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

Submitted electronically via www.regulations.gov

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

Dear Administrator Verma:

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" Proposed Rule (Proposed Rule).

Medicare-eligible Americans deserve access to new and innovative medical devices that are safe and effective. Health insurance providers engage in a wide variety of activities and programs designed to improve health care access, quality, and value. Our member companies implement policies that protect patient safety, emphasize evidence-based care, drive better health outcomes, and support quality reporting. Based on this experience, our comments and recommendations are focused on the following key areas:

- Promoting patient safety, driving value, and using data to optimize clinical outcomes;
- Leveraging existing coverage pathways to achieve intended objectives;
- Evaluating experience before considering pathway expansion; and
- Considering potential unintended consequences and challenges in referencing commercial coverage for Medicare's "reasonable and necessary" standard.

[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.

I. MCIT Pathway

The Proposed Rule establishes a new coverage pathway for FDA-approved breakthrough devices.[2] According to this new coverage pathway, national Medicare coverage (both traditional fee-for-service Medicare and Medicare Advantage) would begin on the same day a device receives FDA approval. In addition to being FDA-designated and approved, the device must be used according to its FDA-approved or cleared indication, be within a Medicare benefit category, not be the subject of a Medicare national coverage determination (NCD), and not otherwise be excluded from coverage by statute or regulation. National Medicare coverage 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 proposed. We have significant concerns that this new approach may put seniors, people with disabilities, and the solvency of the Medicare Trust Fund at risk. Instead, we recommend that CMS leverage existing pathways to promote Medicare enrollee access to safe and effective breakthrough devices.

Focus on Safety, Efficacy and Value

Currently, when a medical device is approved by the FDA, it must be further evaluated by a plan's medical policy committee to assess clinical efficacy and safety for this population. This analysis includes comparing the new device to other devices currently in use. Absent an NCD, health insurance providers use evidence-based guidelines to develop medical coverage policies. The proposed MCIT pathway 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 potential increased health risk.

It is also important to note that the proposed MCIT pathway would apply to breakthrough devices authorized under the 510(k) premarket review process, under which a device manufacturer need only demonstrate that a device is "substantially equivalent" to a device already on the market, rather than conduct studies to assess the safety and effectiveness of that specific device. Similar to the proposed MCIT pathway, the 510(k) process was intended to streamline access to devices and foster innovation. However, there have long been concerns over the limited rigor and scope of the 510(k) process, given that it has been shown that it is often used for "high risk" devices, such as implantable or life-sustaining devices, and has resulted in

[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.

these complex medical devices entering the market without a comprehensive clinical evaluation of their safety, effectiveness, and adverse events.[3]

Additionally, CMS has a responsibility to ensure the most appropriate and cost-effective coverage of medical devices in Medicare. We are very concerned about the potential of this policy to 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, per the Congressional Budget Office (CBO), will be depleted by 2024.

With respect to the MA program, we believe that the costs will be material. Medicare's significant cost policy states that if a new benefit is expected to represent at least 0.1 percent of the national average Medicare per capita costs, Medicare fee-for-service will cover the costs of the coverage until the next MA bid cycle, at which point MA plans could include the new costs in their bids. We believe that the MCIT proposal will exceed this 0.1 percent threshold.

In sum, we are very concerned that the MCIT pathway would require traditional Medicare and Medicare Advantage (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.

Should CMS decide to proceed with the proposal, it is essential that the new pathway include a process for stakeholders to evaluate the medical device for safety, efficacy and value before a Medicare coverage determination is made, as well as a process to enable ongoing evaluations of data during the MCIT coverage period, to protect the Medicare population. We further recommend that CMS make clear that the significant cost policy would apply to devices covered under this pathway.

Require 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 continued coverage and should be a condition of participation in this pathway. An effective post-market outcomes collection effort should include:

- Active tracking and reporting on outcomes by CMS at specified intervals;
- Public transparency of outcome 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

[3] FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process. GAO. January 2009.

- Clear criteria upon which Medicare coverage would be suspended as a result of concerns regarding effectiveness or safety of the medical device, as reported in post-market analyses and/or upon FDA withdrawal of market approval.

Moreover, as CMS notes, data is unlikely to be available to support off-label use on the date of marketing authorization since other indications would not have been studied or reviewed by the FDA and, therefore, should not be covered.

If CMS finalizes its MCIT proposal, we recommend that CMS require manufacturers to provide data on outcomes and/or enter into a clinical study similar to CMS' Coverage with Evidence Development (CED) framework with the aforementioned data collection components. Additionally, it is essential that the device be used only according to its FDA-approved or cleared indication for use, as that is what was reviewed by the FDA and market authorized.

