Charles N. Kahn III
President and CEO

October 30, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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

Dear Administrator Verma:

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 and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Notice of Proposed Rulemaking on the Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (proposed rule).

Medicare Coverage of Innovative Technology (MCIT) Pathway

The 21st Century Cures Act[1] 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

[1] Pub.L. 144-255, December 13, 2016

access to breakthrough technologies, CMS established alternative payment pathways for both the inpatient new technology add-on payment pathway[2] and the outpatient transitional device pass-through payment pathway[3] for devices that receive U.S. Food & Drug Administration (FDA) marketing authorization and breakthrough designation.

As part of the Administration's commitment to ensure Medicare beneficiaries access to breakthrough technologies, CMS proposes the MCIT pathway to ensure consistent national coverage of breakthrough technologies. The MCIT pathway would provide for four years of Medicare coverage for devices that receive both FDA marketing authorization and breakthrough designation. This would be a voluntary program under which a manufacturer would notify CMS of its interest in participation. CMS proposes that coverage would begin on the date of FDA market authorization, and this information would be posted on the CMS website. At the end of the four-year period, coverage determination would 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 Administration's ongoing commitment to ensure Medicare beneficiaries have access to critical life-saving technologies and supports CMS' proposal for the MCIT pathway for devices. National coverage is an important component of CMS' goal to facilitate access to breakthrough technologies, and the proposed MCIT pathway is consistent with the alternative payment pathways CMS established for breakthrough devices in both the inpatient and outpatient payment systems.

To ensure beneficiary access to breakthrough devices, the FAH recommends that CMS develops a transparent process for public notification of when the four-year coverage period for a device begins and ends. To reduce the provider burden associated with a variable start and end dates, CMS should consider a known schedule for beginning and ending coverage; this could be consistent with the quarterly schedule for coding and payment updates. In addition, to ensure that a beneficiary's access to breakthrough device is not restricted due to calendar scheduling conflicts that can occur because of a beneficiary or provider conflict, it is important that coverage does not abruptly end when the four-year coverage period concludes. A known transition period should be established that ensures continued coverage pending a national coverage decision or MAC decision.

CMS appropriately recognizes the need for ensuring coverage for breakthrough devices, but in order to facilitate beneficiary access it is important that CMS also ensures coding guidance and reimbursement for these devices. As CMS notes in the proposed rule, eleven breakthrough devices have variable coverage because of MAC discretion. Without consistent national coding and payment, providers will have increased burden associated with inconsistent guidance provided by the MACs, or even no guidance provided by the MACs.

Lastly, CMS seeks comment on whether the MCIT pathway should be extended to include diagnostics, drugs and/or biologicals that also utilize breakthrough or expedited FDA approval pathways. The FAH recommends that the MCIT pathway be limited to devices until

[2] 84 FR 42292-42297
[3] 84 FR 61295-61296

stakeholders and CMS have more experience with the process. The FAH also urges CMS to ensure that any future expansion goes through notice and comment rulemaking.

Defining "Reasonable and Necessary"

The Medicare Program Integrity Manual 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 proposes to modify this definition to include a separate factor based on commercial health insurers' coverage policies for determining "appropriateness" when an item or service does not meet the initial five factors and otherwise would be non-covered. Specifically, CMS proposes that an item or service would be considered appropriate if it is covered in the commercial market, unless evidence supports a clinically relevant difference between Medicare beneficiaries and commercially insured individuals. CMS also proposes to codify this modified definition at 42 CFR §405.201(b).

The FAH is generally supportive of CMS' proposal to allow the use of commercial insurance coverage as a basis for determining whether an item or service is appropriate, but only to the extent that this is used to expand coverage and is not used to restrict coverage or access to services. The FAH does not support CMS' alternative suggestion to determine "appropriate" based only on commercial insurance. 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 easily accessible for public review. Commercial insurance coverage can vary from state to state and between employers covered by the same commercial insurer. Thus, if CMS finalizes a definition that incorporates commercial insurance coverage, it needs to 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.
In addition, many commercial insurers 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 also proposes to codify this modified definition at 42 CFR §405.201(b). The FAH believes the established language in the Program Integrity Manual is known and understood by all stakeholders and retaining this definition in the Program Integrity Manual allows for flexibility to ensure a beneficiary's access to covered services.

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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,