether an item or service is reasonable and necessary when making NCDs that often apply to a particular patient population. Because it is the same long-standing definition, we do not believe the application of reasonable and necessary determinations on a case-by-case determination, LCDs or NCDs will change. Specifically, for treatments for rare diseases. The application of appropriateness for a small population may be best addressed as a claim-by-claim decision that takes into consideration the individual patient's clinical situation. The MAC will continue to have the flexibility to decide the best approach to coverage on a local level.

Comment: One commenter stated that the definition of appropriateness for Medicare beneficiaries should ensure all beneficiaries are considered – not just the aged.

Response: We thank commenters for their input. We agree that it is important to consider the entire Medicare population, including beneficiaries younger than age 65, when deciding whether an item or service is reasonable and necessary.

(3) *Commercial Insurer Policy Utilization*

Comment: Commenters point out that review of commercial insurer policies to be the sole determinant of appropriate coverage is a "substantial policy change" and needs more stakeholder input. The commenters state that the proposal is vague, stated over 25 questions, and

provided little detail to support framework. Commenters questioned why CMS would need to codify this when the agency has already used its authority to look to commercial policies. One commenter outlined several questions CMS should ask the public to ensure we have appropriate stakeholder input and information before finalizing a definition.

Response: At this time, we are not codifying the proposed modification to the PIM definition that allows commercial insurers to be the sole determinant. As some commenters pointed out CMS currently has the authority and has exercised this authority in the past to review commercial insurer policies as part of the NCD development process. However, we are including regulatory language that will give CMS clear authority to review the majority of commercial insurers in the event that an item or service does not meet the appropriateness criteria that is long established policy. . As part of CMS' consideration, if Medicare coverage is different than the majority of commercial insurers, CMS will include in the national or local coverage determination its reasoning for different coverage. To ensure there is adequate public input, CMS has committed not later than 12 months after the effective date of this rule, CMS will publish for public comment draft methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: Some commenters suggested that if CMS were to adopt a review of commercial insurer policies it should not be based on a single commercial policy, but a majority of commercial payers or use the most restrictive policy in the commercial market. Commenters also stated that commercial insurance policies vary widely and CMS could use any of the policies, including the most restrictive. The commenters continued that CMS should only adopt a commercial insurer policy if it expands coverage.

Response: To ensure there is adequate public input on which commercial insurers are appropriate and to what extent, CMS has committed not later than 12 months after the effective date of this rule, it will publish draft methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: A few commenters suggested that if CMS were to finalize the reasonable and necessary definition that includes consideration of commercial insurer policies, that CMS should consider the model CMS currently uses for compendia (https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/compendia) to determine which commercial insurers to include.

Response: We appreciate the idea and agree that more stakeholder engagement is needed. Therefore, CMS has committed not later than 12 months after the effective date of this rule, it will establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: A commenter asked why the Agency would assess the appropriateness of a service, find it lacking, but then decide to move forward with affirmative coverage because somewhere out in the private insurance landscape the service is covered. This approach would create new areas of important conflicts of interest between manufacturers and payers that would be difficult to monitor.

Response: As the commenter stated, CMS will review commercial insurers only in the event it does not meet the appropriateness criteria. We believe it is important to ensure that we have evaluated all relevant evidence. To ensure we have full stakeholder engagement before we evaluate all commercial insurer policies, we will issue a sub-regulatory guidance for the public to comment. Further, CMS has committed to publish this no later than 12 months after the effective date of this rule. The guidance will establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: Several commenters noted that commercial insurers typically consider other factors such as cost-effectiveness of items or services in making coverage determinations; whereas, CMS does not. There is no single standard for commercial payer coverage policies which could create significant challenges in applying a commercial payer analysis to an item or

service to determine coverage, including some commercial insurers may use Medicare coverage policies as part of its coverage. Commenters wanted to know how CMS will weigh and use these commercial analyses to determine coverage. These same commenters wanted that methodology to be transparent and public.

Response: We agree. After further analyzing the definition along with the public comments it would be challenging to fully implement this part of the reasonable and necessary definition without further engagement with stakeholders. CMS has committed not later than 12 months after the effective date of this rule, it will establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: Commenters noted that, rather than include commercial payer as a separate criteria in the reasonable and necessary definition, CMS should review commercial policies as part of the established NCD/LCD development process to ensure beneficiaries have access to items and services.

Response: We agree. CMS currently may consult commercial insurer policies as part of the NCD and LCD process and we have further committed to establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Comment: CMS received many comments that if we adopted commercial insurer policies as part of the reasonable and necessary definition that transparency would be extremely important in the policies we reviewed. Many commenters stated that commercial insurers' coverage policies are not public or transparent. The commenters stated that the public must have access to the scientific basis of commercial payers' coverage decisions, including sources of data and the data itself.

Response: We agree transparency is an important aspect of the coverage process. After reviewing the public comments, we recognized that implementation of inclusion of commercial

payers would be challenging. Therefore, a transparent analysis of commercial insurers will be part of the NCD and LCD process, which includes public comment period of at least 30 days.

Comment: If the reasonable and necessary definition is finalized with the commercial insurer policy provision, commenters were concerned it will cede essential government decisions to commercial insurers.

Response: We appreciate the comment. Based on comments, we are finalizing a definition that requires CMS to explain why it would not follow a commercial insurer. This will be added to the NCD and LCD process to allow for a stakeholder engagement during the public comment period. In addition, as mentioned in previous responses, CMS committed not later than 12 months after the effective date of this rule, to establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

Commercial Insurer Policy – Universe and Analysis

Comment: CMS received a wide variety of comments regarding which commercial insurers we should review for consideration. The comments ranged from supporting any single plan to working with both national and local health care management groups who have a stake in the various regions to a plurality of plans to commercial insurance changes too rapidly and should not be considered. We also received a few comments to include government insurance plans. A few larger insurers stated that it used fully insured commercial plans and not administrative services only (ASO) commercial plans.

Response: For reasons noted above including concerns there is not enough information or specificity regarding the commercial insurer criteria, we have committed to issuing standards on what types of commercial insurers should CMS consider for making NCDs and LCDs.

Evidence that Supports Clinically Relevant Differences

Comment: Commenters suggested that CMS provide greater specificity regarding its standard for determining when there are "clinically relevant differences between Medicare

beneficiaries and commercially insured individuals." Commenters recommended a variety of factors to consider. A commenter also stated there likely are not clinical differences in the need for DME and medical supplies between the privately insured and Medicare beneficiaries.

Response: We have removed this criteria from the final definition.

Grandfathering

Comment: A few comments stated that CMS should grandfather established NCDs and LCDs that have already been subject to notice, stakeholder comment, and evidence review from any coverage restrictions stemming from incorporation of commercial coverage policies. Another comment stated that CMS should grandfather existing NCDs/LCDs and policies generated through negotiated rulemaking.

Response: CMS does not intend to revise its LCDs and NCDs. We believe initially that definition is the familiar and will not require CMS to revise its coverage decisions. As we write the standards for establishing the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives, we will consider how these standards may effect coverage at that time.

Appeals Process

Comment: Several commenters requested that a new appeals process be developed that allows a beneficiary or provider to use a commercial policy as part of their evidence that an item or service is reasonable and necessary, and then require the MAC to afford this policy significant weight as part of its review on reconsideration. Another commenter requested clarification on how the newly codified reasonable and necessary definition will be used for appeals. Another commenter stated that CMS would need a transparent and accelerated process to appeal coverage policies and articles.

Response: We thank commenters for their input. We added in the final rule that commercial insurer coverage may be used as part of the evidence during an appeal. Nothing in this rule changes the process to appeal a claim.

Final Action: We are finalizing our proposal with modification to define the term "reasonable and necessary" based on the factors currently found in the PIM. Further, for national and local coverage determinations, which have insufficient evidence to meet the long-standing appropriateness criteria, CMS will consider coverage to the extent the item or services are covered by a majority of commercial insurers. To ensure there is adequate stakeholder engagement on the standards, CMS committed, not later than 12 months after the effective date of this rule, it will establish the methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives.

This definition is effective 60 days after publication of this final rule in the *Federal Register.*

B. Application of the "Reasonable and Necessary" Standard to the MCIT Pathway

We proposed that, under the MCIT pathway, an item or service that receives a breakthrough device designation from the FDA would be considered "reasonable and necessary" under section 1862(a)(1)(A) of the Act because breakthrough devices have met the FDA's unique breakthrough devices criteria, and they are innovations that serve unmet needs. While other devices are still considered new to the market, for example, PMAs and even some 510(k)s, the devices designated by the FDA as breakthrough are representative of true innovations in the marketplace. This application of the "reasonable and necessary" standard in this way would ensure 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.

