



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

6120 Executive Blvd., Suite 700, Rockville, MD 20852

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

April 16, 2021

Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA <http://www.regulations.gov>

Re: Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (CMS-3372-IFC)

Dear Acting Administrator Richter:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide additional comments on the Centers for Medicare & Medicaid Services (CMS) Interim Final Rule with Comment Period on Medicare Coverage of Innovative Technology (MCIT) (CMS-3372-IFC). 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. Therefore, we continue to be supportive of the MCIT pathway that would offer beneficiaries nationwide, predictable access to new, breakthrough devices to help improve their health outcomes. We offer the following comments on this rule as the agency considers making further revisions to the rule before implementation:

1. Request for Modification of the Definition of “Reasonable and Necessary,” Which Requires an Item or Service to be “Safe and Effective”; and
2. Request to Rescind the Provision Considering Commercial Health Insurer Coverage Policies.

Request for Modification of the Definition of “Reasonable and Necessary,” Which Requires an Item or Service to be “Safe and Effective”

CMS finalized its proposal to codify the Program Integrity Manual (PIM) definition of “reasonable and necessary” in regulation. This definition applies more broadly than the MCIT and will be used in national coverage determinations (NCDs) and other coverage decisions. The definition has three main elements: an item or service must be (1) safe and effective, (2) not experimental or investigational, and (3) appropriate for the Medicare patients. The safe and effective standard is a key criterion for Food and Drug Administration (FDA) clearance

and approval, and CMS acknowledged in the final rule that not all items and services that may be covered under Medicare are regulated by the FDA. However, the agency believes “safe and effective” is a long-standing consideration in these determinations and an appropriate part of the definition of “reasonable and necessary.”

AMP continues to assert it is not necessary to codify the PIM definition of reasonable and necessary at this time, and that the MCIT pathway can be implemented without this change. We, therefore, respectfully request that CMS not finalize the definition at this time, to ensure that any future changes to the definition can be properly vetted with stakeholders, not only through this public comment period, but also through other means of outreach. It is important that the definition be considered carefully, as this definition will apply across all Medicare coverage decisions, not just the MCIT pathway, as stated above.

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. However, not all laboratory services are regulated under FDA. Laboratory developed testing procedures (LDPs, and 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 may lead to inappropriately restricting coverage, and the potential exclusion of LDPs. Therefore, if CMS chooses to proceed with codifying the PIM definition at this time, AMP requests that CMS remove this requirement from the definition of “reasonable and necessary.” Should CMS not do this, 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 determining “reasonable and necessary”. Codifying this language in regulation may ultimately limit innovation and a thorough examination of the potential change and its implications should be undertaken.

Request to Rescind the Provision Considering Commercial Health Insurer Coverage Policies

Under the codified definition of “reasonable and necessary,” CMS also includes a separate basis under which an item or service would be “appropriate for Medicare patients” that is based on commercial health insurers’ coverage policies. The commercial market analysis would be initiated if an item or service fails to fulfill the existing criteria (3) appropriate for Medicare patients, but does fulfill (1) safe and effective, and (2) not experimental or investigational.

In the final rule, CMS committed to issuing standards on what types of commercial insurers CMS should consider for making NCDs and local coverage determinations. To ensure full stakeholder engagement before the agency evaluates all commercial insurer policies, CMS will issue a sub-regulatory guidance for the public to comment, no later than 12 months after the effective date of this final rule. The guidance will lay out the methodology by which commercial insurer’s policies are determined to be relevant based on the measurement of majority of covered lives.

AMP continues to respectfully request that CMS rescind this proposal, as 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 also does not believe it is appropriate to set these standards through subregulatory guidance, as a change of this magnitude should be subject to public comment.

Moreover, deletion of the commercial health insurer coverage provision would not prevent the ability of existing commercial policies to be incorporated and considered during the coverage policy development process. Commercial coverage policies are already reviewed as part of the existing national and local coverage

determination processes. AMP is concerned that including this provision in the definition 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.

We appreciate the opportunity to provide comments on the final rule for 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,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology