ASSOCIATION FOR MOLECULAR PATHOLOGY
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October 15, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

SUBMITTED ELECTRONICALLY via http://www.regulations.gov

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (CMS-3372-P2)

Dear Administrator Brooks-LaSure:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to comment on this proposed rule repealing the Medicare Coverage of Innovative Technology (MCIT) and definition of "reasonable and necessary" final rule. AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

As experts in molecular diagnostics, we are committed to protecting patient access to high quality care, including access to new, breakthrough devices, and welcome the opportunity to work with the Centers for Medicare & Medicaid Services (CMS) to develop future policies to improve Medicare beneficiaries' access to innovative and beneficial technologies. AMP is pleased to provide comments on the definition of "reasonable and necessary" and the inclusion of the commercial insurer policies in this definition for consideration in future coverage policy rulemaking.

CMS invited comments on the "reasonable and necessary" provisions of this rule. Specifically, feedback was requested on whether the final rule should merely repeal the commercial insurer aspects of the rule, as well as what criteria should be considered as part of the "reasonable and necessary" definition in future rulemaking. We recognize that CMS has received substantial feedback from various stakeholders who are concerned about how the commercial insurer aspects of the rule would be implemented. We hope that our comments and suggestions clarify a path forward for the agency.

Inclusion of Commercial Insurer Policies

Regarding the inclusion of commercial insurer policies in the definition of "reasonable and necessary", AMP has previously submitted comments to the agency objecting to incorporating these policies into the definition and urges that this policy is not revisited should CMS address this issue in future rulemaking[1]. We continue to believe

[1] https://www.amp.org/AMP/assets/AMPComments-MCITPathway-CMS-3372-P-FINAL-11-2-20.pdf

the automatic incorporation of commercial policies would work against efforts to achieve greater transparency, predictability, and provider input as Medicare coverage policies are drafted and finalized. AMP recognizes the agency does not intend to issue subregulatory guidance on this topic, but wishes to reiterate it is not appropriate to set standards such as these through subregulatory guidance, as a change of this magnitude should be subject to public comment. Moreover, omitting the commercial health insurer coverage provision would not prevent CMS from incorporating and considering existing commercial policies during the coverage policy development process. Commercial coverage policies are already reviewed as part of the existing national and local coverage determination processes. Formalizing their inclusion may lead to instances where a product or service that would have been covered previously would become non-covered depending on how a specific commercial payor may have developed a certain coverage decision.

Definition of Reasonable and Necessary

As CMS considers future rulemaking on this topic, AMP continues to assert it is not necessary to codify the definition of "reasonable and necessary" found in Chapter 13 of the Program Integrity Manual (PIM). Prior to any future rulemaking, AMP strongly recommends that the goals of rulemaking and this concept be thoroughly vetted with stakeholders outside of a public comment process. One of our concerns with the change as contemplated by this rule is this definition would apply across all Medicare coverage decisions, not just the proposed MCIT pathway. AMP believes strongly that the inclusion of the term "safe and effective" within the definition of "reasonable and necessary" does not appropriately apply to all items and services considered for coverage under Medicare. The term "safe and effective" is a term that strongly equates with FDA clearance or approval of a service. For the technologies eligible for coverage under the MCIT, CMS states "we no longer believe that the FDA safety and effectiveness standards alone are sufficient to support open-ended Medicare coverage" in the rule. The agency also recognizes that certain devices under the MCIT pathway would lack evidence of benefit in the Medicare population and that devices under the pathway must meet FDA's safe and effective criteria and be reasonable and necessary for Medicare populations.

However, not all laboratory services are regulated under FDA. Laboratory developed testing procedures (LDPs, also known as LDTs) are services regulated under the Clinical Laboratory Improvement Amendment (CLIA) program at CMS. Since these procedures are regulated separately from FDA, AMP is concerned that the inclusion of "safe and effective" within the definition applied to all Medicare services may lead to inappropriately restricting coverage, and the potential exclusion of LDPs. Therefore, if CMS chooses to proceed with codifying the PIM definition in the future, AMP requests that CMS not include "safe and effective" as a requirement in the definition of "reasonable and necessary." AMP alternatively would ask for explicit clarification that use of "safe and effective" is not intended to suggest a necessary role for the FDA in making "reasonable and necessary" determination for Medicare coverage. Codifying this language in regulation may ultimately limit innovation and a thorough examination of the potential change and its implications should be undertaken.

We appreciate the opportunity to provide comments on this proposed rule to rescind the MCIT pathway. Should you have any questions or require additional information, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Samuel K. Caughron, MD FCAP
Chair, Economic Affairs Committee
Association for Molecular Pathology