MCIT would provide by providing national Medicare coverage for devices receiving the FDA breakthrough device designation, which are FDA market-authorized and used consistent with the FDA approved or cleared indication for use (also referred to as the "FDA required

labeling"),[15] so long as the breakthrough device is described in an appropriate Medicare benefit category under Part A or Part B and is not specifically excluded by statute. We believe the criteria for qualification as a breakthrough device, as defined in section 515B(b) of the Food, Drug and Cosmetic Act (21 U.S.C. 360e-3(b)) is sufficient to satisfy the elements of the "reasonable and necessary" standard. The first breakthrough device designation criterion is that a device must "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" (21 USC 360e-3(b)(1)). The second criterion is that the device must satisfy one of the following elements: it represents a breakthrough technology; there are no approved or cleared alternatives; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or availability of the device is in the best interest of patients (21 U.S.C. 360e-3(b)(2)). Thus, breakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. We believe that a device meeting these criteria, once also FDA market authorized, is "reasonable and necessary" for purposes of Medicare coverage.

We recognize that the FDA market authorization of breakthrough devices warrants immediate coverage under the "reasonable and necessary" clause in section 1862(a)(1)(A) of the Act. We previously stated that FDA determinations were not controlling determinations for Medicare coverage purposes under section 1862(a)(1)(A) of the Act. (For more information see the January 30, 1989 **Federal Register** (54 FR 4307) ("FDA approval for the marketing of a medical device will not necessarily lead to a favorable coverage recommendation . . . ") and the August 7, 2013 **Federal Register** (78 FR 48165) ("However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.") Under the Secretary's authority to interpret section 1862(a)(1)(A) of the Act (*supra* section I.A.), we are revising our interpretation

[15] FDA Guidance for Industry, "Medical Product Communications That Are Consistent with the FDA--Required Labeling — Questions and Answers", *available at* https://www.fda.gov/media/133619/download.

of the statute because of the practical concerns that our current standards have delayed access to a unique set of innovative devices that FDA has found to be safe and effective, and we believe are "reasonable and necessary" for purposes of Medicare coverage.

In light of E.O. 13890, the Secretary has determined that application of the current standards for making "reasonable and necessary" determinations may take too long following FDA market authorization of breakthrough devices. More importantly, the existing standard has not always provided Medicare beneficiaries access to certain breakthrough medical devices when needed to improve health outcomes. We proposed that breakthrough devices per se meet the reasonable and necessary standard in order to increase access and to reduce the delay from FDA market authorization to Medicare coverage.

Comment: We received a few comments supporting that FDA-designated breakthrough devices should meet the reasonable and necessary definition under the MCIT pathway.

Response: We appreciate the comments. Under the Secretary's authority to interpret section 1862(a)(1)(A) of the Act (*supra* section I.A.), we are revising our interpretation, we are finalizing this rule as proposed, FDA-designated breakthrough devices are considered reasonable and necessary for purposes of MCIT.

Comment: We received a comment that stated reasonable and necessary should apply to any FDA breakthrough device regardless of entry into MCIT.

Response: We disagree, qualification as a breakthrough device, as defined in section 515B(b) of the Food, Drug and Cosmetic Act (21 U.S.C. 360e-3(b)) is sufficient to satisfy the elements of the "reasonable and necessary" standard. The first breakthrough device designation criterion is that a device must "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" (21 USC 360e-3(b)(1)). The second criterion is that the device must satisfy one of the following elements: it represents a breakthrough technology; there are no approved or cleared alternatives; it offers significant advantages over existing approved or cleared alternatives, including additional considerations

outlined in the statute; or availability of the device is in the best interest of patients (21 U.S.C. 360e-3(b)(2)). Thus, breakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. We believe that a device meeting these criteria, once also FDA market authorized, is "reasonable and necessary" for purposes of Medicare coverage.

Comment: Commenters expressed concern that MCIT eligibility will be based on commercial payer policies.

Response: MCIT eligibility is not based on commercial payer policies. It is solely based on the eligibility criteria outlined in the rule.

Final Action: After consideration of the public comments we received, we are finalizing this policy as proposed.

C. MCIT Pathway

We proposed the MCIT pathway to deliver on the Administration's commitment to provide access to breakthrough devices to Medicare beneficiaries. The MCIT pathway provides up to 4 years of national coverage to newly FDA market authorized breakthrough devices. We are aware that this coverage may also facilitate evidence development on devices for the Medicare population because manufacturers can gather additional data on utilization of the device during the MCIT coverage period.

1. Definitions

In §405.601(a), we proposed that the MCIT pathway is voluntary. Operationally, we proposed that manufacturers of breakthrough devices notify CMS of their intention to elect MCIT shortly after receiving notice from the FDA of being granted the breakthrough device designation. Ideally, this notification would be sent to CMS within 2 weeks of receiving breakthrough designation. However, entities will not be penalized for notifying CMS after that time. Alternatively, submitting a notification to CMS shortly before or concurrently with the date of the FDA marketing application submission should also afford CMS sufficient time to

operationalize MCIT for the device. The CMS Coverage and Analysis Group would establish an email box for these inquiries and notification. This notification alerts CMS to offer guidance to manufacturers about the MCIT pathway and point to resources for coding and payment, which are key conversations to effectuate coverage upon FDA market authorization. We intend to utilize the existing coverage implementation processes to be prepared to offer coverage immediately upon the FDA market authorization when requested by the manufacturer.

In §405.601(b), we proposed the following definitions for the purposes of 42 CFR part 405. We proposed to define "breakthrough device" as a medical device that receives such designation by the FDA (section 515B(d)(1)) of the FD&C Act (21 U.S.C. 360e-3(d)(1)). We also proposed to define, for the sake of clarity in the rule that the acronym MCIT stands for Medicare Coverage of Innovative Technology.

Comment: We received a few comments requesting that we not finalize MCIT and do not include drugs and biologics until there is evidence of a gap in coverage. The commenters suggested including drugs and biologics would require separate rulemaking and need to consider other FDA pathways (e.g., accelerated approval, priority review vouchers, orphan drug designation).

Response: The final MCIT rule will not include drugs or biologics. The final rule will only include FDA-designated breakthrough devices as defined by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)).

Comment: We received several comments that support the definition of breakthrough devices. These comments stated that it "allows Medicare to focus resources and seems to be a reasonable filter to prevent overutilization of the pathway."

Response: We appreciate the comment.

Comment: We received several comments requesting clarification of whether FDA-designated breakthrough devices that are clinical diagnostic lab tests or non-implanted devices are considered eligible for the MCIT pathway.

Response: Any medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway. This includes any clinical lab diagnostic test, including in-vitro diagnostics, and devices that are not implanted, as long as it meets the MCIT eligibility criteria as outlined at §405.603.

Comment: Some commenters stated that the greater predictability afforded by the MCIT pathway would decrease reimbursement risk and increase both manufacturer and investor interest in developing new and innovative therapies. Several commenters stated that investors perceive reimbursement risk as a greater threat to innovation than technology, regulatory, or clinical risks. Some commenters asserted that the MCIT pathway would make it easier for innovators to raise funds necessary for development and refinement of new technologies (e.g., artificial kidney). However, some commenters argued that the MCIT pathway could give specific technologies an unfair advantage that would be unavailable to subsequent market entrants, thereby paradoxically decreasing innovation and market competition. As a modification to the proposed MCIT rule, some commenters suggested that CMS cover iterative refinements of the same breakthrough device for the duration of the original device's MCIT term. Some commenters also suggested coverage under the MCIT pathway for similar but unrelated breakthrough and non-breakthrough designated devices of the same type and indication for the balance of the first device's MCIT term. Other commenters proposed that new market entrants that are very similar to a breakthrough device should each receive the full four years of MCIT coverage.

Response: CMS agrees that the MCIT pathway is likely to promote development and refinement of innovative technologies and support medical advancement. CMS also agrees that iterative refinements of devices are common following FDA market authorization. These often represent material improvements, and Medicare beneficiaries should have access to the improved version of the predicate breakthrough device. In practice, many of these device refinements are

market authorized through a supplement to the initial FDA PMA submission and would therefore remain eligible for coverage through the MCIT pathway for the duration of the original devices MCIT coverage period.

