



## Centers for Medicare & Medicaid Services

### 42 CFR Part 405

[CMS-3372-F3]

RIN 0938-AT88

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

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule repeals the “Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”” final rule, which was published on January 14, 2021, and was to be effective on December 15, 2021.

**DATES:** This final rule is effective December 15, 2021.

**FOR FURTHER INFORMATION CONTACT:** Lori Ashby, (410) 786-6322 or [MCIT@cms.hhs.gov](mailto:MCIT@cms.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

##### A. January 14, 2021 Final Rule

In the January 14, 2021, **Federal Register**, we published a final rule titled “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ‘Reasonable and Necessary’”(86 FR 2987) (hereinafter referred to as the “MCIT/R&N final rule”). The MCIT/R&N final rule established a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to recently market authorized medical devices designated as breakthrough by the Food and Drug Administration (FDA). Under the final rule, MCIT would 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. The MCIT/R&N final rule would also implement 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 Medicare Parts A and B.

#### B. March 2021 Interim Final Rule (IFC) and May 2021 Final Rule to Delay Effective Date

In response to the January 20, 2021, memorandum from the Assistant to the President and Chief of Staff titled “Regulatory Freeze Pending Review” (“Regulatory Freeze Memorandum”) (86 FR 7424, January 28, 2021) and guidance on implementation of the memorandum issued by the Office of Management and Budget (OMB) in Memorandum M-21-14 dated January 20, 2021, we determined that a 60-day delay of the effective date of the MCIT/R&N final rule was appropriate to ensure that--

- The rulemaking process was procedurally adequate;
- We properly considered all relevant facts;
- We considered statutory or other legal obligations;
- We had reasonable judgment about the legally relevant policy considerations; and
- We adequately considered public comments objecting to certain elements of the rule,

including whether interested parties had fair opportunities to present contrary facts and arguments.

Therefore, in an interim final rule with comment period that went on display at the **Federal Register** and took effect on March 12, 2021 (hereinafter referred to as the "March 2021 IFC"), and was published in the March 17, 2021, **Federal Register** (86 FR 14542), we-- (1) delayed the MCIT/R&N final rule effective date until May 15, 2021 (that is, 60 days after the original effective date of March 15, 2021); and (2) opened a 30-day public comment period on the facts, law, and policy underlying the MCIT/R&N final rule.

Many commenters on the March 2021 IFC supported further delaying the MCIT/R&N final rule. Based upon the public comments, we did not believe that it was in the best interest of

Medicare beneficiaries for the MCIT/R&N final rule to become effective on May 15, 2021.

Therefore, in a final rule that went on display at the **Federal Register** and took effect on May 14, 2021 (hereinafter referred to as the “May 2021 final rule”), and was published in the May 18, 2021, **Federal Register** (86 FR 26849), we summarized the comments on the March 2021 IFC and further delayed the MCIT/R&N final rule effective date until December 15, 2021. We explained that the additional delay would provide us an opportunity to address issues raised by stakeholders, especially those related to Medicare patient protections and evidence criteria. We announced that during the delay, we would determine appropriate next steps that are in the best interest of all Medicare stakeholders, and beneficiaries in particular.

### C. September 2021 Proposed Rule to Repeal the MCIT/R&N Final Rule

In the September 15, 2021, **Federal Register** (86 FR 51326) (hereinafter referred to as the "September 2021 proposed rule"), we published a proposed rule that would repeal the January 14, 2021 final rule. The September 2021 proposed rule included a 30-day public comment period on the provisions of the proposed repeal.

## **II. Provisions of Proposed Regulations and Analysis of and Responses**

We received approximately 115 timely items of correspondence in response to the September 2021 proposed rule. Commenters included a broad range of stakeholders, including physicians, professional societies, manufacturers, manufacturer associations, venture capital firms, and patient advocates. In this section of this final rule, we present our proposal to repeal the January 2021 MCIT/R&N final rule, our rationale for the proposal, as well as our summation of and responses to the public comments received.

### A. Proposed Repeal of Medicare Coverage of Innovative Technology Policy

CMS developed MCIT in part due to concerns that delays and uncertainty in Medicare coverage slowed innovation and impaired beneficiary access to important new technologies, specifically those designated as breakthrough devices by FDA. In response to these concerns, the rule provided 4 years of expedited coverage to FDA market authorized Breakthrough

Devices on the first day of FDA market authorization or a select date up to 2 years after the market authorization date as requested by the device manufacturer. While the final rule did not require manufacturers to develop additional scientific evidence supporting the use of the Breakthrough Devices in the Medicare population, manufacturers were aware that, upon conclusion of MCIT coverage, the existing coverage pathways would be available (that is, reasonable and necessary determinations would be made via claim-by-claim adjudication, local coverage determinations (LCDs), and national coverage determinations (NCDs), which include the coverage with evidence development pathway). The NCD and LCD development processes include reviews of publicly available clinical evidence to determine whether or not the items or services are reasonable and necessary and would be covered by Medicare.

As we noted in the September 2021 proposed rule, we believe that the finalized MCIT/R&N rule is not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose. We have had a growing concern that the provisions that we established in the MCIT/R&N final rule to protect Medicare patients may not have been sufficient. We received comments on this issue again in our subsequent rules that delayed the effective date. By repealing that rule, we can better address those safety concerns in the future. As commenters have noted, the agency must balance competing interests. Although we continue to be in favor of increasing access to new technologies, we are also mindful that sometimes those devices have unknown or unexpected risks. The Medicare program will need to include adequate safeguards to act in those situations.

While the rule tried to address stakeholder concerns about accelerating coverage of new devices, concerns persist about the availability of clinical evidence on Breakthrough Devices when used in the Medicare population as well as the benefit or risks of these devices with respect to use in the Medicare population upon receipt of coverage. Based on the comments received

throughout the development of the MCIT pathway, we do not believe that the final rule as currently drafted is the best way to achieve the goals of MCIT as outlined in the MCIT/R&N final rule, in particular, to more precisely meet the needs Medicare beneficiaries and other stakeholders in a timely fashion. We believe that there are other ways to achieve our stated goals. This may include better utilizing existing pathways or conducting future rulemaking.

As noted in the May 2021 final rule, our prior policies permitted the Medicare program to deny coverage for particular devices if we learned that a particular device may be harmful to Medicare beneficiaries. Specifically, Medicare Administrative Contractors (MACs) could have denied claims under certain circumstances (86 FR 26851, May 18, 2021). Under the MCIT/R&N final rule, this case-specific flexibility would have been removed. While we could remove coverage through the NCD process, we would be able to expeditiously remove a Breakthrough Device from the MCIT coverage pathway for only limited reasons, such as if FDA issued a safety communication or warning letter regarding the Breakthrough Device or removed the marketing authorization for a device. This limitation on our authority is impracticable as it may lead to preventable harm to Medicare beneficiaries and it impedes Medicare's ability to make case-by-case determinations regarding whether a device is reasonable and necessary based on clinical evidence. After reviewing Breakthrough Devices with FDA authorization that would be eligible for MCIT, we no longer believe that CMS should grant full national coverage solely based on Breakthrough Designation. While the FDA reviews a device to ensure it meets the applicable safety and effectiveness standard, there is often limited evidence regarding whether the device is clinically beneficial to Medicare patients. We believe this is a key factor in determining coverage under Medicare. The FDA's focus is the safety and effectiveness profile of devices for the intended population, and while these devices may improve symptoms for some patients, the risk – benefit profile may be different for older patients. Further evidence development is needed to better inform medical decision making generally as well as Medicare coverage under the reasonable and necessary standard.

While the MCIT/R&N final rule would have provided expedited Medicare coverage following market authorization for breakthrough designated devices, there is currently no FDA requirement that Medicare beneficiaries must be included in clinical studies needed for market-authorization. Because the MCIT/R&N final rule also did not require data concerning Medicare beneficiaries to fill this gap in evidence specific to Medicare patients, there is the potential that Medicare would cover devices, even in the absence of data demonstrating that the device is reasonable and necessary for Medicare patients. The FDA definition of a medical device is broad, and includes a wide range of products, such as surgical sutures, joint replacements, blood glucose monitors, stents, and implanted valves. After reviewing FDA-designated Breakthrough Devices that have FDA authorization and eligible for MCIT, CMS has concluded that in treating all breakthrough devices similarly, the MCIT/R&N final rule could establish insufficient beneficiary protections for certain devices. Accordingly, we have determined that repealing the MCIT/R&N final rule and revisiting the policy is in the best interest of Medicare patients.

