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April 16, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via www.regulations.gov

RE: [CMS-3372-IFC]: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period

Dear Acting Administrator Richter:

On behalf of America's Health Insurance Plans (AHIP)[1], thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Interim Final Rule.

We share the Administration's commitment to providing Medicare-eligible Americans access to new and innovative medical devices that are safe and effective. We appreciate the intent of the MCIT pathway to encourage medical device innovation and to efficiently bring these products to Medicare patients with life-threatening or debilitating chronic conditions. Health insurance providers engage in a wide variety of activities and programs designed to improve health care access, quality, and value for the populations they serve. Our member companies implement policies that protect patient safety, emphasize evidence-based care, drive better health outcomes, and support quality reporting.

[1] AHIP is a national association representing members that provide health care coverage for millions of Americans across the country. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, quality, access, and well-being for consumers.

Based on this experience, we provided feedback on the rule when it was proposed last year that highlighted our concerns regarding safety, efficacy, and value for the Medicare population. The interim final rule's delay in the effective date and request for additional comments acknowledges these concerns, in addition to raising additional questions regarding operational challenges and the expected volume of devices - greater than estimated by the impact analysis - to be affected by the rule. Given our previously expressed concerns, and in light of the new challenges identified by the Administration, we recommend that the rule be rescinded rather than go into effect on May 15, 2021.

I. MCIT Pathway

The Interim Final Rule establishes a new coverage pathway for FDA-approved breakthrough devices.[2] National Medicare coverage (both traditional fee-for-service Medicare and Medicare Advantage) would begin on the same day a device receives FDA approval, would last up to 4 years, and a two-year "look back" could be used to apply to devices that were FDA-approved prior to the effective date of the final rule.

AHIP does not support the MCIT pathway as currently written due to the following significant concerns:

- The MCIT pathway fails to fully and appropriately evaluate safety, efficacy, and value for the Medicare population prior to or post-coverage;
- Existing, evidence-based coverage pathways could and should be leveraged and streamlined to achieve the same goals;
- The MCIT pathway does not address numerous operational challenges, including those related to decisions on benefit category, coding, and payment levels; and
- The regulatory impact analysis significantly underestimates the volume of devices that could potentially be eligible for the MCIT pathway, further exacerbating the concerns delineated above.

<u>Safety, Efficacy, and Value</u>
Currently, when a medical device is approved by the FDA, it must be further evaluated by a health plan's medical policy committee to assess clinical efficacy and safety for the specific

[2] The Breakthrough Devices Program is for medical devices and device-led combination products that (1) provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating human disease or conditions; and (2) must meet one of the following – represents a breakthrough technology; no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives; or device availability is in the best interest of patients.

population. This analysis includes comparing the new device to other devices currently in use. Absent a National Coverage Determination (NCD), health insurance providers use evidence-based guidelines to develop medical coverage policies. As CMS notes in the rule, because Medicare patients usually have more than one co-morbidity and are likely being treated for more than one condition, CMS has historically reviewed clinical evidence showing that the devices have been studied in the Medicare population or that outcomes are generalizable to the Medicare population.

The MCIT pathway, however, would essentially act as an interim NCD with a less rigorous evidence-based coverage process and potentially result in premature coverage of unproven devices for the Medicare population, exposing seniors and people with disabilities to increased health risks. Of additional concern, once a device is on the market and covered, removing it from the market can be exceedingly difficult, even if additional data indicate safety concerns.

Moreover, CMS has a responsibility to ensure the most appropriate and cost-effective coverage of medical devices in Medicare. We are very concerned this policy will lead to increased fraud, waste, and abuse—along with the attendant added costs. As a consequence, adoption of the MCIT pathway could accelerate exhaustion of the Medicare Trust Fund, which the Congressional Budget Office (CBO) estimates will be depleted by 2024. Furthermore, with respect to the Medicare Advantage (MA) program, we believe that the costs will be material, impact the accuracy of MA bids, and could lead to increased costs or fewer benefits in health plan offerings.

Recent findings in Health Affairs call attention to the relationship between device manufacturers and physicians and the potential to influence physician behavior, raising concerns that Medicare coverage via the MCIT pathway will impact costs across the healthcare landscape as once a device has been approved for Medicare coverage through the MCIT pathway, the device could be subject to the same coverage expectations for the commercial population, without adequate adequate data on cost effectiveness and value.

Absent an evidence-based process to evaluate safety, efficacy, and value for the Medicare population, the MCIT pathway could require traditional Medicare and MA to cover unproven medical devices that could compromise the safety of seniors and people with disabilities; increase fraud, waste, and abuse; and drive up health care costs systemwide and, thus, should not be implemented.

Post-Coverage Collection of Health Outcomes Data

There is currently no requirement in the proposal for manufacturers to conduct clinical studies focused on the Medicare population during coverage under MCIT. Collection and evaluation of health outcomes data for the Medicare population is an essential component of patient safety and continued coverage. An effective post-market outcomes data collection effort should include:

- Active tracking and reporting on outcomes (e.g., safety, effectiveness) by CMS at specified intervals;
- Public transparency of outcomes information collected;
- A requirement to report adverse events to CMS and the Manufacturer and User Facility Device Experience (MAUDE) database within a specified timeframe; and
- Clear criteria upon which Medicare coverage would be suspended as a result of concerns/adverse events regarding effectiveness or safety or effectiveness of the medical device, as reported in post-market analyses and/or upon FDA withdrawal of market approval.