CMS disagrees that the MCIT pathway provides an unfair advantage to a single device, or that it impedes market competition. The FDA defines breakthrough technologies in section 515B(b) of the FD&C Act (21 U.S.C. 360e-3(b)) as those (1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and (2)(A) that represent breakthrough technologies; (B) for which no approved or cleared alternatives exist; (C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term NCD definition, FDA breakthrough-designated devices address an unmet need, and subsequent devices do not enjoy the same prioritized review process or breakthrough designation because there is an existing approved or cleared alternative. CMS similarly would not extend automatic coverage to subsequent similar devices because there would no longer be an unmet need in the market. Subsequent similar FDA market-authorized devices will benefit from any evidence generated through MCIT coverage of the predicate device. Please explain that although not automatically covered under the regulation, contractors could make a favorable coverage decision if a claim is submitted.

Comment: Several commenters requested that CMS include devices that meet the "spirit of breakthrough" regardless of whether the device applied or received the FDA breakthrough designation. Examples commenters gave were second-to-market or subsequent technologies of the same type, even for the same indication or subsequent-to-market non-breakthrough designated technologies that fall under the same class or category as the breakthrough technology and approved for the same indication. Commenters stated that competing devices

from other manufacturers that are not breakthrough devices could be caught in a precarious limbo, at least for a time. At least one commenter, submitted a description of its device and how it meets the spirit of the FDA breakthrough designation.

Response: If the device meets the eligibility criteria as outlined in §405.603, it is eligible for the MCIT pathway. Outside of that designation, CMS is not expanding the eligibility for MCIT. We will, of course, consider whether the subsequent devices satisfy the reasonable and necessary criteria if a claim is submitted for review.

Comment: We received comments supporting expansion of MCIT to include diagnostic radiopharmaceuticals, combination drug or devices (device or drug-led), drugs, biologics and other technologies. At least one commenter wanted CMS to specifically include pain management and antimicrobial therapies. Another commenter stated that certain cellular and tissue-based wound care products (CTPs) do not require the traditional FDA PMA, BLA and 510k processes, but rather are regulated by the FDA under Section 361 as HCT/Ps.

Response: Any medical device that receives such designation by the FDA (section 515B(d)(1)) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway. We received mixed public comments on expanding beyond devices and have determined to finalize the proposed rule which only includes devices that meet the criteria proposed. We need to provide a rationale not to extend automatic coverage further in light of the language in the Executive Order. We don't provide reasons to support the conclusion.

Comment: A few commenters requested that CMS include screening tests and preventive screening tests.

Response: Screening and prevention tests have a unique statutory authorities and are not covered based on 1862(a)(1)(A). . These items and services fall outside the scope of this rule. Medicare has separate regulations for screening and preventive services that have been codified primarily in 42 C.F.R. Part 410, Subpart B.

Comment: We had several commenters request CMS to create new benefit categories or make a determination that an item or service (e.g., software, digital technologies) falls within a benefit category.

Response: Decisions regarding specific items and services and the relevant benefit categories are outside the scope of this rule. For more information on benefit category determinations see the *CMS Innovator's Guide to Navigating Medicare* (https://www.cms.gov/medicare/coverage/councilontechinnov/downloads/innovators-guide-master-7-23-15.pdf).

Comment: The Executive Order was interpreted too narrow. The commenter stated that MCIT should not be tied to the FDA breakthrough device definition but should include other CMS-recognized innovative non-breakthrough technologies (e.g., technologies eligible for New Technology Add-on Payment or Transitional Pass-through Payment). To aid in operationalizing this, commenter recommend that CMS consider preventing MACs from denying coverage of innovative non-breakthrough technologies that meet predetermined criteria.

Response: At this time, CMS will finalize its proposed definition of any medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway. We received mixed public comments on expanding beyond devices and have determined to finalize the proposed rule which only includes devices. At this time, MACs retain the ability to make coverage determinations through current processes of either an LCD or claim by claim adjudication.

Comment: Commenters requested that MCIT include IDEs involving breakthrough devices.

Response: Investigation Device Exemptions (IDEs) are devices defined at 42 CFR § 405 Subpart B. IDE devices are not FDA market authorized or cleared (often referred to as premarket devices). Any IDE device FDA-designated as breakthrough device is eligible for

MCIT when it is FDA authorized for marketing The MCIT pathway begins no earlier than the date the breakthrough device receives FDA market authorization, or the date requested by the manufacturer, provided the requested date is within the four year window for MCIT eligibility..

Comment: CMS should continue working to expand to a wider range of innovative medical devices (outside of breakthrough designation).

Response: We appreciate the comment. CMS continues to review its coverage pathways to find appropriate efficiencies.

Comment: CMS should expand MCIT to include humanitarian use devices. Commenter asserted they approved through an FDA expedited program to get technology to patients with rare conditions.

Response: At this time, we are not expanding the MCIT pathway beyond the proposed rule. This includes any medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway.

Comment: If CMS chooses to retain the fifth criteria proposed in Section 405.603(e), then we would ask that the agency clarify that ineligibility is tied to an absolute national non-coverage determination.

Response: Upon receiving notification by a manufacturer of interest in MCIT, CMS will determine if there is an existing NCD on point. While possible, it is unlikely that there is pre-existing, explicit non-coverage NCD given the breakthrough nature of eligible devices.

Comment: Patient preference should be considered when qualifying devices for MCIT. Commenter gave the example of non-invasive medical devices (including focused ultrasound) that may be strongly preferred by patients.

Response: Any medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway. FDA takes patient preference under consideration as

they make market authorization decisions.

After consideration of the public comments we received, we are finalizing our proposed definition of breakthrough devices.

2. MCIT Pathway Device Eligibility

In §405.603(a) we proposed that the pathway is available to devices that meet the definitions proposed in §405.601. 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), the proposed policy is for devices only.

We proposed in §405.603(b) that the breakthrough devices that received FDA market authorization no more than 2 calendar years prior to the effective date of this subpart (the date the final rule is finalized) and thereafter will be eligible for coverage for claims submitted on or after the effective date of this rule. Claims for breakthrough devices with dates of service that occurred before the effective date of this rule will not be covered claims through MCIT. Breakthrough devices market authorized prior to the effective date of this rule will not be eligible for all 4 years of coverage. For these "lookback" devices, the 4-year period starts on the date of FDA market authorization. We proposed that if a manufacturer initially chooses to not utilize the MCIT pathway, and then chooses to do so some time after the breakthrough device's market authorization, coverage still only lasts 4 years from the date of FDA market authorization. We sought comment on this eligibility criterion for devices and specifically the 2 year lookback.

Comment: Almost all commenters were supportive of a lookback period. Many agreed with a two year interval. A few commenters suggested a four year lookback or unlimited to the start of the Breakthrough Devices Program.

Response: We appreciate the comments. We proposed a two year lookback to try to maximize the benefit of the MCIT rule. We believe this interval includes the recent period that presented the greatest initial confusion and uncertainty for manufacturers of innovative devices

before the MCIT rule. We agree with commenters that the lookback period is important to launch the rule with highest impact. Considering comments, we believe that a two year lookback remains appropriate and maintains efficiency at start up. For breakthrough devices older than 2 years, it is possible that other coverage pathways such as LCDs or NCDs may have been developed and coverage concerns have been addressed. Potential overlap of coverage policies would hinder implementation. In addition, the majority of breakthrough devices were approved in the past 2 years since the program was authorized in 2017 (final agency guidance issued in December 2018 (available at: https://www.fda.gov/media/108135/download). We note that the lookback period is a one-time occurrence since there will not be a need for a lookback period for breakthrough devices approved going forward once the MCIT rule is effective.

We proposed in §405.603(c) that to be part of the MCIT pathway, the device must be used according to its FDA approved or cleared indication for use. We proposed that the device is only covered for use consistent with its FDA approved or cleared indication for use because that is the indication and conditions for use that were reviewed by the FDA and authorized for marketing. Data are unlikely to be available to support uses extending beyond the FDA required labeling for breakthrough devices on the date of marketing authorization. Use of the device for a condition or population that is not labeled ("off-label") will not be covered as that use would not be FDA authorized. We specifically sought comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support.

Comment: Most commenters agreed with the inclusion of the FDA required indication. A number of commenters noted that off indication or off label uses should be included under MCIT as well. Some commenters raised concern for on-indication use of breakthrough devices because the devices are so new to market.

Response: We appreciate the comments. Consistent with the breakthrough device designation, we specified the FDA required indication (on-indication) for MCIT. We did not

specifically provide automatic coverage for off-indication or off-label uses in the proposed MCIT rule, but we do not preclude possible coverage under other coverage mechanisms, such as through the claims process. However, we note that in general there is typically little clinical evidence to support off-label uses of new technology. We are aware that concerns for on-indication use of breakthrough devices were reiterated in recent published articles (Neumann and Chambers. Health Affairs, 12/02/2020; Bach. New York Times, 12/01/2020).