In response to the March 2021 IFC, several medical device manufacturers suggested that, for inclusion in MCIT, FDA pivotal studies should require inclusion of sufficient numbers of Medicare beneficiaries (86 FR 26851, May 18, 2021). We note that a simple proportional requirement may be insufficient, particularly for studies with the smaller sample sizes that are typical for medical devices; valid statistical conclusions require that clinical studies be sufficiently powered to reliably assess risks and benefits in the Medicare population. Certain proponents of accelerated Medicare coverage have argued that FDA's determination that a product meets applicable safety and effectiveness standards for marketing authorization should be sufficient to support Medicare coverage of Breakthrough Devices. However, after further consideration of all public comments, we no longer agree that the FDA safety and effectiveness standards alone are sufficient to support open-ended Medicare coverage. FDA and CMS act under different statutes that have different goals. The standard for Medicare coverage (that is, a

determination that a device is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member) is not synonymous with the standards for FDA marketing authorization of devices, which are not specific to the Medicare population. Since we issued the MCIT/R&N final rule, we have a better understanding and a growing realization of the consequences of incorporating FDA standards into Medicare decision making to the degree stated in the final rule. We have fully considered the implications, especially in terms of how this would hamper CMS' ability to address unanticipated harms that may arise in the Medicare population. CMS no longer believes that it is appropriate to grant all FDA market authorized Breakthrough Devices automatic coverage solely based on its Breakthrough Designation. While the FDA reviews devices to ensure they meet applicable safety and effectiveness standards, there is often limited evidence regarding whether the device is clinically beneficial to Medicare patients. As stated earlier, this is an important consideration in determining the type of coverage under Medicare. For example, when only limited evidence on health outcomes was studied for the Medicare population, it is unclear whether Medicare should cover the device with evidence development or should only provide coverage for certain patients, practitioners, or health care facilities. Immediate, broad, unrestricted Medicare coverage under this circumstance could lead to patient harm. Information specific to Medicare populations is important to better inform medical decision making generally, as well as Medicare coverage under the reasonable and necessary standard. Among other things, FDA conducts premarket review of certain devices to evaluate their safety and effectiveness and determines if they meet the applicable standard to be marketed in the United States. In doing so, FDA relies on scientific and medical evidence that does not necessarily include patients from the Medicare population. In general, under the Medicare statute, CMS is charged with determining whether items and services are reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member. One consideration for CMS in making national coverage determinations under the reasonable and necessary standard is whether the item/service

improves health outcomes for Medicare beneficiaries. For CMS, the evidence base underlying the FDA's decision to approve or clear a device for particular indications for use has been crucial for determining Medicare coverage through the NCD process. CMS looks to the evidence supporting FDA market authorization and the device indications for use for evidence generalizable to the Medicare population, data on improvement in health outcomes, and durability of those outcomes. If there are no data on those elements, it is difficult for CMS to make an evidence-based decision whether the device is reasonable and necessary for the Medicare population.

It is important to determine whether Medicare beneficiaries' health outcomes are improved because these individuals are often older, with multiple comorbidities<sup>1</sup>, and are often underrepresented or not represented in many clinical studies.

#### 1. Evidence Development and Patient Safety

The Medicare national coverage determination process includes a robust review of available clinical evidence and focuses on the Medicare population to make reasonable and necessary determinations. In contrast, the MCIT pathway would establish an expedited 4-year coverage pathway for all Breakthrough Devices that fall under a Medicare benefit category without a specific requirement that the device must demonstrate it is reasonable and necessary for the Medicare population. In general, Medicare patients have more comorbidities and often require additional and higher acuity clinical treatments which may impact the outcomes differently than the patients generally enrolled in early clinical trials. These considerations are often not addressed in the device development process.

When we issued the MCIT/R&N final rule on January 14, 2021, we responded to commenters who suggested that CMS should take a different approach. Some commenters

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<sup>1</sup> Davide L Vetrano, MD, Katie Palmer, PhD, Alessandra Marengoni, MD, PhD, Emanuele Marzetti, MD, PhD, Fabrizia Lattanzio, MD, PhD, Regina Roller-Wirnsberger, MD, MME, Luz Lopez Samaniego, PhD, Leocadio Rodríguez-Mañas, MD, PhD, Roberto Bernabei, MD, Graziano Onder, MD, PhD, Frailty and Multimorbidity: A Systematic Review and Meta-analysis, *The Journals of Gerontology: Series A*, Volume 74, Issue 5, May 2019, Pages 659–666, <https://doi.org/10.1093/gerona/gly110>.



suggested that we should require manufacturers to provide data about Medicare outcomes before providing coverage as reasonable and necessary. Other commenters suggested that we provide incentives to manufacturers to include Medicare beneficiaries in clinical studies, similar to CMS's Coverage with Evidence Development (CED) paradigm, before coverage under section 1862(a)(1)(A) of the Act was allowed (86 FR 2990, January 14, 2021).<sup>2</sup> In response to the March 2021 IFC, additional commenters supported evidence development as part of the requirements to participate in the MCIT pathway. Some commenters noted that some clinical trials that were conducted to support market authorization through the Breakthrough Devices pathway lack data on patients older than 65, patients with disabilities, and patients with end stage renal disease (ESRD). They asserted that the absence of this clinical information poses some uncertainty about whether FDA's determination of safety and efficacy could be generalized to the Medicare population (86 FR 26850 and 26851, May 18, 2021).

In response to commenters' concerns about expedited coverage without adequate evidentiary support, CMS agrees that guaranteeing coverage for all Breakthrough Devices receiving market authorization for any Medicare patient could be problematic if there is insufficient evidence demonstrating a health benefit or addressing the additional risks for Medicare beneficiaries (86 FR 26850 and 26851, May 18, 2021). We noted that a Breakthrough Device may only be beneficial in a subset of the Medicare population or when used only by clinicians within a certain specialty to ensure benefit. Without additional clinical evidence on the device's clinical utility for the Medicare population or appropriate providers, it is challenging to determine appropriate Medicare coverage of newly market-authorized Breakthrough Devices (86 FR 26850 and 26851, May 18, 2021).

We recognize that the breakthrough designation may be granted by FDA before sufficient clinical evidence is available to prove there is a health benefit for Medicare patients. FDA has

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<sup>2</sup> 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>.

explained in guidance that because decisions on requests for breakthrough designation will be made prior to marketing authorization, FDA considers whether there is a “reasonable expectation that a device could provide for more effective treatment or diagnosis relative to the current standard of care (SOC) in the U.S” for purposes of the designation. This reasonable expectation can be “supported by literature or preliminary data (bench, animal, or clinical)”.<sup>3</sup> Without sufficient evidence developed to show the device improves health outcomes for Medicare beneficiaries, it may be challenging for the Medicare program to determine the health benefit of these devices for Medicare beneficiaries. Public comments expressed concern about how the Medicare population is often excluded from clinical trials due to age and health status.

Previously, in the MCIT/R&N final rule, we noted that “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” (86 FR 2988, January 14, 2021).<sup>4</sup> Through further consideration of the breakthrough designation process, we have changed our position on this issue and determined that Breakthrough Device designation is not, by itself, sufficient for expedited Medicare coverage purposes. Rather, as explained previously, we understand that FDA may grant a device breakthrough designation when the device has shown a “reasonable expectation” of providing more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition relative to the current U.S. SOC and that it meets the other criterion for designation in section 515B(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C) Act (21 U.S.C. 360e-3(b)(2)). CMS acknowledges that we have changed our position on this issue after further consideration of public comments and after considering the full range of FDA designated Breakthrough Devices from diagnostic laboratory tests to implanted valves. As noted

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<sup>3</sup> Food and Drug Administration, Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff, 9, available at: <https://www.fda.gov/media/108135/download>.

<sup>4</sup> 86 FR 2988 (January 14, 2021) available at <https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00707.pdf>.

previously, we do not believe that granting broad national coverage solely on Breakthrough Device designation alone is in the best interest of beneficiaries or the Medicare program, as this approach does not provide CMS with the necessary flexibility to establish beneficiary safeguards, similar to the patient protections we include in NCDs, specifically CED NCDs, for some of these devices that do not have an evidence base generalizable to the Medicare population. Under the MCIT/R&N final rule, CMS would not be able to include any beneficiary safeguards until the conclusion of the 4-year expedited coverage period and upon completion of an NCD. While we acknowledge that improvements can be made to the existing coverage processes, the inability for CMS to establish beneficiary safeguards under the MCIT/R&N final rule is a significant limitation that can lead to potential beneficiary harm. For these reasons we no longer believe it is in the best interest of Medicare patients to base expedited multiyear, broad national coverage through section 1862(a)(1)(A) of the Act on Breakthrough Device designation alone.

