November 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

**Re: Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"**

Dear Administrator Verma:

The American College of Radiology (ACR), representing nearly 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the MCIT Notice of Proposed Rulemaking (NPRM).

## Medicare Coverage of Innovative Technology Pathway

*Proposals*
CMS proposes that the MCIT pathway would provide immediate national coverage for breakthrough devices beginning on the date of United States Food and Drug Administration (FDA) market authorization and continue for up to four years, unless the Agency determines the device does not have a Medicare benefit category as determined by CMS as part of the MCIT pathway process.

*ACR Comments and Perspectives*
While the NPRM recognizes 16 Breakthrough Program devices that have successfully navigated the FDA's authorization pathways, it is the ACR's understanding that the number of devices currently in the Premarket Approval (PMA), 510(k), and De Novo pipelines and benefiting from the Breakthrough Devices Program may be as many 300 products currently in-process. To our knowledge, the FDA does not publically identify those devices that have been designated as Breakthrough Program devices until the device has successfully navigated the pathway and achieved FDA market authorization. The ACR believes greater transparency and an opportunity for public feedback on MCIT coverage decisions would help ensure programmatic integrity. We therefore encourage CMS to provide public notice and an opportunity for public comment prior to accepting a device under the MCIT pathway. Additionally, to further enhance transparency, we would encourage CMS, in coordination with FDA, to maintain on each Agency's website, an

up-to-date list of all devices being considered under the Breakthrough Devices and MCIT programs.

The ACR believes CMS should require manufacturers to submit clinical data information within the 4-year MCIT coverage cycle. A phased-in approach with data submission beginning in year 2 will help the agency identify adverse events, utilization among Medicare beneficiaries, and improvements in healthcare outcomes. We implore CMS not to use the existing guidance on coverage with evidence development (CED) and to allow manufacturers to determine the best approach to share outcomes data. A formal clinical study is not feasible in the limited time allotted. This process will improve transparency and assist with an appropriate coverage process once the MCIT pathway ends. Adoption of these medical devices into clinical practice will require physician participation and input.

**Defining "Reasonable and Necessary"**

*Proposals*
CMS proposes to include a separate basis under which an item or service would be deemed "reasonable and necessary" that is based on commercial health insurers' coverage policies. The commercial market analysis would be initiated if an item/service fails to fulfill the existing criteria, but fulfills safe and effective and not experimental or investigational criteria. CMS believes that this approach would be consistent with Executive Order 13890 that directs the Agency to make technologies "widely available, consistent with the principles of patient safety, market-based policies, and value for patients".

*ACR Comments and Perspectives*
The ACR supports the proposal to add consideration of commercial insurance coverage to the definition of "reasonable and necessary". The College believes that such consideration would ensure continuity of patient care as beneficiaries move from commercial insurance to Medicare coverage.

Specifically, the ACR supports CMS' statement that "…greater access to innovative treatments provides beneficiaries with more opportunity to improve health…" and agrees with the proposal to adopt the least restrictive coverage policy for the item or service, as appropriate for Medicare patients.

As an example, CT colonography (CTC), an effective screening option for prevention and early detection of colorectal cancer, is currently covered widely by commercial insurers and available to patients under age 65, but is not covered by Medicare. Patients are able to utilize CTC as a colorectal cancer screening option beginning at age 50 (in many cases age 45 as now recommended by the American Cancer Society and the recent United States Preventive Services Task Force draft guidelines), but must choose a different screening option once they are covered under Medicare. Many patients cannot or will not undergo a colonoscopy or other screening test and rather choose to forego this important cancer screening. The best screening test is the test that gets done.

## Conclusion

The ACR appreciates the opportunity to provide comments on the MCIT proposed rule. The ACR looks forward to continued dialogue with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Kathryn Keysor at 800-227-5463 ext. 4950 or via email at kkeysor@acr.org.

Respectfully Submitted,

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Chief Executive Officer