



**Association of
American Medical Colleges**
655 K Street, NW, Suite 100, Washington, DC 20001-2399
T 202 828 0400
aamc.org

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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-3372-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule, Medicare Coverage and Innovative Technology (MCIT) and Definition of “Reasonable and Necessary,” 85 *Fed.Reg.* 54327 (September 1, 2020). As will be discussed below, the AAMC has several comments and concerns regarding the MCIT. While the AAMC understands that both the MCIT proposal and the definition of reasonable and necessary are linked to the Executive Order on Protection and Improving Medicare of Our Nation’s Seniors (EO 13890) we believe that the proposed definitional change of reasonable and necessary requires consideration of many additional issues and a substantial amount of clarification that should occur through a future rulemaking. Therefore, the proposed definitional change should not be finalized. The AAMC also has many concerns about the MCIT and believes that it needs substantial revisions. Our comments are below.

The AAMC is a not-for-profit association dedicated to transforming health through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 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 their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

In this proposed rule CMS proposes the creation of a pathway for Medicare beneficiaries to have faster access to new, innovative medical devices that the Food and Drug Administration (FDA) has designated as breakthrough. The MCIT pathway would provide Medicare coverage starting on the date of FDA market authorization and would continue for four years. In addition, CMS proposes to change the definition of “reasonable and necessary” which is one of the longstanding standards used by Medicare to determine coverage. Under the proposal, in addition to the item or service being safe and effective and not experimental, it would be considered appropriate for Medicare patients if it is covered in the commercial insurance market, except where “evidence supports that there are clinically relevant

differences between Medicare beneficiaries and commercially insured individuals.” In addition, CMS would be promoting the definition of reasonable and necessary from the Program Integrity Manual (PIM) to the code of federal regulations (CFR). (p. 54328) making it binding on cases brought before Administrative Law Judges and reducing the flexibility to quickly modify the definition in the future as medical practice and technology change.

The Medicare Coverage of Innovation Technology

The purpose for creating the MCIT is to make FDA approved devices designated as breakthrough devices available to Medicare beneficiaries more quickly. The statutory criteria for a breakthrough device are: (1) the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions and (2) the device must represent breakthrough technology; no approved or clear alternatives exist; it offers significant advantages over existing approved or cleared alternatives; or the device availability is in the best interest of patients. The AAMC supports making breakthrough technology available to the Medicare population as quickly as is reasonable but has significant concerns about the CMS proposal that in general, automatically provides coverage for a device that has FDA approved marketing and FDA designation as a breakthrough device. Because Medicare beneficiaries often are underrepresented in clinical trials, the safety and effectiveness of devices and other items and services for the Medicare population may be unknown. The AAMC urges CMS to put in place the following protections to ensure that the MCIT will not inadvertently endanger Medicare beneficiaries who receive? breakthrough devices:

Device manufacturers should be required to submit to CMS data, whether from ongoing clinical trials or from other sources, such as claims data. Clinical trials should be required to recruit individuals from among the Medicare population and provide information about the number of Medicare beneficiaries in the clinical trial and report the clinical outcomes.

1. CMS should regularly monitor and analyze all available data and make it available to researchers. In the event that the data show that Medicare beneficiaries are being harmed by the device, or other concerns are raised, the Agency should determine whether the device should be withdrawn from the MCIT. We do not believe any device should be guaranteed 4 years in the MCIT.
2. While 4 years should be the maximum amount of time that a device can be in the MCIT pathway, it can be withdrawn sooner as described above. No device should be guaranteed 4 years in the MCIT. A national coverage decision (NCD) should be developed for any device withdrawn from the MCIT pathway.
3. The MCIT should apply to breakthrough devices only and should be limited to the FDA indication that received breakthrough designation. Once CMS has sufficient experience with the program the Agency can determine whether to undertake another rulemaking to expand it to certain drugs and biologicals.

Following further work and input from stakeholders the Agency can use a future rulemaking to propose a method that expedites the availability of breakthrough devices while continuing to offer sufficient protections to Medicare beneficiaries.