Clinical studies that are conducted in order to gain market authorization for FDA Breakthrough Devices are not required to include information on patients with similar demographics and characteristics of the Medicare population. A potential reason there may not be a strong evidence base specific to the Medicare population could include the desire by device manufacturers to demonstrate the safety and effectiveness of a device as clearly as possible. To achieve this aim, many studies impose stringent exclusion criteria that disqualify individuals with certain characteristics, such as comorbidities and concomitant treatment, that might make the effect of the investigational device more difficult to determine. Consequently, the safety and effectiveness of a device for older patients with more comorbidities may not be well understood at the time of FDA market authorization.

Additionally, there may be devices designated as breakthrough that do not have adequate data on the effectiveness of the device for the Medicare population. Without such evidence, it is possible that Medicare would be covering and paying for devices that may have little or no

Medicare relevant clinical evidence to assist physicians and patients in making treatment decisions. Separate from information and evidence submitted for breakthrough designation and market authorization, is the concept of post-market evidence development. Without requiring any evidence development specific to Medicare patients following market authorization, there may not be any evidence to demonstrate whether the device is beneficial after the conclusion of MCIT coverage after 4 years. Evidence-based coverage policy is essential to our objective of improving health outcomes while delivering greater value. Supportive clinical evidence that ensures a device is both safe and effective and reasonable and necessary in the Medicare population is crucial in order to grant coverage for a device under section 1862(a)(1)(A) of the Act. Such evidence is used to determine whether a new technology meets the appropriateness criteria of the longstanding Medicare Program Integrity Manual Chapter 13 definition of reasonable and necessary.<sup>5</sup> We believe that it is important to require manufacturers participating in an innovative coverage pathway, such as MCIT, to produce evidence that demonstrates the health benefit of the device and the related services for patients with demographics similar to that of the Medicare population.

In response to the March 2021 IFC, some commenters cited evidence that FDA-mandated postmarket studies are not reliably completed (less than 20 percent of required studies are completed within 3 to 5 years after market authorization),<sup>6</sup> and asserted that evidence demonstrating a device's health benefit in Medicare beneficiaries is essential. Commenters also recommended that CMS outline in guidance documents the types of evidence that would be acceptable for applications for national or local coverage determinations once the MCIT pathway's 4 years had expired, such as real-world data or randomized, controlled trials (86 FR 26851, May 18, 2021). By voluntarily developing this evidence during the time a device is covered under the MCIT pathway, the manufacturer could have the evidence base needed for one

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<sup>5</sup> CMS, Medicare Program Integrity Manual, Chapter 13, 13.5.4, *available at* <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf>

<sup>6</sup> Rathi et al.

of the other coverage pathways after the MCIT pathway ends. The MCIT/R&N final rule did not require manufacturers of Breakthrough Devices to develop evidence as part of their participation requirements under MCIT. In the May 2021 final rule, we noted that numerous commenters, including physicians with experience in clinical research and medical specialty societies, sought modifications to the MCIT/R&N final rule regarding evidence development, including the addition of real-world evidence requirements. We agree that guidance documents or similar publications outlining the types of evidence that would be acceptable for requests for NCD and LCDs is a good idea. We are continuing to explore additional opportunities to more efficiently publish relevant health outcomes for different disease treatments. CMS is working on the best and most efficient manner to communicate what are important health outcomes. As was noted by commenters in response to the March 2021 IFC, early and unrestricted adoption of devices may have adverse consequences that may not be easy to reverse. CMS expects physicians to consider the available evidence and assess the care needs of each patient when considering the best treatment options. However, by guaranteeing coverage of devices based solely on breakthrough status and FDA marketing authorization, rather than also taking into account whether the device provides an effective, reasonable and necessary treatment for Medicare patients, there may be an incentive for physicians to use a device that has coverage under the MCIT pathway rather than a device that is not covered under the MCIT pathway but is nonetheless covered under an existing coverage pathway and that may be more beneficial to patients. We believe that providers' clinical treatment decisions should take the individual needs of the patient into account; therefore, we seek to avoid incentivizing the use of MCIT-covered devices when an alternative item or service may be more appropriate.

While the MCIT/R&N final rule may provide beneficiaries and manufacturers an assurance of national Medicare coverage, evidence development under MCIT as previously finalized is voluntary and there was no requirement that manufacturers conduct studies to generate evidence to demonstrate clinical benefit to Medicare patients. We acknowledge that we

no longer believe that voluntary evidence development, as provided for in the MCIT/R&N final rule, is in the best interests of Medicare beneficiaries as we believe such evidence is key to determining the best treatments for Medicare patients to ensure that the benefits of treatments outweigh the potential harms. For devices that lack evidence that is generalizable to the Medicare population, we believe it is important for such evidence to be developed and some public commenters suggested that we establish the coverage criteria (for example, provider experience, site of service, availability of supporting services) to ensure delivery of high-quality, evidence-based care.

While we proposed to repeal the MCIT/R&N final rule, and we now finalize the repeal of the MCIT/R&N rule, this action does not prohibit coverage of Breakthrough Devices. As we noted in the May 2021 final rule, even without the MCIT/R&N final rule in effect, a review of claims data showed that Breakthrough Devices have received and are receiving Medicare coverage when medically necessary. As more Breakthrough Devices achieve market authorization, and as we continue to examine claims data, we are learning that many of the eligible Breakthrough Devices are coverable and payable through existing mechanisms, such as bundled payments. Some Breakthrough Devices may be addressed by an existing LCD or NCD. New items and services can also be adjudicated on a claim-by-claim basis and be covered and paid under the applicable Medicare payment system if the MAC determines them to be reasonable and necessary for specific patients upon a more individualized MAC assessment. The MACs may take into account a beneficiary's particular clinical circumstances to determine whether a beneficiary may benefit from the device. CMS acknowledges, among other factors, that MCIT was developed in response to stakeholder concerns about time lags and coverage uncertainty for devices subject to claim-by-claim coverage determinations. While these paths provide some coverage, it may not meet stakeholders' expectations of faster and more predictable coverage.

## 2. Limitations of the MCIT Pathway

The MCIT/R&N final rule limited MCIT only to Breakthrough Devices. In accordance with section 515B of the FD&C (21 U.S.C. 360e-3), FDA's Breakthrough Devices Program is for certain medical devices and device-led combination products, and can include lab tests.<sup>7</sup> To be granted a Breakthrough Device designation under the Breakthrough Devices Program, medical devices and device-led combination products must meet two criteria. The first criterion is that the device provides 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.
- Device availability is in the best interest of patients (for more information see

21 U.S.C. 360e-3(b)(2)).

Some commenters to the September 2020 MCIT/R&N proposed rule expressed concern that the MCIT pathway could give specific technologies an unfair advantage that would be unavailable to subsequent market entrants, thereby decreasing innovation and market competition (86 FR 2998 and 2999). Commenters submitted a variety of alternative approaches to covering second-to-market and non-breakthrough designated new technology to remedy this unintended consequence. Some commenters supported that CMS cover iterative refinements of the same Breakthrough Device for the duration of the original device's MCIT term. Other commenters suggested coverage under the MCIT pathway for subsequent similar breakthrough and non-breakthrough designated devices of the same type and indication for the balance of the first device's MCIT term. Yet other commenters proposed that new market entrants that are very

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<sup>7</sup> Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff, available at <https://www.fda.gov/media/108135/download>.

similar to a Breakthrough Device should each receive the full 4 years of MCIT coverage, not tied to the timeline of the original product.

We acknowledge that we have changed our policy position on this issue after further consideration of all public comments received as we have worked to develop the MCIT pathway. We carefully considered the likelihood of reliance by stakeholders, including manufacturers and patients on the MCIT/R&N final rule and our decision to repeal the rule. Because the rule has never gone into effect we believe there has been minimal, if any, reliance on the MCIT/R&N final rule. Further, we believe we can work with stakeholders to achieve appropriate coverage through existing mechanisms. We also agree with commenters that there are many drawbacks to limiting coverage through the MCIT pathway only to those devices that are part of the Breakthrough Devices Program, and we now believe that any future alternative coverage pathway should not include this limitation. As noted previously, the potential incentives created by offering immediate coverage of Breakthrough Devices may disincentivize development of innovative technologies that do not meet the criteria for the Breakthrough Devices Program, such as some non-breakthrough-designated second-to-market devices and subsequent technologies of the same type. Additionally, we now believe a more flexible coverage pathway that leverages existing statutory authorities may be better able to provide faster coverage of new technologies to Medicare beneficiaries while prioritizing patient health and outcomes.