Comment: Commenters noted that the FDA label indication only is not sufficient since other factors have important roles in determining positive outcomes from device therapy such as physician training and experience and facility capabilities and experience.

Response: We appreciate the comments and agree. We proposed provider and facility requirements in the proposed reasonable and necessary definition (please say what they were and where they are addressed in other comments) and finalize these requirements to maximize positive health outcomes for the Medicare population. We will look to the appropriate sources for provider and facility requirements for implementation purposes.

Comment: Commenters noted that new FDA approved indications should be included.

Response: We appreciate the comments and agree. We recognize that new FDA approved indications for a breakthrough device could be added during the MCIT period. We believe the new FDA required indication would also meet the MCIT definition and would be eligible for the duration of the breakthrough device MCIT period.

In §405.603(d) and (e), we additionally proposed limitations to what is coverable under the Act. In §405.603(e), we proposed that if CMS has issued an NCD on a particular breakthrough device, that breakthrough device is not eligible for MCIT. We proposed this because, once the device has been reviewed by CMS for the FDA required approved or cleared indication for use; CMS has made a coverage determination based on the available evidence for that technology. We believe this would happen rarely because breakthrough devices are new technologies that are not likely to have been previously reviewed through the NCD process. In

§405.603(f), we acknowledge that devices in the MCIT pathway may be excluded due to statute or regulation (for example, 42 CFR 411.15, Particular services excluded from coverage) and, like other items and services coverable by Medicare, the device must fall within the scope of a Medicare benefit category under section 1861 of the Act and the implementing regulations. If the device does not fall within a Medicare benefit category as outlined in the statute and implementing regulations, the device is not eligible for Medicare coverage; therefore, the device would not be eligible for the MCIT pathway.

Comment: CMS proposed that the breakthrough device must fall into an existing benefit category to be included under MCIT. Commenters supported the benefit category designation. Several comments recommended the inclusion of breakthrough devices that do not fall within an existing benefit category, for example, digital health technologies, or to modify existing benefit categories to include these devices.

Response: We appreciate the comments. However, in general, for Medicare coverage, an item or service must fall within an existing benefit category. Benefit categories are generally established by statute. CMS is unable to create a new benefit category or alter the language of existing benefit categories in this rule.

After consideration of the public comments we received, we are finalizing the rule as proposed with slight modification, as we indicated with a placeholder in the proposed, to update 405.603(b) with the latest date for the lookback to be the date two years prior to the effective date of the rule.

3. General Coverage of Items and Services under the MCIT Pathway

We proposed in §405.605 that devices covered under the MCIT pathway are covered no differently from devices that are covered outside of MCIT. In other words, provided the items and services are otherwise coverable (that is, not specifically excluded and not found by CMS to be outside the scope of a Medicare benefit category), covered items and services could include the device, reasonable and necessary surgery to implant the device, if implantable, related care

and services of the device (for example, replacing reasonable and necessary parts of the device such as a battery), and coverage of any reasonable and necessary treatments due to complications arising from use of the device. What the MCIT pathway offers compared to other pathways is predictable national coverage simultaneous with FDA market authorization that will generally last for a set time period.

The proposed MCIT pathway would support and accelerate beneficiary access to certain innovative devices. CMS encourages manufacturers that have breakthrough devices covered under MCIT to develop additional data for the healthcare community.

Comment: Commenters questioned for clarification of whether breakthrough diagnostic medical tests are eligible for MCIT.

Response: Diagnostic medical tests are considered FDA medical devices and fall within an existing benefit category. Based on this categorization, breakthrough designated diagnostic medical tests would be eligible to be included under MCIT.

Comment: Commenters questioned whether breakthrough medical devices that are approved for screening indications, for example cancer screening tests, would be eligible under MCIT.

Response: We appreciate the comments. MCIT is based on a specific Medicare authority. Since screening tests and preventive services have separate and distinct statutory authorities, items and services used for screening and preventive services are outside the scope of the MCIT rule.

Comment: Commenters suggested the inclusion of medical devices approved under different FDA designations, such as IDE, Humanitarian Device Exemption (HDE) and devices that have not received the breakthrough device designation.

Response: We appreciate the comments. Medical devices that receive breakthrough designation from the FDA and meet the definition and inclusion criteria in the final rule will be eligible for MCIT. By the definition, non-breakthrough devices will not be eligible for MCIT

but in general other coverage mechanisms such as the claim review process, NCDs, or LCDs may be available. We note that for certain other medical devices that have received FDA IDE there are existing coverage regulations (42 CFR § 405 Subpart B). The IDE regulation generally applies to devices that have not yet received formal FDA approval. Some breakthrough devices may also have IDE status and may be eligible for coverage under the IDE regulation and also may be subsequently eligible for coverage under MCIT once the breakthrough device receives FDA market authorization.

Comment: Commenters requested clarification of what is covered under MCIT – the device only or the device and the implantation of the device if required.

Response: MCIT would cover both the breakthrough device and the implantation of the device. Other items and services for the diagnosis and treatment of the patient's illness would be recoverable as usual through existing coverage regulations and policies or when determined to be reasonable of the local Medicare Administrative Contractors (MACs) in the claims appeals process. There are existing Medicare coverage and payment policies that also may apply to other items and services that may be used for treatment during hospitalizations and complications that may arise from the device treatment in subsequent hospitalizations. MCIT rule does not supersede existing coverage and payment policies on routine and related items and services for the diagnosis and treatment of the patient's illness.

After consideration of the public comments we received, we are finalizing this section of the proposed rule with only a minor textual clarification to also include reasonable and necessary procedures to *use* the breakthrough device. The proposed text stated only reasonable and necessary procedures to implant the device, which would not be representative of the universe of breakthrough devices.

4. MCIT Pathway for Breakthrough Devices: 4 Years of Coverage

In §405.607(a), we proposed that the MCIT pathway for coverage would begin on the same date the device receives FDA market authorization. We proposed this point in time to

ensure there is no gap between Medicare coverage and FDA market authorization. This start date supported the MCIT pathway's focus of ensuring beneficiaries have a predictable access to new devices.

Comment: CMS proposed that MCIT coverage would start on the day of FDA approval of the breakthrough device and last for 4 years. Several commenters supported the MCIT start date as proposed on the day of FDA approval. A number of other commenters recommend flexibility in the start date to be determined by the manufacturer since the breakthrough device may not be immediately available in the market on the date of FDA approval. Commenters noted that flexibility would allow the manufacturer time to be fully prepared for device dissemination with set coding, payment, and evidence development if the manufacturer voluntarily chooses.

Response: We appreciate comments and agree. We recognize that not all breakthrough devices may be immediately available in the market on date of FDA approval due to various factors including production, large scale distribution, and coding. We have modified and, in the final rule, will include flexibility in the start date of MCIT to be determined by the manufacturer within certain parameters. We note that regardless of the date the manufacturer selects to begin MCIT coverage, they are eligible only during the four year period beginning on the date of FDA market authorization. Therefore, if a manufacturer waits one year after receiving FDA approval to request MCIT coverage of an item or service, the relevant item or service will have three years of coverage under MCIT. For implementation purposes, manufacturers must inform CMS of the desired future start date. We believe that the clarity and transparency of MCIT will assist manufacturers in developing product development and deployment plans earlier so the 4 years of MCIT can be used more efficiently.

While we believe it is in the best interest of the manufacturer to invoke MCIT coverage early in the 4-year coverage period there may be breakthrough devices that can achieve the desired level of evidence development in less time. Because the time period for evidence

development is dependent on the nature of the device and the disease or clinical condition for which it is intended we are comfortable with manufacturers electing their MCIT coverage start date (within the parameters outlined above). We further believe that it is counterintuitive for a breakthrough device manufacturer to opt-into MCIT coverage toward the end of the 2-year opt-in window. However, manufacturers have expressed interest in this type of flexibility and CMS is not in a position to predict the various reasons a manufacturer may find themselves in a position of needing to wait to opt-in.

Comment: Commenters noted the potential time delays from coverage, coding, and payment.

Response: We appreciate the comments and agree that enhanced coordination of coverage, coding and payment would be useful. While a detailed description of coding and payment is beyond the scope of the MCIT rule and resides in other payment rules, CMS, as directed by EO 13890, has worked to streamline coverage, coding, and payment. We have established new collaborations internally to enhance efficiency going forward.