Use Existing Coverage Pathways to Achieve the Intended Objectives

Creating an entirely new pathway will make implementation efforts difficult, particularly if beneficiaries receive breakthrough devices and then the four-year MCIT pathway ends without the device receiving an NCD. While we agree with a hard end date for the MCIT pathway, the device should be required to go through the standard NCD process during the MCIT four-year pathway ends, if the proposal is finalized. Otherwise, adequate tracking for every beneficiary and device and the timeframes during which the beneficiaries have the devices could be extremely challenging.

As a potential alternative to the MCIT, 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 utilized to accelerate coverage of breakthrough devices.

Alternatively, 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.

We recommend that CMS leverage an existing coverage pathway to streamline access to innovative devices rather than create an additional, complex, and potentially duplicative pathway. If the proposal is finalized, the device should be required to go through the standard NCD process during the MCIT approval period in order to protect Medicare beneficiaries and assure continuity of care.

Assess Experience Before Any Expansion

CMS is seeking input on whether the proposed MCIT pathway should be expanded to include diagnostics, drugs, and/or biologics that use breakthrough or expedited approaches at FDA – or even expanded to all diagnostics, drugs, and/or biologics, breakthrough and non-breakthrough. Opening the pathway to diagnostics, drugs and biologics will significantly expand the universe of MCIT candidates and magnify any unintended consequences of the proposed MCIT pathway, including the potential for expanded Medicare coverage of high-cost drugs without regard to evidence on efficacy or the existence of lower-cost alternatives. There have been numerous examples of drugs approved by the FDA that were later found to have significant safety issues. Researchers at Yale School of Medicine found that nearly a third of drugs approved by the FDA from 2001-2010 had major safety issues after the drugs were approved and made more widely available. Further, an additional 71 out of 222 drugs were withdrawn and required a *black box* warning on side effects. Many of these side effects were seen at a median timeframe of 4.2 years.[4]

If the MCIT proposal is finalized, we strongly recommend that it not be expanded to include breakthrough or non-breakthrough diagnostics, drugs, and biologics until a thorough assessment can be made regarding the experience with breakthrough devices for this population.

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 Proposed Rule would codify and add to the definition so that commercial coverage of an item or service could serve as evidence of appropriateness in CMS' "reasonable and necessary" assessment.[5]

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[4] Downing NS, Shah ND, Aminawung JA, Pease AM, Zeitoun JD, Krumholz HM, Ross JS. Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010. JAMA. 2017 May 9;317(18):1854-1863.

[5] The full definition of "reasonable and necessary", with proposed changes italicized, is as follows:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate *for Medicare patients*, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it
    - Meets all of the following criteria:
        - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
        - Furnished in a setting appropriate to the patient's medical needs and condition;

Furthermore, unlike the proposed MCIT pathway, the modifications to the definition of "reasonable and necessary" would apply to all items and services, not just breakthrough devices. In fact, the nature of the MCIT pathway is such that FDA-designated breakthrough devices would automatically be considered to have met the definition of "reasonable and necessary" for purposes of Medicare coverage.

Challenges in Assessing Commercial Coverage and Potential Unintended Consequences

If CMS finalizes its proposed definition, there are significant questions that must be addressed regarding the threshold for commercial coverage. Clearly, the threshold for commercial coverage to determine "appropriateness" should be greater than a single commercial insurance plan offering. Coverage by a majority of health insurance providers or a majority of commercial enrollees would be more representative of "appropriateness."

Moreover, due to geographic variations in utilization and adherence to evidence, commercial coverage policies are typically nuanced to reflect this variation and 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 the revised definition of "reasonable and necessary" and a preferable approach may be to allow the Medicare Administrative Contractors (MAC) to tailor coverage based on what they observe in the commercial market.

Additionally, some state Medicaid programs may reference Medicare's definition of "reasonable and necessary" and, as a result, this modified definition could, by reference, become the coverage standard for Medicaid. 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 that the proposed addition referencing commercial coverage in the definition of "reasonable and necessary" could have unintended consequences both within and beyond the Medicare program and fails to account for the challenges in assessing commercial coverage, we recommend that CMS give additional consideration to threshold and flexibility issues before finalizing any modification to Medicare's definition of "reasonable and necessary."

- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative; *OR*

o *Is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.*

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 enrollees with access to innovative and evidence-based items and services.

Sincerely,

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