### 3. Future Coverage Policy Rulemaking

While we proposed to repeal the MCIT/R&N final rule as it is currently written, we considered future policies and potential rulemaking to provide improved access to innovative and beneficial technologies. We are committed to exploring other policy options and statutory authorities for coverage that better suit the needs of Medicare beneficiaries and other stakeholders when the items or services are supported by adequate evidence. For example, we are planning on initiating several coverage process improvements, including engaging the Agency for Healthcare Research and Quality (AHRQ) to explore updating the CED study



criteria, as well as exploring options of expediting the NCD process. It is our goal to address these issues in future rulemaking and/or subregulatory guidance.

*Comment:* Commenters from multiple stakeholder groups (manufacturers, physicians, associations, etc.) agreed with CMS' proposal to repeal the MCIT/R&N final rule as they believe that the MCIT pathway as originally constructed was flawed and would not achieve the intended outcome of removing delays and uncertainty to improve beneficiary access to innovative technologies.

*Response:* We appreciate commenters' support for our proposal to repeal the MCIT/R&N final rule. We agree with commenters that while the MCIT/R&N final rule attempted to improve timeliness and predictability of coverage for new technologies, it was flawed in a number of ways that would have prevented predictable, timely coverage for beneficial devices and technologies. We agree with commenters that one of MCIT's limitations is that the MCIT/R&N final rule would have granted up to 4 years of open-ended Medicare coverage for FDA designated Breakthrough Devices upon market authorization, with no conditions of coverage beyond the FDA approved or cleared indication(s) for use. Further, the rule only granted expedited coverage for designated Breakthrough Devices; it did not grant the same coverage to devices or technologies that may treat the same condition but are not FDA designated as a Breakthrough Device, or older devices/technologies that may be more beneficial. This uneven approach to important beneficial devices was concerning and must be addressed.

*Comment:* Some commenters from multiple stakeholder groups reiterated their concerns that the provision of expedited coverage for certain devices (that is, Breakthrough Devices) without adequate evidence on the Medicare population and no requirement to develop the evidence places beneficiaries at risk of significant harms. Commenters noted that this is especially problematic since Medicare beneficiaries often have comorbidities and may respond differently than other populations that comprise that majority of most clinical trial participants.

*Response:* We agree that the lack of requirements in the MCIT/R&N final rule for manufacturers to continue to develop evidence demonstrating improved health outcomes in the Medicare population was problematic. When there is a lack of evidence specific to the Medicare population it makes it difficult for CMS to ensure that devices are not posing additional risks in the Medicare population. Continuing to develop evidence generalizable to the Medicare population is important not only to payers, but is key to patients, their caregivers and their treating clinicians to make the most informed decisions for their treatment. We continue to believe that it is important to require manufacturers participating in any innovative coverage pathway, such as MCIT, to produce evidence that demonstrates the health benefit of the device and the related services for patients with demographics similar to that of the Medicare population. It is our intention to address this issue in future rulemaking and we intend to hold at least two stakeholder public meetings in calendar year (CY) 2022 to inform our future policy-making in this space.

*Comment:* Several commenters noted that CMS already has mechanisms in place to provide coverage of Breakthrough Devices and that the repeal of the MCIT/R&N final rule would not prohibit coverage of these devices.

*Response:* We appreciate stakeholders' acknowledgement that even without the MCIT pathway, Breakthrough Devices have received and are able to receive Medicare coverage when medically necessary. We also recognize that it is important that stakeholders have transparent, predictable coverage. We are committed to working through this issue as we explore other policy options within our statutory authorities, including future rulemaking. As noted previously, we are planning on initiating several coverage process improvements, including engaging AHRQ to explore updating the CED study criteria, as well as exploring options of expediting the NCD process, and future rulemaking.

*Comment:* Many commenters indicated that a multitude of revisions would be needed to overcome MCIT's limitations and achieve its intended goals of faster and more predictable

Medicare coverage. Commenters cited examples of revisions such as a process that would include benefit category determination (if needed), coding, payment, timeframes for coordinating with FDA, and clinical evidence assessment and development.

*Response:* We agree that the final MCIT/R&N rule has significant limitations and needs modifications. We will consider these issues as we engage in future rulemaking.

*Comment:* Some commenters reiterated their concerns that the MCIT/R&N final rule does not specify, nor can it require, coverage criteria beyond the FDA approved or cleared indication(s) for use such as patient criteria and/or provider or facility qualifications or experience. Commenters expressed that clinical trial populations are typically different from the Medicare population, and thus, the evidence supporting those indication(s) for use are less germane to the Medicare population. Without an evidence development requirement pre or post coverage that includes Medicare patients, commenters are concerned about the absence of generalizable clinical evidence. Without information on Medicare patients, commenters are concerned about providers inferring proven performance of breakthrough devices regardless of patient characteristics or facility capabilities.

*Response:* We appreciate these comments. We will consider these comments as we refine our coverage processes. It is our intention to address this issue in future rulemaking and we intend to hold at least two stakeholder public meetings in CY 2022 to inform our future policy-making in this space.

*Comment:* There is general agreement among commenters that CMS can address the limitations of the MCIT pathway in future rulemaking. Several commenters recommended that CMS increase efforts to facilitate early engagement among manufacturers, CMS and FDA to discuss suitable trial designs, evidentiary goals, and to ensure that study populations are representative of the Medicare population.

*Response:* We appreciate the support for our proposal. We will consider all of these comments as we explore other policy options and statutory authorities as we explore future

rulemaking to provide appropriate expedited access to innovative and beneficial technologies. We will hold at least two public stakeholder meetings in CY 2022 as we consider several initiatives to improve the coverage process.

*Comment:* Commenters offered suggestions for CMS to consider in the future as it develops an alternative expedited coverage pathway, including recommendations for how CMS could improve the MCIT pathway and better leverage and improve existing coverage mechanisms, such as parallel review, coverage with evidence development (CED) or the investigational device exemption (IDE) process, in addition to conducting future rulemaking. For example, commenters expressed strong support for CMS to leverage the CED paradigm to provide Medicare beneficiaries with access to new devices and technologies while additional evidence is generated to document a proven benefit for Medicare patients. These commenters noted CMS' past efforts with CED, specifically Transcatheter Aortic Valve Replacement (TAVR), and noted that CMS could require post market studies and data collection through a modified CED paradigm to ensure that beneficiaries are gaining appropriate access to new technologies that improve health outcomes. Some commenters recommended that CED be time-limited so that the access restrictions that can sometimes accompany CED decisions do not last indefinitely especially in instances when the evidentiary questions of interest have been addressed. Commenters expressed the importance of collecting real world data to fill post-market evidence gaps and encouraged CMS to incorporate such data collection in an improved coverage pathway. These commenters noted that these new technologies need careful monitoring in real world populations.

*Response:* We appreciate all of the submitted recommendations for CMS to consider as we develop an alternative expedited coverage pathway. It is our intention to address this issue in future rulemaking and we intend to hold at least two stakeholder public meetings in CY 2022 to inform our future policy-making in this space.

Additionally, we currently have a number of initiatives underway to leverage existing coverage mechanisms and inform our efforts to facilitate improvements in coverage pathways. For example, CMS is engaged with the AHRQ to review the current CED study criteria and determine whether the criteria should be revised or updated. Similar to the last CED revision, if a revision is needed, we will use a transparent process that will include public participation such as public comment on any proposed revisions to the CED study criteria, and we will provide as well for public participation in a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting which CMS will announce a date through a **Federal Register** notice and on the CMS Coverage website. For general information on MEDCAC, please see <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC>.

*Comment:* Many commenters representing a wide-range of stakeholder groups offered additional suggestions on improvements CMS can make to NCDs, including a recommendation that CMS should omit trial design specifications within NCDs and that CMS should address coverage of new indications in NCDs. Some commenters encouraged CMS to review NCD requests and issue NCD implementation instructions within specified timeframes. Several commenters asked that CMS prohibit concurrent NCD and LCD processes.

*Response:* We appreciate these comments and helpful suggestions offered by commenters on how CMS can improve the NCD process. We will consider these comments as we explore other policy options and statutory authorities to provide appropriate expedited access to innovative and beneficial technologies.

*Comment:* Several commenters requested that CMS ensure equity between fee-for-service and Medicare Advantage (MA) beneficiaries in an alternative expedited coverage pathway. Some of these commenters noted that MA plans often impose restrictive prior authorization requirements or decline to cover services that are routinely covered and paid for under fee-for-service Medicare, simply due to the absence of a LCD or NCD.

*Response:* We appreciate these comments and will consider this as we explore other policy options that may help to ensure coverage consistency among Medicare beneficiaries regardless of whether they are enrolled in fee-for-service or MA.