We proposed in §405.607(b)(1) that the MCIT pathway for breakthrough devices ends 4 years from the date the device received FDA market authorization. We proposed this 4 year time period because it could allow manufacturers to develop clinical evidence and data regarding the benefit of the use of their device in a real world setting. For example, we believe 4 years would allow most manufacturers sufficient time to complete FDA required post-approval or other real-world data collection studies that may have been a condition of FDA market authorization. This assumption is based upon our historical experience with studies conducted through coverage with evidence development (CED). Many of these studies were completed within approximately 4 years Further, this time period allows Medicare to support manufacturers that, whether required by the FDA or not, have an interest in better understanding the health outcomes of their device in the Medicare population, including impacts on patient-reported and longer-term outcomes.

Further, in §405.607(b) we proposed reasons that the MCIT pathway may end prior to 4 years. This included circumstances whereby the device became subject to an NCD, regulation, statute, or if the device could no longer be lawfully marketed.

Comment: Most commenters were supportive of the four year period. Some commenters suggested longer duration up to 5 years at CMS discretion or if the manufacturer is actively conducting a clinical study.

Response: We appreciate the comments and believe the 4 year duration of MCIT continues to be an adequate time period to foster innovation. We recognize the importance of continuing data collection and evidence development but have not mandated evidence development. We believe, with the transparency of MCIT, that manufacturers will be able to appropriately plan studies that could be completed within 4 years. In general evidence on improvements in health outcomes for Medicare patients not only would help support coverage through other mechanisms after MCIT but also importantly help physicians and patients in choosing the treatment that is best suited for the individual patient.

Comment: A large number of respondents supported voluntary evidence development. Many commenters noted that the FDA already requires post market-authorization data collection in most cases. Many commenters argued that manufacturers should discuss their evidence development plans with CMS soon after FDA market-authorization. CMS, in turn, should be clear and transparent about any evidence gaps and any additional evidence needed to reach the reasonable and necessary threshold required for durable coverage after MCIT coverage ends. Commenters suggested that CMS be more flexible in agreeing to acceptable study designs and outcomes, including use of real world data. Commenters stated that manufacturers already have considerable incentive to meet the reasonable and necessary standard to assure coverage continuity after MCIT. Some commenters objected to a one-size-fits-all mandate for evidence development noting a diversity of devices come through the FDA breakthrough program. They argued that a voluntary evidence development regime allows flexibility for manufacturers to

manage their own clinical study and evidence development programs in line with their goals and business needs.

A larger number of commenters supported mandatory evidence development. One commenter did not support the MCIT pathway, but if implemented, argued that mandatory evidence development mitigates the risks of this regulation. A number of commenters stated that early coverage tied to mandatory evidence development strikes an economically appropriate balance. Some commenters noted that post-market clinical studies may more efficiently capture longer-term outcomes than within conventional clinical studies. Several commenters stated that mandatory evidence development is appropriate provided that it is efficient, streamlined, and time-limited. Several commenters noted that post-market evidence development is essential for development and refinement of clinical practice guidelines that inform evidence-based clinical practice. Other commenters noted that mandatory data collection is necessary to assure appropriate use of technologies, and that use without oversight could be economically disastrous. Furthermore, they stated that low-value practice patterns may be very difficult to reverse once they are established.

Response: CMS is not mandating evidence development during MCIT coverage. After coverage through the MCIT pathway ends, all existing coverage pathways will remain available to manufacturers to establish durable coverage. CMS will require breakthrough devices to meet the long-established reasonable and necessary coverage standard, just as they would without the MCIT pathway. CMS anticipates that most manufacturers will voluntarily pursue robust evidence development to secure durable coverage after MCIT coverage sunsets.

We are aware of stakeholders' interest in CMS providing detailed, specific, and actionable guidance to manufacturers on evidence deficits relative to the long-established reasonable and necessary threshold. We are considering the feasibility of this approach. CMS notes that the expected diversity of breakthrough devices speaks to flexibility in evidence development. In some instances, manufacturers may wish to participate in conventional clinical

studies; in others, a registry-based clinical study may offer the most robust and cost-efficient option. Manufacturers may also wish to pursue studies that rely on real-world evidence, but they are strongly encouraged to review these study designs with CMS. Manufacturers are encouraged to engage CMS soon after FDA market authorization with an evidence development plan that addresses any identified evidence gaps.

CMS believes that rigorous and publicly available evidence is necessary to inform beneficiaries, the clinical community, and the public about the risks and benefits of available treatment options. Published studies are also necessary for breakthrough devices to be included in evidence-based guidelines, which feature heavily in CMS' assessment of accepted standards of medical practice. Therefore, CMS requires that stakeholders publish evidence in the peer-reviewed clinical literature and applies rigorous methodologic standards in evidence review supporting local or national coverage analyses.

Comment: As related to the ending of MCIT, a number of commenters noted safety concerns of breakthrough devices over the four years. Commenters noted the need to continue to monitor use and outcomes and to suspend MCIT if the FDA withdraws approval or there are concerns with safety in post-market data.

Response: We appreciate the comments and agree on the need to monitor harms.

These concerns are particularly relevant to the suggested 4 year duration of MCIT. We believe appropriate mechanisms should be in place to end automatic coverage in certain scenarios. In general, safety is within the FDA authority. However, there are appropriate commonalities when the health outcomes are higher mortality or higher numbers of strokes or heart attacks. Based on overall comments on safety, we will include a mechanism in the final rule to allow suspension or termination of MCIT when FDA has issued a warning letter, medical device safety communication, or black box warning and CMS determines that harms outweigh benefits for Medicare patients.

Comment: A series of comments cited FDA guidance that the Breakthrough Devices

Program allows for greater uncertainty of risks and benefits than non-breakthrough approval processes because the breakthrough devices meet an important and unmet clinical need. Several commenters also note that the FDA relies more heavily on post-market data collection for these devices, and often breakthrough devices lack data on long-term safety and effectiveness at the time of FDA market authorization. Several commenters cited evidence that many FDA mandated post market studies are never completed and that the FDA safety and surveillance system is both flawed and insufficient to assure beneficiary safety during MCIT coverage. One commenter noted that lax FDA safety reporting may allow continued CMS coverage despite important safety problems. One commenter suggested that CMS should mandate safety reporting to both CMS and the FDA Manufacturer and User Facility Device Experience (MAUDE) database at regular intervals as a condition of MCIT coverage. Several commenters suggested that CMS should regularly review FDA safety reports for covered breakthrough devices. Several commenters argued that any safety warnings or product recalls should terminate coverage within the MCIT coverage pathway.

One commenter noted that Medicare beneficiaries are likely to perceive that FDA market-authorized and CMS-covered items or services have been established as safe and effective. Another commenter suggested that Medicare beneficiaries will be unwitting clinical trial subjects if they are treated with a breakthrough device through the MCIT coverage pathway. Several commenters stated that the proposed MCIT regulation lacks any mechanism for stakeholder input, especially specialty societies, into operator and institutional requirements that protect beneficiary safety prior to national coverage. A large number of commenters noted that absent mandatory evidence development, the MCIT regulation lacks a mechanism to assure safety, outcomes, and quality of care for covered breakthrough devices. Several commenters suggested that CMS should monitor safety events using registries, FDA safety reports, and claims data monitoring.

Response: The Administration is committed to encouraging medical innovation and to

ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. The MCIT regulation meets this goal for FDA market-authorized breakthrough devices. However, patient safety is always a central concern, and CMS agrees that the MCIT regulation must balance early access to innovative medical devices with strong patient safety protections.

CMS has developed a number of process steps to address this important balance of access and safety. First, the Administration has championed transparency as a critical mechanism for beneficiary empowerment in decision-making about their own healthcare. Accordingly, devices covered through the MCIT pathway will be publicly posted on the CMS website. We aim to also indicate publicly available clinical evidence related to the device. Patients and their clinicians are strongly encouraged to review this information. With access to this information, CMS believes that patients and their clinicians are best able to consider the risks and benefits of innovative new treatments in the context of their personal health and values. Second, CMS will continue to engage with relevant stakeholders – notably specialty societies with expert knowledge of the available treatments. CMS recognizes that these guidelines may evolve with greater experience with breakthrough devices and may assist CMS and clinicians in coverage of the devices after MCIT coverage sunsets. CMS advises operators and institutions to consider them carefully when offering breakthrough devices covered through the MCIT pathway. Third, CMS will coordinate with the FDA to receive regular feedback on important safety signals and concerns. As a practical matter, CMS will rely on existing FDA safety and surveillance publicly available reporting structures as an important mechanism for identifying safety concerns about covered breakthrough devices. While evidence development is voluntary, manufacturers have strong incentives to develop evidence that addresses any gaps identified through engagement with CMS at the onset of MCIT coverage. If these gaps are insufficiently addressed during the MCIT coverage pathway, manufacturers may risk not meeting the reasonable and necessary evidentiary threshold when MCIT coverage sunsets. Where manufacturers voluntarily pursue evidence

development through robust clinical registries, those data may also provide detailed and timely data on safety of breakthrough devices under real-world conditions. Lastly consistent with some suggestions from commenters, we revised the rule to specify that coverage of a breakthrough device through MCIT can end if the FDA removes market authorization of a breakthrough device or at the discretion of the Secretary, subsequent to an FDA medical device safety communication or Warning Letter about the breakthrough device.

