601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

October 12, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

RE: [CMS-3372-P2]: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Dear Administrator Brooks-LaSure:

On behalf of 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" (R&N) proposed rule to repeal the final rule published on January 14, 2021 and which would be effective on December 15, 2021. AHIP strongly supports CMS' proposal and recommendations to repeal the MCIT/R&N final rule.

We share the Administration's commitment to encouraging medical device innovation and providing Medicare beneficiaries access to new and ground-breaking devices that are safe, effective, and reasonable and necessary. 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.

Based on this experience, we provided feedback on the rule when it was proposed last year that highlighted our serious concerns regarding safety, efficacy, and value for the Medicare population and recommended that the rule be recscinded. In the proposed rule, CMS references many of the same concerns AHIP raised as its rationale for repeal of the final rule, which we appreciate. We also appreciate CMS' commitment to consider input from stakeholders for potential future rulemaking on improved access to innovative and beneficial technologies and look forward to continued engagement with CMS on these policies.

[1]AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

I. MCIT Pathway

The final rule established a new coverage pathway for FDA-approved breakthrough devices.[2] National Medicare coverage (applicable to both original 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's primary concerns with the MCIT pathway relate to its failure to fully and appropriately evaluate safety, efficacy, and value for the Medicare population prior to or post-coverage and its failure to allow for swift action to protect beneficiaries if it becomes apparent that a particular device can be harmful to the Medicare population. In addition, our comments on the final rule noted a number of unaddressed operational issues, including how and when CMS would communicate to health insurance providers information on benefit category and appropriate billing codes, for example.[3]

Safety, Efficacy, and Value

Because Medicare patients usually have more than one co-morbidity and are likely being treated for more than one condition and because there is no FDA requirement that Medicare beneficiares be included in the clinical studies needed for market authorization, CMS has historically reviewed clinical evidence showing that devices have been studied in the Medicare population or that outcomes are generalizable to the Medicare population. However, the MCIT pathway would essentially act as an interim and less-rigorous National Coverage Determination (NCD) and, as CMS notes in the proposed 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." (86 Fed. Reg. 51327)*

Moreover, repeal of the MCIT/R&N final rule would not preclude coverage of breakthrough devices for Medicare beneficiaries. As CMS notes, *"Many of the eligible Breakthrough Devices are coverable and payable through existing mechanisms"* and, in fact, *"a review of claims data showed that Breakthrough Devices have received and are receiving Medicare coverage when medically necessary." (86 Fed. Reg. 51330)*

We concur with CMS's focus on the very important responsibility of the agency to ensure the most appropriate coverage of medical devices for Medicare beneficiaries. We expressed concern in our previous comments that the final rule could lead to increased fraud, waste, and abuse—

[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.

[3] For a full discussion of AHIP's concerns with the final rule, see AHIP's April 16, 2021 comment letter.

along with the attendant added costs. As CMS notes in the proposed rule, *"… 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." (86 Fed. Reg. 51329)*

Additionally, under the MCIT/R&N final rule evidence development is voluntary with no requirement that manufacturers conduct studies to generate evidence to demonstrate clinical benefit to Medicare patients. We agree with CMS that voluntary evidence development is not in the best interests of Medicare beneficiaries; rather, *"…evidence is key to determining the best treatments for Medicare patients to ensure that the benefits of treatments outweigh the potential harms." (86 Fed. Reg. 51329)* Any future rulemaking on this pathway or other mechanisms for Medicare coverage should include a requirement for clinical evidence with objective outcome measures in the appropriate patient populations.

Post-Market Removal for Safety Reasons

Currently, CMS Medicare Administrative Contractors (MACs) can deny claims under certain circumstances, such as if it becomes apparent that a particular device may be harmful to Medicare beneficiaries. However, the final rule would remove this case-specific flexibility, taking away a valuable tool to expeditiously remove a device from coverage and protect Medicare beneficiares in a timely manner. We agree with CMS' statement in the proposed rule that *"… this limitation on our authority is impracticable as it may lead to preventable harm to Medicare beneficiaries …" (86. Fed. Reg. 51328)*

II. Definition of "Reasonable and Necessary"

Current law 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. 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 final rule codified this definition and gave CMS authority to review the majority of commercial insurers in making national and local coverage determinations in the event that an item or service did not meet the regulatory appropriateness criteria.

AHIP's primary concerns with the proposed codification and modification of the definition of "reasonable and necessary" relate to the implementation challenges and potential unintended consequences.[4]

Challenges and Potential Unintended Consequences

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. Furthermore, in some instances, commercial coverage may be dictated by state benefit mandates (which may or may not be evidence-based). It is not clear how these differences would be reflected in any measurement of a majority of covered lives. We appreciate CMS's acknowledgement of these concerns – *"Expanding the reasonable and necessary definition to systematically consider commercial insurer coverage presents implementation and appeals process challenges that would likely persist." (86 Fed. Reg. 51330)*

CMS' proposal to repeal the final rule also acknowledges concerns received that the definition included in the 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." (86 Fed. Reg. 51331)*

If CMS considers future rulemaking to define "reasonable and necessary," we recommend that CMS engage health insurance issuers and other stakeholders in advance of any future rulemaking to solicit input on the current definition and any additional or different criteria that may be considered in any proposed modification of the definition. In addition, CMS should focus on delineating the levels of reliable evidence that are needed to establish different items and services as "safe and effective".

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

[4] For a full discussion of AHIP's concerns with the final rule, see AHIP's April 16, 2021 comment letter.