*Comment:* A few commenters suggested that as CMS takes future action to provide for an alternative expedited coverage pathway, that it provide expedited coverage for a class of devices rather than of a single device to ensure there is not inconsistent or delayed coverage of similar devices or technologies.

*Response:* We appreciate the comment and will consider this as we explore other policy options. It is our intention to address this issue in future rulemaking and we intend to hold at least two stakeholder public meetings in CY 2022 to inform our future policy-making in this space.

*Comment:* Some commenters reiterated their concerns that the MCIT pathway has the unintended consequence of limiting access to competitive devices. These commenters recommended that CMS consider broadening the technologies eligible for an expedited coverage pathway to replace MCIT beyond Breakthrough Devices in order to ensure a competitive and innovative marketplace. Several commenters suggested that such an expedited coverage pathway should not only include Breakthrough Devices but also other medical products that are the subject of FDA expedited programs, such as those that receive breakthrough therapy designation or are granted accelerated approval. Commenters specifically requested that screening tests, diagnostics, drugs and biologicals be included.

*Response:* We appreciate the comments and will further consider these comments as we explore other policy options and statutory authorities.

*Comment:* As noted previously, some commenters requested that drugs and biological products be included in an alternative expedited coverage pathway as they believe that delayed access to innovative drug and biologic therapies is just as detrimental as delays to innovative

devices. However, a few commenters expressed the viewpoint that drugs and biological products not be included as inclusion may lead to unnecessary delays and access issues.

*Response:* We appreciate the comments and will further consider these comments as we explore other policy options and statutory authorities.

*Comment:* Several commenters reiterated their concerns that since the MCIT/R&N final rule was solely a coverage rule, a number of operational issues that would inhibit the successful implementation of the MCIT pathway still need to be addressed, including benefit category determination, coding and payment issues. Commenters indicated that the goals of MCIT cannot be achieved until these operational issues are resolved. Several commenters offered suggestions as to how CMS could remedy these issues, including modifications to existing operational processes. For example, these commenters recommended that CMS could adapt the processes used for the IDE, new technology add-on payment (NTAP) and transitional passthrough (TPT) to establish codes and payment for technologies in an expedited coverage pathway. Some commenters requested that any future rulemaking for an alternative expedited coverage pathway include coding and payment information.

*Response:* We appreciate these comments and agree we should consider all of the operational issues as we work to develop an alternative expedited coverage pathway. We will consider this comment as we initiate coverage process improvements, including engaging AHRQ to explore updating the CED criteria, as well as exploring options of expediting the NCD process, including future rulemaking.

*Comment:* Several commenters that explicitly stated their opposition to or disappointment with our proposal to repeal the MCIT/R&N final rule provided information and examples specific to their technologies for why an expedited coverage pathway similar to MCIT is needed. These commenters lauded MCIT as a significant advancement in removing delays in national coverage after FDA market authorization and uncertainty in the timing and duration of coverage to improve beneficiary access to innovative technologies.

*Response:* The majority of the comments citing specific examples of how MCIT is beneficial to its specific technology would likely face the operational challenges because after review of the commenters' devices, it was not clear whether there was a benefit category for the devices. At least one commenter's device would be part of a bundled payment and not separately payable. Because the MCIT/R&N final rule did not address BCD issues, the MCIT/R&N final rule would likely not have resulted in the full coverage they were seeking. We are aware that there is concern when coverage decisions are made at the MAC level, specifically when an LCD is not applicable. This coverage uncertainty may also influence provider decision-making because they are reluctant to submit claims for services that may not be paid for by Medicare.

*Comment:* A commenter requested that CMS clarify how it intends to approach coverage and payment for prescribed digital therapeutics (PDTs) and include the information in the preamble to this final rule since it had not been addressed in prior MCIT/R&N rulemaking.

*Response:* We appreciate this comment. However, we are not responding to specific technology evaluations in this final rule as they are out of scope. We will consider this comment as we initiate several coverage process improvements.

*Comment:* Some commenters stated CMS should allow the MCIT/R&N final rule to go into effect on December 15, 2021, and subsequently issue a proposed rule with appropriate revisions to the MCIT pathway or release subregulatory guidance that addresses the numerous concerns rather than finalizing the repeal.

*Response:* We appreciate commenters sharing their belief that the rule should go into effect, but we disagree. While we acknowledge that some stakeholders are seeking a replacement pathway simultaneously upon repeal, we need time to more fully evaluate the comments received on the September 2021 proposed rule, and in particular the feedback offered by commenters on how we can improve upon the MCIT pathway.



The final MCIT/R&N rule had major flaws that must be addressed to ensure there is a balance between expedited coverage of devices and patient protections. As we discussed earlier, these flaws also included operational concerns regarding benefit category determinations, coding and payment implementation with expedited coverage. Further, Breakthrough Devices have not necessarily demonstrated a health benefit in the Medicare population. Most importantly, we believe that evidence development must be part of an expedited coverage process, as needed. Based upon these significant concerns with the MCIT pathway, both from the Agency and from several commenters, we believe it is important to move forward with repealing the MCIT/R&N final rule rather than letting it go into effect and modifying it after the fact. We believe that letting the MCIT/R&N final rule go into effect and later modifying it would cause disruptions in health care delivery as there would be confusion and uncertainty among stakeholders, most importantly beneficiaries and their treating clinicians. For example, since the January 2021 MCIT/R&N final rule is a coverage rule only, there could be confusion and disruption stemming from devices receiving MCIT approval without a clear path for appropriate coding and payment. As noted previously, under the January 2021 MCIT/R&N final rule, there is no requirement for evidence that MCIT devices will specifically benefit the Medicare target population. Additionally, the MCIT/R&N final rule limits tools the CMS has to deny coverage when it becomes apparent that a particular device can be harmful to the Medicare population. If the January 2021 MCIT/R&N final rule were to go into effect, and a device is later found to be harmful to Medicare recipients is approved under the MCIT pathway, CMS would be limited in the actions it can take to expeditiously withdraw or modify coverage to protect beneficiaries. Finally, it is not clear that CMS has legal authority under the *Allina* Supreme Court ruling to use subregulatory guidance to modify aspects of the MCIT/R&N final rule as some commenters suggested.

*Comment:* Of the commenters who disagreed with the proposed rule to repeal the MCIT/R&N rule, most acknowledged the limitations of the MCIT pathway and indicated that

modifications were needed, such as the inclusion of coding and payment information and evidentiary standards. A number of these same commenters expressed that while they were disappointed with CMS' proposal to repeal MCIT, they appreciated CMS' ongoing commitment to finding solutions, including an alternative expedited coverage pathway.

*Response:* We appreciate the comment and will consider the suggested modifications as we move forward.

*Comment:* Many commenters requested that if CMS were to move forward with repealing the MCIT/R&N final rule, CMS should release a proposed rule offering an alternative expedited coverage pathway simultaneously or as soon as possible thereafter. These commenters requested that CMS provide a timeline for releasing a new rule for an alternative expedited coverage pathway. These commenters noted that an alternative expedited coverage pathway is an urgent need to address the long-standing concerns that Medicare coverage is often slow and unpredictable and impedes beneficiary access to innovative technologies. Some commenters raised concerns that following repeal, CMS would not continue with the forward momentum to create an alternative expedited coverage pathway.

*Response:* We appreciate these comments. As we move forward with repealing the MCIT/R&N final rule, we want to reassure stakeholders that CMS does not intend to maintain the status quo. We remain committed to our goal of establishing an alternative expedited coverage pathway that better achieve the goals of timely and predictable Medicare coverage of devices while ensuring that Medicare covers items and services on the basis of scientifically sound clinical evidence and with appropriate safeguards. CMS acknowledges that more can be done to address the current uncertainty surrounding Medicare coverage of new medical technologies and while we are unable to provide a specific timeframe for doing so, we are working expeditiously to develop an alternative expedited coverage pathway with adequate patient safeguards to ensure devices are safe for Medicare patients and an evidence base that is generalizable to Medicare beneficiaries is further generated.

*Comment:* Some commenters stated that CMS has received sufficient public input on potential improvements to MCIT and existing coverage pathways over the course of three public comment periods on the MCIT pathway, other commenters encouraged CMS to conduct town halls to obtain further stakeholder feedback. Numerous commenters expressed willingness to be a resource for CMS as it developed future policies.

*Response:* Stakeholder engagement is a vitally important component of our efforts to develop an alternative expedited coverage pathway that provides an appropriate balance of innovation and beneficiary protections. We value the diverse viewpoints, perspectives, and options offered by commenters. As we move forward, we will continue to be open and transparent and will work with stakeholders in efforts to achieve consensus whenever possible.