Comment: Nearly a fifth of the comments received on the proposed rule were from individuals who urged Medicare to cover artificial kidney technology. The majority of these comments were from people who are affected by or care for someone affected by a form of kidney disease and/or End Stage Renal Disease. While some specifically mentioned MCIT, most did not.

Response: CMS appreciates every comment and thanks commenters for sharing their personal stories and how their lives or the life of someone they care for could be improved by coverage of artificial kidney technology when it becomes broadly available.

Comment: A large number of comments addressed the issue of how CMS should establish durable coverage after MCIT coverage sunsets. Several commenters acknowledged that CMS has limited resources and cannot open an NCD for all MCIT devices without securing more resources in the Coverage and Analysis Group. One commenter warned that an excessive emphasis on coverage review for MCIT devices could delay consideration of important non-breakthrough NCD requests. Several commenters recommended that CMS be more transparent about the existing NCD wait list, the expected timing of any new NCDs, and the prioritization criteria for NCDs. They argued that manufacturers will need this information when considering which pathway is best after MCIT. The largest proportion of commenters stated that there should not be any automatic opening of an NCD, including if there is no LCD by 6 months after the end of MCIT coverage. Many commenters believe that manufacturers should instead have flexibility in choosing a coverage pathway. A smaller number of commenters recommended

automatic opening of an NCD with sufficient time for seamless coverage after MCIT coverage sunsets. Several of these commented that because the MCIT pathway establishes national coverage that an NCD is the appropriate coverage pathway after MCIT coverage sunsets. A small number of commenters argued that coverage for devices in the MCIT pathway should continue indefinitely to the FDA label absent an LCD or NCD that specifically constrains coverage.

Response: As previously noted, devices approved through the FDA breakthrough device program may have greater uncertainty about the risks and benefits of treatment than non-breakthrough devices, and they generally lack data on long-term safety and effectiveness at the time of FDA market authorization. By contrast, CMS heavily considers demonstration of improved health outcomes in making positive coverage determinations. All of the conventional coverage pathways will be available for MCIT devices after the pathway sunsets, and our regulatory reasonable and necessary coverage standard will apply. Manufacturers and stakeholders must be aware of the important distinctions between FDA and CMS review criteria and use the time during the MCIT coverage pathway to close any evidence gaps that may be identified at the time of FDA market authorization.

Based on the comments, we are aware not every manufacturer wishes to pursue the NCD coverage pathway. CMS already publishes an NCD Wait List (available here: https://www.cms.gov/Medicare/Coverage/DeterminationProcess) which is updated every month as need be and we are aware of stakeholder interest in guidance on how CMS will prioritize formal and complete NCD requests. Additionally, CMS intends to stay abreast of clinical evidence development for breakthrough devices in the MCIT pathway, and focus on whether there is new evidence in the published, peer-reviewed literature that addresses gaps identified at the time of FDA market authorization, especially whether there is compelling evidence that the device improves patient health outcomes. To allow greater stakeholder flexibility and efficient use of CMS resources, CMS will not automatically open a National Coverage Determination

(NCD) as a part of the MCIT coverage pathway. As previously noted, the full range of coverage options at the end of the MCIT pathway includes opening an NCD or and claim submission to a MAC. MACs may either open Local Coverage Determinations (LCDs) or cover the breakthrough device on a claim-by-claim basis after MCIT coverage sunsets. After consideration of the public comments we received, we are finalizing the proposed rule and adding modifications consistent with the safety concerns raised by commenters. We updated the text to allow for coverage to end prior to 4 years at the discretion of the Secretary subsequent to an FDA medical device safety communication or Warning Letter. Additionally coverage will end if the FDA removes authorization of a device.

Final Action:

In summary, the MCIT pathway will be voluntary for manufacturers on an opt-in basis, and would provide immediate or near immediate national coverage depending upon the manufacturer's chosen start date. MCIT coverage expires four years after the date of FDA approval, irrespective of when the manufacturer requested activation of their MCIT coverage, at which point, the manufacturer may request CMS to undertake an NCD for the breakthrough device. We sought public comment on all of our proposals, and have included summaries of the comments received and the responses to those comments in this document.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following sections of this document that contain information collection requirements (ICRs).

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes131041.htm, released May 2019). In this regard, the table that follows presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES FOR MCIT

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Compliance Officer	13-1041	34.86	34.86	69.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The proposed coverage pathway allows for a voluntary participation and therefore necessitates that manufacturers of breakthrough devices notify CMS of their intent to enter the MCIT pathway. Therefore, the burden associated with notifying CMS is the time and effort it would take for each of the organizations to send CMS an email or letter. We anticipate two MCIT pathway participants in the first year based upon the number of medical devices that

received FY2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles.

We estimate notifying CMS of intent to participate in MCIT would involve 15 minutes at $69.72 per hour by a compliance officer. In this regard, we estimate 15 mins per notification at a cost of $17.43 per organization (0.25 hours x $69.72). In aggregate, we estimate 0.5 hours (0.25 hours x 2 submissions) at $34.86 ($17.43 x 2 submissions).

After the anticipated initial 2 submitters, over the next 3 years we expect 3 submitters in year 2, 4 submitters in year 3, and 5 submitters in year 4 to notify CMS of interested in the MCIT pathway. We expect this increase in submitters each year to level off at this point. In this regard, we estimate the same 0.25 hours per submission at a cost of $17.43 per organization. Similarly, in aggregate, we estimate, for year 2 (0.75 hours at $52.29 an hour), for year 3 (1.0 hour at $69.72 an hour), and for year 4 (1.25 hours at $87.15 an hour).

The proposed requirements and burden will be submitted to OMB under control number 0938-NEW.

IV. Regulatory Impact Statement

This final rule makes Medicare coverage policy updates pursuant to the authority at section 1862(a)(1)(A) of the Act. We are using regulatory action per the October 3, 2019 "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors" to create a swift Medicare coverage pathway to allow beneficiaries across the nation to access breakthrough devices after FDA market authorization and define "reasonable and necessary".

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and

Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule reaches the economic threshold and thus is considered a major rule.

CMS considered several alternatives for defining "reasonable and necessary." These alternatives included not defining the term in regulation, define the term as finalized in this rule (commercial insurer coverage may be considered under the Medicare program), and define the term as commercial insurer coverage being the sole determinant of coverage under the Medicare program. Given the direction in E.O. 13890 to clarify standards we proposed and finalized in regulation, the definition of the term "reasonable and necessary." The definition we are finalizing provides consistency and flexibility regarding the role of commercial insurer coverage in the Medicare program and the majority of public comments did not support the commercial payer alternative without more public engagement. We believe the final rule is consistent with what the public requested.

The impact of defining "reasonable and necessary" is hard to quantify without knowing the specific items and services that would be included in future NCDs and LCDs and the criteria that CMS will use for determining which commercial insurers will be considered. Additional information regarding which commercial insurers and policies will be developed within 12 months of the effective date of this rule. In order to demonstrate the potential impact on Medicare spending, we developed scenarios that illustrate the impact of implementing the three alternatives for defining "reasonable and necessary." The number of NCDs and LCDs finalized in a given year can vary and the cost of items and services within the coverage decisions varies.

Further, while we reviewed coverage of items and services, we did not take into account unique Medicare rules regarding which type of providers/clinicians may furnish certain services, place of service requirements, or payment rules. Our analysis is based on whether Medicare covered or non-covered an item or service and whether we could find coverage for that item or service by any commercial insurer. Lastly, this impact analysis is based on the numbers of NCDs and LCDs finalized in 2020. (See Table 2 below)

In 2020, CMS and the MACs finalized 3 NCDs and 31 LCDs. (This number represents new LCDs in 2020 and made publically available via the Medicare Coverage Database. If more than one MAC jurisdiction issued an LCD on the same item or service with the same coverage decision, only 1 of the LCDs was included in the count.)

