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October 12, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

submitted at www.regulations.gov

RE: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," Proposed Rule, CMS-3372-P

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to comment on the proposed rule that repeals the rule that was finalized January 14, 2021, Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 86 Fed. Reg 51326 (September 15, 2021).

The AAMC is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

CMS Should Repeal The Final MCIT Rule

The final rule provided four years of expedited coverage to FDA market authorized Breakthrough Devices. The final rule also did not require manufacturers to conduct studies post-coverage that would demonstrate clinical benefit to Medicare patients. In our comment letter on that rule we supported making breakthrough technology available to Medicare beneficiaries as quickly as possible. It is important to note that Medicare beneficiaries have available to them other avenues for gaining access to Breakthrough Devices, such as through the national coverage determination process. In our prior comment letter, we raised the concern that because Medicare beneficiaries are underrepresented in clinical trials their safety and effectiveness for the Medicare population may be unknown. In this proposed rule CMS echoes that concern that the rule "may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the

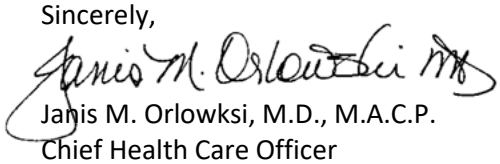
Medicare Patients." (p.51327). **The AAMC agrees with CMS and strongly supports repeal of the final rule.**

CMS Should Repeal the Revised Definition of "Reasonable and Necessary" and Return to the Long-Standing Definition

CMS also proposes to repeal the revised definition of "reasonable and necessary" which would have been expanded to consider commercial insurer coverage as a criteria for coverage for the Medicare population. The AAMC opposed finalizing the expanded definition, writing that "any change in the long-standing definition must be made with caution, after a careful consideration of any unintended consequences to the Medicare beneficiaries." Of particular concern is that most commercial coverage is aimed at younger populations and therefore may not be an appropriate source for making decisions about Medicare coverage. **The AAMC supports the CMS proposal to repeal the expanded definition of "reasonable and necessary."**

If you need additional information, please contact Ivy Baer, Senior Director and Regulatory Counsel (ibaer@aamc.org).

Sincerely,



Janis M. Orlowksi, M.D., M.A.C.P.
Chief Health Care Officer

Cc: Ivy Baer, JD, MPH