Absent mandatory and continued data collection and evidence development, the MCIT pathway lacks a mechanism to ensure safety and efficacy specific to the Medicare population post-coverage and should not be implemented.

Existing, Evidence-Based Coverage Pathways Can Achieve the Intended Objectives

There are numerous alternatives to creating a new pathway to coverage that can be leveraged and streamlined to achieve the same goals. Existing alternative pathways can be used to protect seniors and people with disabilities and avoid the complexity of circumstances in which people receive breakthrough devices and then the four-year MCIT pathway ends without the device receiving an NCD.

For example, the Parallel Review Medicare coverage pathway was created in 2011 to allow for FDA and CMS to simultaneously review clinical data for the express purpose of accelerating the time between FDA approval and CMS NCDs. Given the complementary goals of the Parallel Review pathway and the proposed MCIT pathway, the Parallel Review pathway could be effectively used to accelerate coverage of breakthrough devices.

In addition, the existing NCD process could be adapted and streamlined to allow for rapid reviews, while still fully considering the evidence needed to ensure the safety and effectiveness of devices. CMS' Coverage with Evidence Development (CED) framework could also be used to promote data collection on outcomes and effectiveness through participation in clinical studies post-coverage.

One or more of CMS' existing coverage pathways should be leveraged and streamlined to provide access to innovative devices rather than creating an additional, complex, and potentially duplicative pathway that does not fully protect the Medicare population from devices that are not proven safe or effective.

Operational Challenges

CMS acknowledges that the rule "did not directly address operational issues, such as how the agency would establish coding and payment levels for particular devices, which are both central to prompt market access." CMS notes that it must make several decisions before it can properly pay claims, such as whether the device falls within a Medicare benefit category, the setting where the device is furnished, whether there is an existing payment methodology that applies to the particular breakthrough device, and whether there is an appropriate billing code for the device. Additional operational challenges include the timeline for development of the website for CMS to disclose the list of devices to which the MCIT pathway applies, how often updates would be made to the list, and how notification of those updates would be made as providers and health plans work to keep track of approvals to ensure beneficiary access.

We agree that CMS did not take into consideration the operational challenges of implementing the MCIT pathway. These operational challenges are significant and will remain a concern regardless of if or when the rule is implemented, thereby strengthening the rationale for why the pathway should not be implemented.

Volume of Affected Devices

The regulatory impact analysis of the MCIT rule was based on the expectation that the MCIT pathway would initially apply to a relatively small number of devices (2-5 devices) and would remain fairly consistent in the short-term and increase gradually over time. This estimate was based on the number of devices that were designated as breakthrough devices through fiscal year 2018, when there were 97 FDA-designated breakthrough devices.

However, new publicly reported data from the FDA shows a much higher number of devices designated as breakthrough devices – more than 400 devices have been designated as breakthrough devices. While not all will become market authorized, this data suggests that a large number of market-authorized breakthrough devices may be eligible for the MCIT pathway than was initially estimated, making the impact of the rule on safety, efficacy, and value even more significant.

Given the previously flawed assumption about the potential volume of FDA breakthrough devices and the significantly greater volume of devices potentially eligible for the MCIT

pathway, we believe the risk to safety, efficacy and value for the Medicare population requires that the pathway not be implemented.

II. Definition of "Reasonable and Necessary"

Under current law, the Secretary has authority to determine whether an item or service is "reasonable and necessary" for purposes of Medicare coverage. Factors used to make this determination have not been established in regulation but instead are found in Chapter 13 of the Medicare Program Integrity Manual (section 13.5.4). These factors include whether the item or service is safe and effective, appropriate, and not experimental or investigational. The Interim Final Rule would codify this definition and include language giving CMS authority to review the majority of commercial insurers in making national and local coverage determinations in the event that an item or service does not meet the regulatory appropriateness criteria. No later than 12 months after the rule's effective date, CMS would release for public comment a draft methodology by which commercial insurer policies are determined to be relevant based on the measurement of a majority of covered lives for purposes of making Medicare coverage determinations.

AHIP is concerned about potential unintended consequences of including commercial coverage as an indicator of appropriateness for the purpose of Medicare coverage.

Challenges in Assessing Commercial Coverage and Potential Unintended Consequences
Absent a methodology by which commercial insurer policies would be determined to be relevant, there remains significant challenges to this approach. For example, commercial coverage policies typically reflect geographic variations in prescribing practices and adherence to evidence. They may rely on different evidence-based guidelines, clinical criteria, and medical management practices that best address the unique circumstances faced in different localities. It is not clear how these differences would be reflected in any measurement of a majority of covered lives.

Furthermore, in some instances, commercial coverage may be dictated by state benefit mandates, which may or may not be evidence-based. While this has long been an issue at the individual state level, referencing commercial coverage in the standard for Medicare coverage would exacerbate this challenge on a much broader scale, potentially exposing Medicare beneficiaries to state mandated benefits with little to no supporting evidence.

Given the uncertainties and potential unintended consequences of assessing commercial coverage for purposes of Medicare coverage, we strongly recommend this approach not be implemented.

Thank you again for the opportunity to submit these comments. We look forward to continuing to work with the Administration on the most effective approaches to providing Medicare beneficiaries with access to innovative and evidence-based items and services.

Sincerely,

Elizabeth Cahn Goodman, DrPH, JD, MSW
Executive Vice President, Government Affairs and Innovation