Even with the repeal of the MCIT/R&N final rule, we have a number of initiatives underway and in development within our existing authorities. These initiatives take into account the feedback CMS has received on the MCIT pathway to date, and we will leverage these initiatives to inform future policy making in this space.

Further, CMS has multiple pathways to facilitate engagement such as the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) and the public input process through the **Federal Register**. We are also receptive to informal engagement with stakeholders, including with manufacturers who are interested in the development of a new expedited coverage pathway. In addition, we are also exploring other potential avenues to facilitate timely and transparent stakeholder engagement, including listening sessions or town hall meetings, in order to receive additional feedback from stakeholders that can help inform CMS' development of an alternative expedited coverage pathway. In addition, we are initiating coverage process improvements, including engaging AHRQ to explore updating the CED study criteria, as well as exploring options of expediting the NCD process, including future rulemaking.

*Comment:* Some commenters who disagreed with CMS' proposal to repeal the MCIT/R&N final rule asserted that the patient protections in place in the MCIT/R&N final rule, specifically the reliance on FDA safety and efficacy requirements to grant coverage to Breakthrough Devices under MCIT, were sufficient to prevent beneficiary harm. Some of these commenters stated that CMS will be endangering the patients it is trying to protect if MCIT does not go into effect on December 15, 2021. Some commenters also noted that the data Medicare needs to evaluate a device has already been generated during the FDA approval process.

*Response:* We disagree that there are sufficient patient protections in the MCIT/R&N final rule. After consideration of all public comments received as we have worked to develop the MCIT pathway, and as we indicated in the September 2021 proposed rule, we no longer believe that FDA safety and effectiveness standards alone are sufficient to support open-ended Medicare coverage. FDA and CMS act under different statutes that have different goals and the standard for Medicare coverage (that is, a determination that a device is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member) is not synonymous with the standards for FDA marketing authorization of devices, which are not specific to the Medicare population. CMS acknowledges that we have changed our position on this issue after further consideration of public comments and a review of all FDA-designated Breakthrough Devices eligible for MCIT. As noted previously, granting all eligible FDA-designated Breakthrough Devices national coverage, the MCIT/R&N final rule establishes insufficient beneficiary protections for a subset of devices and must be revised.

Further, we strongly disagree that our repeal of the MCIT/R&N final rule will cause harm to beneficiaries. While there is no guaranteed national coverage that does not mean a given FDA-designated Breakthrough Device is non-covered. CMS' MACs are empowered to make reasonable and necessary coverage determinations on any device where there is not a nationally policy in place, including FDA-designated Breakthrough Devices. We reviewed fee-for-service

claims data for several recent market-authorized breakthrough devices. The majority of the FDA market authorized Breakthrough Devices that would have been eligible for the MCIT pathway: were already paid through an existing mechanism, were directed to a pediatric population, were a diagnostic lab test, were subject to an existing NCD; or had no benefit category or an uncertain benefit category. Of those that would be separately payable by Medicare on a claim-by-claim basis, the reviewed devices were covered when reasonable and necessary and paid under the applicable Medicare payment system. Further, in general, there are typically many treatment options available in the practice of medicine and even if one particular item is not covered, beneficiaries have access to other treatment options.

*Comment:* Some commenters expressed that beneficiaries and their physicians should be provided with more latitude to assess the advantages and risks of a medical device to treat an individual's specific medical condition.

*Response:* Patients and their treating clinicians should have latitude to make informed treatment decisions. If we were to guarantee coverage of devices based solely on breakthrough status and FDA marketing authorization, rather than also consider whether the device provides an effective, reasonable and necessary treatment for Medicare patients, there may not be enough information for patients and their treating clinicians to make an adequately informed decision with respect to use of the device for Medicare beneficiaries. Further, there may be an incentive for use of a device that has coverage under the MCIT pathway rather than a device that is not covered under the MCIT pathway which may be more beneficial to patients. This could adversely impact beneficiaries if there is another item or service available to treat the patient that has an evidence-base to suggest that it may lead to better health outcomes for Medicare patients.

*Comment:* Commenters asserted that the repeal of the MCIT/R&N final rule will undercut evidence development as innovators hold off on study development and enrollment while waiting on CMS to conduct rulemaking with evidentiary standards and other modifications to the MCIT pathway. These commenters also contend that CMS' repeal of the MCIT/R&N

final rule could further stifle innovation by undercutting incentives to encourage investment in device development.

*Response:* Innovation is important to CMS and we strongly encourage innovators to develop reliable evidence to demonstrate that their device is beneficial for Medicare patients. If one of the biggest impediments to innovation is uncertainty, demonstrating with reliable evidence a device's value in treating Medicare patients will largely assist in removing that uncertainty. Ultimately, it is the responsibility of the innovator or manufacturer to demonstrate the value of their device. Evidence development should continue with or without CMS support.

*Final Decision:* After review of the public comments received, we are finalizing the repeal of the January 2021 MCIT/R&N final rule as proposed in the September 2021 proposed rule without modification.

#### B. Definition of "Reasonable and Necessary"

In general, section 1862(a)(1)(A) of the Act permits Medicare payment under Part A or Part B 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. The definition of "reasonable and necessary" in the MCIT/R&N final rule mirrored the longstanding CMS Program Integrity Manual's definition of "reasonable and necessary" with a modification to the appropriateness factor to specify when and how (upon publication of guidance) we would utilize commercial insurer coverage policies.

Expanding the reasonable and necessary definition to systematically consider commercial insurer coverage presents implementation and appeals process challenges that would likely persist. In the preamble to the MCIT/R&N final rule, in response to commenters concerns that the commercial insurer appropriateness criterion was vague, we stated our intention to gather additional public input on the methodology by which commercial insurers' policies are determined to be relevant to the reasonable and necessary appropriateness criteria. We stated that not later than 12 months after the effective date of the MCIT/R&N final rule (that is,

December 15, 2021), we would publish for public comment, a draft methodology for determining when commercial insurers' policies could be considered to meet the reasonable and necessary definition appropriateness criterion for coverage of an item or service. Comments received in response to the March 2021 IFC expressed concern about how the commercial insurer policy provision would be implemented. Commenters also expressed concerns that the R&N definition included in the MCIT/R&N final rule, and more specifically the commercial insurance aspects of the definition, will remove existing flexibilities and potentially impact CMS' ability to ensure equitable health care access for all Medicare beneficiaries. Additionally, commenters suggested that the reasonable and necessary definition should be included in a separate rule as MCIT and R&N are independent and distinct provisions with different implications for Medicare policy. In light of our proposal to repeal the R&N definition, including the commercial insurance aspects of the MCIT/R&N final rule, we will not be issuing subregulatory guidance by March 15, 2022, on consideration of commercial insurer coverage policies when there is insufficient evidence to make a national or local coverage determination.

While we proposed to fully repeal the MCIT/R&N final rule as it is currently written, we invited comments on the R&N aspect of our proposal. In lieu of fully repealing the R&N rule, we considered whether the final rule should instead merely repeal the commercial insurance aspects of the rule. We also asked if CMS does consider future rulemaking to include defining reasonable and necessary, what criteria should CMS consider as part of the reasonable and necessary definition? For example, should CMS maintain the codification of the definition of "Reasonable and Necessary" as found in the Chapter 13 of the CMS Program Integrity Manual (PIM) or consider different criteria?

*Comment:* Most commenters supported the full repeal of the reasonable and necessary definition in the MCIT/R&N final rule. Similar to the past two public comment periods, many commenters requested that CMS bifurcate MCIT and R&N into separate rules because they are independent and distinct provisions with different implications for Medicare policy.

Commenters noted that the codification of a R&N definition is significant because it affects all Medicare items and services and represents a change from current practice. Commenters reiterated their position that the definition needs more public input and CMS should ensure it receives feedback from all interested parties, which is a broader group than the audience with expertise and interest in the MCIT pathway.

*Response:* We agree that further stakeholder engagement on the topic is warranted; and therefore, we will finalize the repeal of the R&N definition. Similar to what we described previously for MCIT, we are exploring potential opportunities for obtaining additional stakeholder feedback via listening sessions, town hall meetings, or other means. We acknowledge the requests made by a number of commenters to bifurcate MCIT and R&N into separate rules for the purposes of future rulemaking. We will consider these comments as we address these issues in the future.

*Comment:* The commenters cited concerns that if codified, the definition of reasonable and necessary in the MCIT/R&N final rule would remove flexibility and may impact CMS's ability to ensure equitable health care. Some stated that the definition as finalized would be problematic for lab tests.

*Response:* Further stakeholder engagement on the topic is warranted. We will consider these comments as we address these issues in the future.