Change in definition of “reasonable and necessary”

The definition of “reasonable and necessary” is a cornerstone to Medicare coverage of items and services. Any change in the long-standing definition must be made with caution, after a careful consideration of any unintended consequences to the Medicare beneficiaries. The AAMC is concerned that the proposed change remains in a formative stage and is not ready to be finalized. Therefore, the Association strongly urges CMS to not finalize the proposed change at this time for the reasons discussed below.

It is unclear whether CMS intends for the change to apply to all “items and services” or only to technologies. The preamble states that the change would be “for items and services that are furnished under Part A and Part B” (54328). Yet, the regulation that will be modified is at 42 CFR Subpart B, Medical Services Coverage Decisions Which Relate to Health Care Technology. It seems that the intended scope of the change in “reasonable and necessary” is not limited to breakthrough devices. We have significant concerns about the breadth of the applicability of the proposed change.

The AAMC believes that more information must be provided by CMS before commenters can fully respond to the proposal. Often Medicare is the leader in coverage and commercial insurers follow. It is unclear why CMS believes that the policies of commercial insurers should set a standard for Medicare coverage particularly, as CMS acknowledges, Medicare and commercial insurers cover very different populations. Commercial insurers generally cover people 64 and under while the Medicare population is predominantly 65 and older. CMS needs to provide an explanation as to why insurance coverage for a healthier, younger population should set a standard for Medicare beneficiaries. In addition, commercial insurance coverage is not developed through a public process and the basis for the decision, including what information was part of the review of an item or service, is not known.

CMS must be explicit about what it means by “commercial insurers.” Would the term apply to any insurer, regardless of the number of covered lives it insures, or should the term only include insurers that cover a minimum number of covered lives nationally or on a state-by-state basis? What is the minimum number? Are short-term limited duration health plans to be considered, or only those that offer more comprehensive benefits that are somewhat akin to Medicare fee-for-service? Would Medicare Advantage (MA) plans be considered private insurers? While MA plan must cover everything covered by fee-for-service Medicare, it can cover more services than Medicare fee-for-service.

The regulatory language uses an “or” between 405.201(b)(3)(i) and (ii), which seems to indicate that coverage by commercial insurers (“unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant”) would replace the other criteria (i). Those criteria are that the item and service:

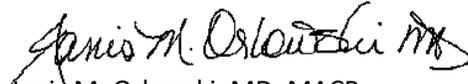
1. is furnished in accordance with accepted standards of medical practice for the diagnosis and treatment of the patient’s condition or to improve the function of a malformed body member;
2. furnished in a setting appropriate to the patient’s medical needs and conditions;
3. ordered and furnished by qualified personnel;
4. meets but does not exceed the patient’s medical needs; and
5. is at least as beneficial effective as an existing and available medically appropriate alternative.

The AAMC does not support replacing these criteria, which have been in place and provide important protections for Medicare beneficiaries, with a criterion that looks at commercial insurance. We have concerns about this proposal, even if this criterion was only used when the initial criteria are not met, as stated in the preamble (54332). If only a few Medicare beneficiaries are enrolled in a clinical trial it is uncertain whether sufficient evidence would be available to establish whether clinically relevant differences exist between Medicare beneficiaries and individuals covered by commercial insurance. The AAMC suggests that the Agency work with experts to make clear how much evidence would be needed to support the use of a particular device (or item or service) for the Medicare population; for example, the percentage of trial participants who must be 65 years or older. Without this requirement it is unclear how it would be possible to determine whether “evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant” and thus whether a device should not be covered by Medicare.

AAMC is also concerned that CMS’ proposal to promote the reasonable and necessary definition from the PIM to the CFR will reduce needed flexibility in the application of coverage by Medicare contractors. Under current policy, the PIM is not binding on all Medicare contractors (i.e. administrative law judges are not bound to follow the sub-regulatory guidance in the manual). AAMC believes promotion of the reasonable and necessary guidance to the manual may reduce contractor flexibility in the application of long-standing Medicare coverage principles.

If you have questions or require additional information please contact Ivy Baer, ibaer@aamc.org or 202-828-0499.

Sincerely,



Janis M. Orlowski, MD, MACP
Chief Health Care Officer

Cc: Ivy Baer