



Charles N. Kahn III
President and CEO

April 16, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” Delay of Effective Date; Public Comment Period (CMS-3372-IFC)

Dear Acting Administrator Richter:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children’s, and cancer services.

The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Interim Final Rule on the Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” Delay of Effective Date.

The FAH recommends that CMS separate the provisions addressing the definition of “reasonable and necessary” from the MCIT pathway and proceed along two distinct timelines instead of maintaining a single rule. Although these issues are both coverage policies, they are independent policies that can be separated into two rules. This would allow CMS to implement the MCIT pathway and provide additional time to examine the issues related to the definition of “reasonable and necessary.” In addition, this would ensure equitable access to all Medicare beneficiaries for lifesaving and life-enhancing medical devices and provide CMS and stakeholders with additional time to address any unintended obstacles to ensure equitable health care from the decisions related to the definition of “reasonable and necessary.”

Medicare Coverage of Innovative Technology (MCIT) Pathway

The 21st Century Cures Act¹ established the Breakthrough Devices Program to expedite the development and review of medical devices that meet two criteria: (1) the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or conditions and (2) either represents a breakthrough technology; there is no approved or cleared alternative technology; offers significant advantages over existing approved or cleared alternatives; or the availability of the device is in the best interest of patients.

To facilitate access to breakthrough technologies, CMS established alternative payment pathways for both the inpatient new technology add-on payment pathway² and the outpatient transitional devicepass-through payment pathway³ for devices that receive U.S. Food & Drug Administration (FDA) marketing authorization and breakthrough designation.

As part of the Agency's commitment to ensure Medicare beneficiaries access to breakthrough technologies, CMS finalized the MCIT pathway to ensure consistent national coverage of breakthrough technologies. The MCIT pathway can provide four years of national coverage for devices that receive both FDA marketing authorization and breakthrough designation. This will be a voluntary program under which a manufacturer will notify CMS of its interest in participation. CMS will publicly post information about devices covered through the MCIT pathway on its website, including available clinical evidence related to the device that can be reviewed by patients and their clinicians. CMS will discontinue MCIT coverage when FDA has issued a warning letter, medical device safety communication, or black box warning and CMS determines the harms outweigh the benefits for Medicare beneficiaries. At the end of the four-year period, coverage determination will be consistent with the established process in which coverage is based on a national coverage determination or determined by the Medicare Administrative Contractors (MACs).

The FAH commends the Agency's ongoing commitment to ensure Medicare beneficiaries have access to critical life-saving technologies and supports CMS's coverage for these devices through the MCIT pathway. National coverage is an important component of CMS's goal to facilitate access to breakthrough technologies, and the MCIT pathway is consistent with the alternative payment pathways CMS established for breakthrough devices in both the inpatient and outpatient payment systems.

The FAH urges CMS to implement the MCIT pathway to ensure all Medicare beneficiaries have access to breakthrough technologies through national coverage. The FAH also urges CMS to develop a transparent public notification process for when the four-year coverage period begins and ends and ensure that coverage does not end abruptly when the coverage period concludes. Lastly, CMS should also provide coding guidance and reimbursement for these devices to ensure consistent national coding and payment.

¹ Pub.L. 144-255, December 13, 2016.

² 84 FR 42292-42297.

³ 84 FR 61295-61296.

Defining “Reasonable and Necessary”

The Medicare Program Integrity Manual (PIM) includes the definition the MACs use when making local coverage determinations to establish whether an item or service is “reasonable and necessary” for purposes of section 1862(a)(1)(A) of the Social Security Act. Specifically, the item or service must be:

- 1) Safe and effective;
- 2) Not experimental or investigational; and
- 3) Appropriate, including the duration and frequency that it considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient’s medical needs and conditions;
 - 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.

CMS finalized the definition of the terms “reasonable and necessary” based on the current PIM definition with a modification to consider commercial insurance coverage. When making the determination of “reasonable and necessary” for items or services that have insufficient evidence to meet the long-standing appropriateness criteria, CMS will consider coverage to the extent the items or services are covered by a majority of commercial insurers. CMS finalizes this modified definition at 42 CFR §405.201(b).

Use of Commercial Insurance

The FAH is generally supportive of CMS’s decision to allow the use of commercial insurance coverage as an adjunct to the longstanding criteria when those criteria do not result in Medicare coverage. Because commercial insurance coverage is not developed through a public process that includes notice and comment, and there is no central repository of commercial insurers’ coverage policies easily accessible for public review, the FAH continues to believe that CMS should develop a transparent process that allows for public review of the commercial insurance policies being considered by CMS and the MACs and provide clinical demographic and utilization information on the beneficiaries of those coverage policies. This is essential information to ensure that a commercial insurance policy does not unintentionally impact health care access for some Medicare beneficiaries. In addition, many commercial insurer coverage policies are revised mid-year, which can result in a more restrictive coverage policy. When Medicare coverage is based on a commercial insurer’s policy that becomes more restrictive, CMS needs to ensure that coverage is maintained until stakeholders have the opportunity to review the commercial policy changes. In addition, any proposed Medicare coverage policy changes should have a 60-day notice and comment period.

CMS finalized that no later than 12 months after the effective date of this rule, CMS will establish the methodology by which commercial insurers' policies are determined to be relevant based on the measurement of the majority of covered lives. CMS indicates this will ensure adequate stakeholder engagement but did not specify how stakeholders will provide input.

The FAH believes CMS should obtain comments about its proposed methodology through a public notice and comment period. Although the FAH supports CMS's decision to use commercial insurance coverage when Medicare coverage would otherwise not be available, we remain concerned that CMS has not provided sufficient details about the methodology for using commercial insurers' policies to adequately comment on this additional criterion for the definition of "reasonable and necessary." Without a transparent process that allows notice and comment through rulemaking, instead of expanding the definition of "reasonable and necessary," the use of commercial insurance coverage could have the unintended consequence of reducing health care access for all beneficiaries.

Codifying the Definition

CMS also finalized this modified definition at 42 CFR §405.201(b). The FAH believes the established language in the PIM is known and understood by all stakeholders and retaining this definition in the PIM allows for flexibility to ensure beneficiary access to covered services. As such, we strongly recommend that CMS reexamine its decision to codify the definition of "reasonable and necessary" and instead retain the definition in the PIM. As this Administration and health care providers work to ensure equitable health care access for all Medicare beneficiaries, retaining the definition in the PIM allows CMS the flexibility to ensure this important goal.

The FAH appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at 202-624-1534, or Erin Richardson, Senior Vice President at erichardson@fah.org or 202-624-1516.

Sincerely,

A handwritten signature in black ink, appearing to read "Erin Richardson", written in a cursive style.