*Comment:* Several commenters questioned whether a codified definition is necessary as they believe that the current definition in Chapter 13 of the CMS Program Integrity Manual is a sufficient framework that preserves the necessary flexibility to provide appropriate access. A significant number of commenters indicated their support for maintaining the definition in subregulatory guidance. Commenters noted that CMS has not provided a clear rationale for why codification of the definition in regulation is necessary or beneficial and that CMS should more clearly articulate the benefits and drawbacks associated with codification as compared to the status quo.



*Response:* We will finalize our proposed rule to repeal the R&N definition. As noted previously, we believe further stakeholder engagement on the definition is warranted. We will consider these comments as we address these issues in the future.

*Comment:* The majority of commenters supported the repeal of the commercial insurer criterion in the R&N definition. Commenters reiterated that commercial coverage policies already can (and have been) reviewed by CMS as part of the NCD process. Commenters further note that formalizing their inclusion could lead to an item or service that had been covered previously becoming non-covered depending on how a specific commercial payor may have determined coverage. Commenters reiterated their concerns regarding implementation of commercial insurer policy provisions, the potential of unnecessarily restricting coverage by relying on commercial insurer policies designed for a different population with different incentives, commercial insurer policies' lack of transparency, and potential for fraud and abuse. A few commenters cited a concern that some commercial plans consider costs in their decisions which could potentially violate the Medicare statutory prohibition regarding consideration of cost in coverage determinations. Lastly, a commenter questioned why CMS would want to cede this authority to other entities.

*Response:* We appreciate these comments. We agree with commenters that CMS can (and has) reviewed commercial policies in recent years as part of a national coverage analysis. After further consideration of public comments, we no longer agree with our position in the January 2021 MCIT/R&N final rule that it is necessary to include regulatory language to give us clear authority to review commercial insurers' policies. Because we are finalizing the full repeal of the R&N definition, we will not be issuing subregulatory guidance on consideration of commercial insurer coverage policies when there is insufficient evidence to make a national or local coverage determination. Further, we would like to clarify that while CMS has a long-standing position to not consider costs when making coverage determinations, it is not because of a statutory prohibition.

*Comment:* Though commenters were largely opposed to the inclusion of the commercial insurance aspects of the R&N definition, some commenters offered alternative approaches for CMS to consider in applying commercial payer policies. Specifically, some commenters recommended commercial policies only be utilized as evidence to support expansion of coverage on a proposed policy or asking for a reconsideration of an existing one.

*Response:* We appreciate these comments. As noted previously, we can use the private market as a source of evidence for coverage.

*Comment:* A few commenters disagreed with CMS' proposal to fully repeal the definition of R&N. These commenters expressed their support for a R&N definition in line with the definition in Chapter 13 of the PIM. One of these commenters specifically encouraged CMS to codify the R&N definition stating that it is a much needed step and something that CMS has sought to do for decades.

*Response:* We appreciate these comments. However, after considering the totality of the comments, we believe that the overarching issues raised by commenters, in particular issues regarding the need for more clarity and broader stakeholder input, warrant further consideration and engagement before moving forward with a codified definition of R&N. As other commenters noted, a codified definition of R&N is a considerable change from current practice and will affect all Medicare services. We believe it is important to provide for additional stakeholder feedback on this topic that includes a wider group of stakeholders than those who may have offered input during rulemaking for the MCIT/R&N final rule. We look forward to engaging with stakeholders in the future as we determine appropriate next steps that are in the best interest of the Medicare program and all stakeholders.

*Comment:* Some commenters expressed opposition to only repealing the commercial aspects of the R&N definition. A commenter stated that trying to leave part of the rule in place now does not provide adequate opportunity for comment, as stakeholders do not truly know what is being proposed for comment.

*Response:* We appreciate these comments. We acknowledge that commenters representing a wide range of stakeholder groups want more clarity from CMS and more opportunities to provide input before we move forward with codifying a definition of R&N. As noted previously, we look forward to engaging with stakeholders on this topic.

*Comment:* Commenters provided many suggestions as to what criteria CMS should consider as part of the R&N definition in response to our solicitation for that information in the September 2021 proposed rule. Specifically, a commenter noted that a definition of R&N should take into consideration the perspective of providers and enhance the ability of providers to use their medical judgment. Another commenter stated that CMS should adhere to a definition that is patient-focused. Some commenters noted that Medicare should consider the definition of appropriateness for Medicare beneficiaries since not all beneficiaries are aged 65 and older, and all beneficiaries should be considered. A commenter recommended that the definition should be expanded to include maintenance or prevention of deterioration of function as well. Some commenters expressed concern with the inclusion of ‘safe and effective’ in the definition and contend that Medicare coverage should not be dependent on meeting standards established by FDA for a different purpose. Some commenters recommended that CMS eliminate the inclusion of “at least as beneficial as an existing and available medically appropriate alternative” in the definition. A commenter stated that it was problematic as it appears to impose a comparative effectiveness requirement for coverage.

*Response:* We appreciate the informative and helpful recommendations provided by commenters. We will consider these comments for potential future policy development. As noted previously, we intend to provide additional opportunities for stakeholders to provide feedback on this topic and look forward to further engagement with stakeholders.

*Final Decision:* After review of the public comments received, we are finalizing the repeal of the January 2021 MCIT/R&N final rule as proposed in the September 2021 proposed rule without modification.

### C. Effect of Proposed Repeal

In the September 2021 proposed rule, we stated that if the MCIT/R&N final rule is repealed as proposed, the revisions to part 405 of title 42 of the Code of Federal Regulations would not occur and the text would remain unchanged. Specifically, a definition of “reasonable and necessary” would not be included among the terms defined at 42 CFR 405.201(b) and the guidance that the rule would have required (subregulatory guidance on the topic of utilization of commercial insurer polices) would not be introduced. Additionally, subpart F, which wholly consisted of Medicare Coverage of Innovative Technology, would not be added, and subpart F would remain reserved for other purposes.

After review of the public comments received, we are finalizing the repeal of the January 2021 MCIT/R&N final rule as proposed in the September 2021 proposed rule without modification.

## **III. Regulatory Impact Analysis**

### A. Statement of Need

The purpose of this final rule is to repeal the MCIT/R&N final rule. As stated in the preceding sections, we are repealing MCIT because this coverage policy is not in the best interest of Medicare beneficiaries. We are repealing the definition of R&N because further stakeholder engagement on the topic is warranted based on stakeholder feedback. CMS developed MCIT in part due to concerns that delays and uncertainty in Medicare coverage slowed innovation and impaired beneficiary access to important new technologies, specifically those designated as breakthrough devices by FDA. We believe that the finalized MCIT/R&N rule is not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the

Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose.

The definition of “reasonable and necessary” in the MCIT/R&N final rule mirrored the longstanding CMS Program Integrity Manual’s definition of “reasonable and necessary” with a modification to the appropriateness factor to specify when and how (upon publication of guidance) we would utilize commercial insurer coverage policies. This final rule to not codify the definition of R&N maintains the status quo with respect to the use of the CMS Program Integrity Manual’s definition and is responsive to the numerous stakeholders who requested that, if CMS were to develop a definition of reasonable and necessary, that the stakeholder engagement process would require more than public comment via rulemaking.

Through this final rule we repeal the MCIT/R&N final rule and, as stated previously, intend to work with stakeholders to develop a coverage policy and definition for R&N that addresses the concerns they raised. CMS plans on hosting at least two stakeholder meetings with several audiences, including, but not limited to, manufacturers, clinicians, patients, and disability groups.

This final rule repeals the MCIT pathway and codification of the definition of “reasonable and necessary.” Because the January 2021 final rule effective date was delayed until December 15, 2021, the MCIT coverage pathway and definition of “reasonable and necessary” have not been implemented, and no payments for items and services have been made in relation to these provisions because they have not taken effect. In the January 2021 final rule, we included a robust regulatory impact analysis of these provisions. Because the final rule did not go into effect, and this final rule repeals the provisions, there has not been an impact from these provisions nor will there be an impact, relative to current coverage practice, upon repeal; however, effects would be non-negligible relative to the future trajectory without this repeal.

In the September 2021 proposed rule, we examined the impact of the repealing the MCIT/R&N 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)).

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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The MCIT/R&N 2021 final rule reached the economic threshold and thus was considered a major rule. Because this final rule completely repeals the provisions, this rule also reaches the economic threshold and its finalization is a major rule. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence

also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

## B. Detailed Economic Analysis

### 1. MCIT Pathway

CMS considered alternatives to repealing the MCIT pathway and the definition of reasonable and necessary, such as maintaining the provisions of the MCIT/R&N final rule and further delaying the effective date. For the reasons described in detail in section II. of this rule such as patient safety and need for further public engagement, we chose to repeal the provisions. We note that further delay of the MCIT/R&N final rule would not alter the patient safety concerns inherent in the MCIT pathway.