Of the NCDs finalized in 2020, all 3 resulted in expanded national Medicare coverage. Because none of those NCDs resulted in non-coverage we did not evaluate whether commercial insurers also covered. Therefore, based on 2020 data for NCDs only, the impact would be $0 for all three alternatives.

Of the 31 LCDs, 27 provided Medicare positive coverage and 4 resulted in non-coverage. For those items and services non-covered we identified 3 of those items and services were covered in at least 1 commercial insurer policy. For these non-covered items and services we can establish that the possible range of the cumulative cost of covering them could be from $0 to $3.4 billion for a single year (based on price and approximate Medicare beneficiary utilization). Because our analysis looked for any commercial insurer that covered the item or service, the cost may be less when utilizing commercial insurer polices that represent a majority of covered lives (CMS will publish draft guidance explaining its methodology within 12 months of the effective date of this rule). In addition, even if a commercial insurer covers an item or service, for the final rule it is not a requirement to automatically adopt the commercial insurers' coverage. Therefore, not all items and services that are non-covered by Medicare and covered by a can be assumed covered under this rule. Rather, commercial insurer coverage is a factor that CMS will

take into account as part of the body of evidence in determining coverage through the NCD and LCDs processes. Because not all commercial insurer positive coverage will necessarily transfer to Medicare coverage and because CMS still to define which types of commercial insurers (based on majority of covered lives) are relevant, we believe that commercial insurer coverage impact is likely much smaller, closer to 15-25% of $3.4 billion, that is, $51 - $880 million. Under the third alternative which requires Medicare to rely on any coverage by a commercial insurer in order to achieve Medicare coverage, the cost would much higher. Using the same data for the first 2 alternatives, there were 4 LCDs that resulted in Medicare non-coverage, and 3 commercial insurers covered the item or service. Assuming that for this third assumption that Medicare must cover these items and services, the cost to the program could be at least $3.4 billion for a year for the commercial insurer as sole determinant of coverage. Because our analysis looked for any commercial insurer that covered the item or service, the cost may be less when utilizing commercial insurer polices that represent a majority of covered lives.

TABLE 2: ILLUSTRATED IMPACT FOR THE MEDICARE PROGRAM BY DEFINITION OF REASONABLE AND NECESSARY

	Estimated Change in Medicare Costs for the Alternatives Considered		
	No Change (not codifying a definition)	**Codified Definition**	**Commercial Insurer Coverage as Sole Determinant**
Coverage Determinations (NCDs and LCDs)	$0	$51-880 million	$3.4+ billion

Regulatory alternatives to this final rule for MCIT were to combine Medicare coverage with clinical evidence development under section 1862(a)(1)(E) of the Act, to take no regulatory action at this time, or to adjust the duration of the MCIT pathway. Combining coverage with clinical evidence development would have met the E.O. 13890 overarching goal of beneficiary access to breakthrough devices. However, this alternative did not meet the other E.O. 13890 aims of minimizing time between FDA market authorization and Medicare coverage and wide availability. The timing of coverage would depend upon the manufacturer being able to initiate a

clinical study and the wide availability of coverage could be an issue if providers did not have the infrastructure necessary to participate in the clinical study. The pathway had the benefit of reducing the potential for patient harm by ensuring Medicare had clinical evidence while providing coverage. CMS chose to not to pursue combining coverage with evidence development for breakthrough devices because we wanted to meet the timing and wide availability aims of E.O. 13890.

CMS also considered taking no regulatory action and trying to leverage the existing Medicare coverage pathways or proposing subregulatory policies to achieve the streamlined coverage process described in E.O. 13890. We could not develop subregulatory policies to achieve the desired national coverage and access envisioned in E.O. 13890 because, as described in this preamble, the existing coverage pathways do not consistently provide swift, national beneficiary access to innovative devices. As discussed elsewhere in the preamble, the nature of the problem being addressed by this final rule is a potential delay between a milestone such as FDA market authorization and CMS coverage; as such, we requested comment on a policy option of shortening of the duration of the MCIT pathway from the proposed 4 years to 1 year.

The impact of implementing the MCIT pathway is difficult to determine without knowing the specific technologies that would be covered. In addition, many of these technologies would be eligible for coverage in the absence of this rule, such as through a local or national coverage determination, so the impact for certain items may be the acceleration of coverage or adoption by just a few months. Furthermore, some of these devices would be covered immediately if the MACs decide to pay for them, which would result in no impact on Medicare spending for devices approved under this pathway. However, it is possible that some of these innovative technologies would not otherwise be eligible for coverage in the absence of this rule. Because it is not known how these new technologies would otherwise come to market and be reimbursed, it is not possible to develop a point estimate of the impact. In general, we believe 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.

The decision to enter the MCIT pathway is voluntary for the manufacturer. Because manufacturers typically join the Medicare coverage pathway that is most beneficial to them, this could result in selection against the existing program coverage pathways (to what degree is unknown at this point). In addition, the past trend of new technology costing more than existing technology could lead to a higher cost for Medicare if this trend continued for technologies enrolling in the MCIT pathway. Nevertheless, new technology may also mitigate ongoing chronic health issues or improve efficiency of services thereby reducing some costs for Medicare.

In order to demonstrate the potential impact on Medicare spending, the CMS Office of the Actuary (OACT) developed three hypothetical scenarios that illustrate the impact of implementing the proposed MCIT pathway. Scenarios two and three assume that the device would not have been eligible for coverage in the absence of the proposed rule. (See Table 2) The illustration used the new devices that applied for a NTAP in FY 2020 as a proxy for the new devices that would utilize the MCIT pathway. The submitted cost and anticipated utilization for these devices was published in the **Federal Registe**r.[16] In addition, we assumed that two manufacturers would elect to utilize the MCIT pathway in the first year, three manufacturers in the second year, four manufacturers in the third year, and five manufacturers in the fourth year each year for all three scenarios. This assumption is based on the number of medical devices that received FY 2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles and our impression from the FDA that the number of devices granted breakthrough status is increasing. For the first scenario, the no-cost scenario, we assumed that all the devices would be eligible for coverage in the absence of the proposed rule. If the devices received payment nationally and at the same time then there would be no additional cost under

[16] FY 2020 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (84 FR 19640 and 19641) (May 3, 2019) *available at* https://www.govinfo.gov/content/pkg/FR-2019-05-03/pdf/2019-08330.pdf (accessed October 17, 2019).

this pathway. For the second scenario, the low-cost scenario, we assumed that the new technologies would have the average costs ($2,044) and utilization (2,322 patients) of similar technologies included in the FY 2020 NTAP application cycle. Therefore, to estimate the first year of MCIT, we multiplied the add-on payment for a new device by the anticipated utilization for a new device by the number of anticipated devices in the pathway ($2,044 x 2,322 x 2 = $ 9.5 million). For the third scenario, the high-cost scenario, we assumed the new technologies would receive the maximum add-on payment from the FY2020 NTAP application cycle ($22,425) and the highest utilization of a device (6,500 patients). Therefore, to estimate for the first year of MCIT, we estimated similarly ($22,425 x 6,500 patients x 2 = $ 291.5 million). For subsequent years, we increased the number of anticipated devices in the pathway by three, four, and five in the last two scenarios until 2024.[17] In addition to not taking into account inflation, the illustration does 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). It is not possible to explicitly quantify these offsetting costs but they could substantially reduce or eliminate the net program cost. However, by assuming that only two to five manufacturers will elect MCIT coverage, we have implicitly assumed that, while more manufacturers could potentially elect coverage under MCIT, the majority of devices would have been covered under a different coverage pathway. Therefore, a substantial portion of the offsetting costs are implicitly reflected.

Based on this analysis, there is a range of potential impacts of the proposed MCIT coverage pathway as shown in Table 2. The difference between the three estimates demonstrates how sensitive the impact is to the cost and utilization of these unknown devices.

TABLE 3: ILLUSTRATED IMPACT ON THE MEDICARE PROGRAM BY MCIT

17 An indirect cost of the proposed rule would be increased distortions in the labor markets taxed to support the Medicare Trust Fund. Such distortions are sometimes referred to as marginal excess tax burden (METB), and Circular A-94—OMB's guidance on cost-benefit analysis of federal programs, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf—suggests that METB may be valued at roughly 25 percent of the estimated transfer attributed to a policy change; the Circular goes on to direct the inclusion of estimated METB change in supplementary analyses. If secondary costs—such as increased marginal excess tax burden is, in the case of this final rule—are included in regulatory impact analyses, then secondary benefits must be as well, in order to avoid inappropriately skewing the net benefits results, and including METB only in supplementary analyses provides some acknowledgement of this potential imbalance.