As described in the MCIT/R&N final rule, the impacts of the MCIT pathway and defining “reasonable and necessary” were hard to quantify without knowing the specific Breakthrough Devices that would seek MCIT and other items and services that would be included in future NCDs and LCDs and the criteria that CMS would use for determining which commercial insurers will be considered.

In the MCIT/R&N final rule specifically for MCIT, we considered regulatory alternatives to combine Medicare coverage with clinical evidence development under section 1862(a)(1)(E) of the Act, to take no regulatory action, or to adjust the duration of the MCIT pathway.

The impact of implementing the MCIT pathway was difficult to determine without knowing the specific Breakthrough Devices that would be covered. In addition, many of these devices would be eligible for coverage in the absence of the rule, such as through a local or national coverage determination, so the impact for certain items may be the acceleration of coverage 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 Breakthrough Devices would not otherwise be eligible for coverage in the absence of the rule.

Because it was not known how these new technologies would otherwise come to market and be reimbursed, it was not possible to develop a point estimate of the impact. In general, we believed the MCIT coverage pathway would have ranged 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 would have been voluntary for the manufacturer. Because manufacturers typically join the Medicare coverage pathway that is most financially 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.

To demonstrate the potential impact on Medicare spending, for MCIT the CMS Office of the Actuary (OACT) developed three hypothetical scenarios that illustrate the impact of implementing the MCIT pathway. Scenarios two and three assumed that the device would not have been eligible for coverage in the absence of MCIT (see Table 1). The illustration used the new devices that applied for a NTAP in fiscal year (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 Register**.<sup>8</sup> 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

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<sup>8</sup> 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).



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 MCIT. If the devices received coverage and payment nationally and at the same time then there would be no additional cost under 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 ( $\$2,044 \times 2,322 \times 2 = \$ 9.5$  million). For the third scenario, the high-cost scenario, we assumed the new technologies would receive the maximum add-on payment from the FY 2020 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 ( $\$22,425 \times 6,500 \text{ patients} \times 2 = \$ 291.5$  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.<sup>9</sup> 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 would elect MCIT coverage, we implicitly assumed that, while more manufacturers could potentially elect coverage

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<sup>9</sup> An indirect effect of the final rule would be decreased 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 and cost savings—such as decreased marginal excess tax burden, 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.

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 was a range of potential impacts of MCIT as shown in Table 1. The difference between the three estimates demonstrates how sensitive the impact is to the cost and utilization of these unknown devices.

Because MCIT has not yet been implemented, we lack evidence with which to update the earlier estimates, so Table 1, only differs from the analogous table accompanying the MCIT/R&N final rule in terms of the sign (that is, the direction) on the estimates and a shifting of the time horizon by one year so as to avoid stating this MCIT would have effects in the nearly-ended FY 2021.

**TABLE 1: ILLUSTRATED IMPACT ON THE MEDICARE PROGRAM BY MCIT COVERAGE PATHWAY**

	<b>Costs (in millions)</b>			
	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>
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

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. For the MCIT/R&N final rule, 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. We determined that small businesses potentially impacted by that rule 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). Because the impact of this final rule is ultimately no change in current coverage policy, we determined that small businesses identified would not be impacted by this final rule. Given the nature of the breakthrough devices market authorized thus far and the timely notification of the MCIT/R&N final rule's delay of effective date, we do not anticipate that small businesses would have made investment decisions or experienced a loss of anticipated positive reimbursement as a result of the MCIT/R&N final rule. Because MCIT has not gone into effect, and we are repealing the rule, payments have not occurred under MCIT; therefore, the impact of this final rule is neither an increase nor decrease in revenue for providers. We are not preparing a further analysis for the RFA because we have determined, and the Secretary of the Department of Health and Human Services (the Secretary) certifies, that this 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.

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 this 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 final rule would not change the way they are currently covered through the Medicare program.

## 2. “Reasonable and Necessary” Definition

In order to demonstrate the potential impact on Medicare spending for the definition of “reasonable and necessary” in the MCIT/R&N final rule we developed scenarios that illustrated the impact of implementing the two alternatives considered (no change/not codifying a definition and codifying a definition). One of the options was making no change, that is not codifying the definition of “reasonable and necessary” in regulations. 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 was based on whether Medicare covered or non-covered an item or service and based on the numbers of NCDs and LCDs finalized in 2020 (see Table 1). In 2020, CMS and the MACs finalized 3 NCDs and 31 LCDs. (This number represents new LCDs in 2020 and made publicly 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 would have covered the item or service. Therefore, based on 2020 data for NCDs only, the impact would be \$0.

Of the 31 LCDs, 27 provided Medicare positive coverage and 4 resulted in non-coverage. For these non-covered items and services, we established 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 policies that represent a majority of covered lives. In addition, even if a commercial insurer covers an item or service, the final rule did not require automatic Medicare coverage. Therefore, not all items and services that are non-covered by Medicare but covered by commercial insurance would be presumed covered under the MCIT/R&N final rule. Rather, commercial insurer coverage would have been a factor that CMS would have taken 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 translate to Medicare coverage and because CMS was to define which types of commercial insurers (based on majority of covered lives) would be relevant, we believe that commercial insurer coverage impact is likely much smaller, closer to 15 to 25 percent of \$3.4 billion, that is, \$51 to \$880 million.

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

	Estimated Change in Medicare Costs for the Alternatives Considered for the MCIT/R&N Final Rule	
	No Change (not codifying a definition)	Codified Definition
Coverage Determinations (NCDs and LCDs)	\$0	\$51-880 million

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 2021, that threshold was approximately \$158 million. This final rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$158 million in any one year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a 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.

*Comment:* A few commenters expressed concerns regarding the financial impact of the MCIT/R&N final rule, including that CMS' impact estimate of \$0 to \$4 billion over the first several years indicated that CMS could not assess the potential impact given the multiple variables involved. Another commenter asserted that the MCIT/R&N final rule significantly underestimated anticipated spending and would accelerate Medicare Trust Fund insolvency.

*Response:* We acknowledge that assessing the financial impact of MCIT, with multiple variables and limited access to publicly available data to derive impacts, makes it difficult to estimate precise spending on the policy. For future rulemaking, we anticipate this estimate to become more finely tuned as more public-facing data about Breakthrough Devices becomes available.

#### C. Alternatives Considered

CMS considered alternatives to repealing the MCIT pathway and the definition of reasonable and necessary, such as maintaining the provisions of the MCIT/R&N final rule and further delaying the effective date. For the reasons described in detail in section II. of this final rule such as patient safety and need for further public engagement, we chose to repeal the provisions. We described the impact of these MCIT alternatives in Table 1. The alternative considered for not codifying the definition of "reasonable and necessary" was to codify the definition. We describe the impact of codifying the definition in Table 2.

#### D. Accounting Statement and Table

We have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table addresses the costs that would have been incurred through implementing the MCIT/R&N final rule, but, due to this final rule repealing that rule, reflects that those costs will not be incurred under the policies.

As required by OMB Circular A-4 (available at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), we have

prepared an accounting statement in Table 3 showing the classification of the impact associated with the provisions of this final rule.

**TABLE 3: ACCOUNTING STATEMENT**

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Unit Rate			Source Citation (RIA, preamble, etc.)
				Year Dollar	Discount Rate	Period Covered	
<b>TRANSFERS</b>							
Federal Annualized monetized transfers: "on budget" (\$millions/year) MCIT		(34.0)	(1,044.1)	2022	7%	2022-2025	RIA This reflects the repeal of MCIT. We estimated a zero-cost scenario for each of the fiscal years 2022-2025.
		(34.9)	(1,071.7)	2022	3%	2022-2025	
		(51.0)	(880.0)	2022	7%	2022-2025	
Definition of "Reasonable and Necessary"							RIA This reflects the repeal of the reasonable and necessary definition.
		(51.0)	(880.0)	2022	3%	2022-2025	
From whom to whom?	From: Federal Government		To: Medicare Providers				

NOTE: Items in parentheses indicate negative numbers.

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

*Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 9, 2021.*

## 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 part 405 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).

#### **§405.201—[Amended]**

2. Section 405.201 is amended in paragraph (b) by removing the definition for “Reasonable and necessary”.

#### **Subpart F—[Removed and Reserved]**

3. Remove and reserve subpart F, consisting of §§ 405.601 through 405.607.

**Dated:** November 9, 2021.

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**Xavier Becerra,**

Secretary,

Department of Health and Human Services.