COVERAGE PATHWAY

	Costs (in millions)			
	FY 2021	**FY 2022**	**FY 2023**	**FY 2024**
No-cost Scenario	$0	$0	$0	$0
Low-cost Scenario	$9.5	$23.7	$42.7	$66.4
High-cost Scenario	$291.5	$728.8	$1,311.9	$2,040.7

We believe the assumptions used in the three scenarios are reasonable to show the possible wide range of impacts for implementing this proposed pathway, in particular for a technology that would not have otherwise been eligible for coverage.

Comment: A commenter supported CMS' assertion that new technology may mitigate ongoing chronic health issues or improve efficiency of services thereby reducing some cost for Medicare, and that incentivizing breakthrough medical devices will lead to both direct cost offsets (i.e., cost savings) and indirect benefits (e.g., quality of life, clinical outcomes) across multiple therapeutic areas. Another expressed concern that funding for MCIT will result in neutrality adjustments across the Physician Fee Schedule (PFS).

Response: We appreciate these comments. Payment for Medicare covered physician services and other services paid under the PFS are subject to statutorily-required budget neutrality adjustments, determined based on the utilization of particular services. The RIA did not incorporate changes to PFS as we do not expect that it is likely PFS will require adjustment.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Some hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We reviewed the Small Business Administration's Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes to determine the NAICS U.S. industry

titles and size standards in millions of dollars and/or number of employees that apply to small businesses that could be impacted by this rule.[18] We determined that small businesses potentially impacted may include surgical and medical instrument manufacturers (NAICS code 339112, dollars not provided/1,000 employees), Offices of Physicians (except Mental Health Specialists) (NAICS code 621111, $12 million/employees not provided), and Freestanding Ambulatory Surgical and Emergency Centers (NAICS code 621493, $16.5 million/employees not provided). During the first 4 years of MCIT, we anticipate approximately 14 surgical and medical instrument manufacturers may participate, and based off of U.S. Census data, the majority of this businesses type are small businesses with less than 1,000 employees (968 out of 1,093 businesses have less than 500 employees).[19] As such, this final rule will impact less than 5 percent of these businesses, and the revenue impact, if any, would not be negative. Rather, it would be a positive impact because MCIT would provide Medicare coverage (and subsequent payment) to providers who purchase the devices from these manufacturers. For Offices of Physicians (except Mental Health Specialists) and Freestanding Ambulatory Surgical and Emergency Centers that may be providing the breakthrough devices, the majority are small businesses with less than 1,000 employees (4,060 out of 4,385 and 160, 367 out of 161, 286 have less than 500 employees, respectively).[20] Given that we estimate, at most in the high-cost scenario, that 6,500 beneficiaries would utilize breakthrough devices through MCIT per year, and even if each beneficiary were to access services at only one of these small businesses (that is, no two beneficiaries used the same office or center), still less than 5 percent of these small businesses would be impacted by MCIT. As such, the revenue impact, if any, would not be negative, rather, it would be a positive impact because MCIT would provide Medicare coverage

[18] Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes, *available at* https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf
[19] 2017 County Business Patterns and 2017 Economic Census. Number of Firms, Number of Establishments, Employment, Annual Payroll, and Preliminary Receipts by Enterprise Employment Size for the United States, All Industries: 2017 (release date: May 6, 2020).
[20] *Id.*

(and subsequent payment) to providers. Overall, this final rule results in a payment, not a reduction in revenue. We are not preparing a further analysis for the RFA because we have determined, and the Secretary certifies, that the proposed rule and this subsequent final rule will not have a significant negative economic impact on a substantial number of small entities because small entities are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business. Rather, for small entities that develop or provide breakthrough devices to patients, the proposed rule and this final rule are a means for the device to be covered through the Medicare program, which does not detract from revenue and could be viewed as a positive economic impact. With the limited information we had to base this estimate, we solicited public comment on improvements to this estimate for this final rule.

After consideration of the public comments we received, we are finalizing the rule as proposed.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the proposed rule and the final rule would not have a significant impact on the operations of a substantial number of small rural hospitals because small rural hospitals are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business. Obtaining breakthrough devices for patients is at the discretion of providers. We are not requiring the purchase and use of breakthrough devices. Providers should continue to work with their patients to choose the best treatment. For small rural hospitals that provide breakthrough devices to their patients, this proposed rule is a means for the device to be covered through the Medicare program.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold was approximately $156 million. This final rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this final rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (E.O. 13771), titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. The proposed rule, is being finalized as proposed, and is expected to impose no more than *de minimis* costs and thus be neither an E.O. 13771 regulatory action nor an E.O. 13771 deregulatory action.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.201 is amended in paragraph (b) by adding a definition for "Reasonable and necessary" in alphabetical order to read as follows:

§ 405.201 Scope of subpart and definitions.

* * * * *

(b) * * *

Reasonable and necessary means that an item or service is considered--

(i) Safe and effective;

(ii) Except as set forth in § 411.15(o) of this chapter, not experimental or investigational; and

(iii) Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it meets all of the following criteria:

(A) 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;

(B) Furnished in a setting appropriate to the patient's medical needs and condition;

(C) Ordered and furnished by qualified personnel;

(D) Meets, but does not exceed, the patient's medical need; and

(E) Is at least as beneficial as an existing and available medically appropriate alternative; or

(F) Not later than March 15, 2022, CMS will issue draft subregulatory guidance on the methodology of which commercial insurers are relevant based on the measurement of majority of covered lives. For national and local coverage determinations, which have insufficient evidence to meet paragraphs (b)(3)(i) through (v) of this section, CMS will consider coverage to the extent the items or services are covered by a majority of commercial insurers. As part of CMS' consideration, CMS will include in the national or local coverage determination its reasoning for its decision if coverage is different than the majority of commercial insurers.

* * * * *

3. Subpart F, consisting of §§405.601—405.607, is added to read as follows:

Subpart F -- Medicare Coverage of Innovative Technology

Sec.

Subpart F--Medicare Coverage of Innovative Technology

§**405.601 Medicare coverage of innovative technology.**

(a) *Basis and scope*. Medicare coverage of innovative technology (MCIT) is a program that provides national, time-limited coverage under section 1862(a)(1)(A) of the Act for certain breakthrough medical devices. Manufacturer participation in the pathway for breakthrough device coverage is voluntary.

(b) *Definitions*. For the purposes of this subpart, the following definitions are applicable:

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)).

MCIT stands for Medicare coverage of innovative technology.

§**405.603 Medical device eligibility.**

The MCIT pathway is available only to medical devices that meet all of the following:

(a) That are FDA-designated breakthrough devices.

(b) That were FDA market authorized on [Enter date 2 years prior to effective date of final rule] and thereafter.

(c) That are used according to their FDA approved or cleared indication for use.

(d) That are within a Medicare benefit category.

(e) That are not the subject of a Medicare national coverage determination.

(f) That are not otherwise excluded from coverage through law or regulation.

§**405.605 Coverage of items and services.**

Covered items and services furnished within the MCIT pathway may include any of the following, if not otherwise excluded from coverage and according to existing coverage and/or payment policies as applicable:

(a) The breakthrough device.

(b) Any reasonable and necessary procedures to implant and/or use the breakthrough device.

(c) Reasonable and necessary items and services to maintain the breakthrough device.

(d) Related care and services for the breakthrough device.

(e) Reasonable and necessary services to treat complications arising from use of the breakthrough device.

§**405.607 Coverage period.**

(a) *Start of the period*. The MCIT pathway begins on the date requested by the manufacturer in an email to CMS at any time opting in to the MCIT pathway provided the requested start date is no earlier than ---

(1) The date the breakthrough device receives FDA market authorization; or

(2) The date requested by the manufacturer, provided that such a date is not later than 2

years after the date described in paragraph (a)(1) of this section.

(b) *End of the period*. The MCIT pathway for a breakthrough device ends as follows:

(1) No later than 4 years from the date the breakthrough device received FDA market authorization.

(2) Prior to 4 years if a manufacturer withdraws the breakthrough device from the MCIT pathway.

(3) Prior to 4 years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes noncovered through law, regulation, or at the discretion of the Secretary subsequent to an FDA medical device safety communication or Warning Letter.

(4) Prior to 4 years if the FDA removes authorization of a device, the breakthrough device is removed from the MCIT pathway.

Dated: December 31, 2020.

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Seema Verma,

Administrator,
Centers for Medicare & Medicaid Services.

Dated: January 5, 2021.

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Alex M. Azar II,

Secretary,
Department of Health and Human Services.

[FR Doc. 2021-00707 Filed: 1/12/2021 4:15 pm; Publication Date: 1/14/2021]