



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

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

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Proposed Medicare Coverage of Innovative Technology (MCIT) (CMS-3372-P). 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 are supportive of the proposed MCIT pathway that would offer beneficiaries nation-wide predictable access to new, breakthrough devices to help improve their health outcomes and we offer the following comments on the proposal:

1. Support for the Proposed Medicare Coverage of Innovative Technology (MCIT) Pathway;
2. Request for Inclusion of Clinical Laboratory Tests in the MCIT Pathway;
3. Request for Clarification on the Definition of "Reasonable and Necessary," Which Requires for an Item or Service to be "Safe and Effective"; and
4. Request to Rescind the Proposal Considering Commercial Health Insurer Coverage Policies.

Support for the Proposed Medicare Coverage of Innovative Technology (MCIT) Pathway

AMP supports CMS' proposed MCIT pathway to provide coverage for breakthrough medical items and services and believes this proposal aligns well both with CMS' goals to bring new and innovative technologies to

beneficiaries sooner to help improve their health outcomes, as well as the Administration’s goals outlined in President Trump’s *Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors* (EO 13890). AMP agrees with the Agency that current Medicare coverage options have led to challenges that hamper national coverage and supports this policy change to provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to 4 years. Ultimately, this will expedite patient access to innovative products and devices to diagnose and treat life-threatening illnesses. Further, we support CMS’ decision to make participation voluntary for the proposed MCIT pathway as manufacturers should be able to decide when they choose to opt-in.

Request for Inclusion of Clinical Laboratory Tests in the MCIT Pathway

While AMP generally supports the proposed MCIT pathway, we request that CMS expand it to include clinical laboratory tests. CMS specifically seeks comment on whether the MCIT pathway should also include “diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA [Food and Drug Administration] (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval) [12] or all diagnostics, drugs and/or biologics.” FDA-designated breakthrough devices, as proposed under § 405.603(a), would include FDA-cleared or approved clinical laboratory tests that receive breakthrough designation as devices. Furthermore, CMS’ press release states that the MCIT pathway could accelerate Medicare coverage for innovative products such as “devices harnessing new technologies like implants or gene-based tests to diagnose or treat life-threatening or irreversibly debilitating diseases or conditions like cancer and heart disease.”¹

Clinical laboratory tests should also have the option for coverage under the MCIT pathway. Clinical laboratory tests eligible under the proposed MCIT pathway should include both those tests in which the laboratory has voluntarily chosen to undergo and achieve FDA-clearance or approval as a breakthrough device, as well as those tests as designated by the Secretary. Inclusion of the latter category would ensure that laboratory developed testing procedures are also eligible to seek national coverage under this pathway. Addition of this category of tests would not only further expedite patient access to innovative tests but would also align with current HHS policy on LDTs². To accurately accommodate the addition of laboratory developed testing procedures, AMP also requests that use of the term “device” be removed and replaced with “item or service” or “products,” as the use of “devices” would no longer accurately describe all items eligible under this pathway. Additionally, in the final rule, we ask that CMS state that submission of an application for an LDP to the FDA is not a condition for Medicare coverage.

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

CMS is proposing to codify the definition of “reasonable and necessary” in regulation and to apply this definition to additional services, not just those participating in the MCIT pathway; the application of this proposed definition will be expansive as it will be used for national coverage determinations (NCDs) and other coverage decisions. The proposed 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.

¹ CMS Press Release, “CMS Acts to Spur Innovation for America’s Seniors,” Aug. 31, 2020, *available at* <https://www.cms.gov/newsroom/press-releases/cms-acts-spur-innovation-americas-seniors>

² HHS Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests <https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html>

AMP does not feel it is necessary to codify the definition of reasonable and necessary at this time as the MCIT pathway can be implemented as proposed without this change. Moreover, AMP has concerns with the implications of some parts of the existing language as well as proposed new provisions of the definition. It is important that this definition be considered carefully as the definition will apply across all Medicare coverage decisions, not just the MCIT pathway, as stated above.

If finalized, CMS would require a Medicare item or service to be “safe and effective” in order to meet the definition of “reasonable and necessary.” Currently, the requirement that a service be safe and effective is included in the section 3.6.2.2 of the Medicare Program Integrity Manual (PIM). 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, namely laboratory testing services. The term “safe and effective” is a term that strongly equates with FDA clearance or approval of a service. However, laboratory testing services are not regulated under FDA, but under the Clinical Laboratory Improvement Amendment (CLIA) program under CMS. It is important to note that certain items and services can be furnished without FDA premarket review, such as laboratory-developed tests (LDTs). Therefore, AMP requests that CMS remove this requirement within the existing PIM.

Request to Rescind the Proposal Considering Commercial Health Insurer Coverage Policies

Under the proposed 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 defining (3) appropriate for Medicare patients but does fulfill (1) safe and effective and (2) not experimental or investigational.

CMS is proposing to allow the Agency to review commercial health insurer coverage policies and analyze them for coverage parameters applicable to the Medicare population. This proposal would add a new component that would allow the appropriateness criteria to be met if a commercial insurer already provides coverage. We 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. Moreover, deletion of the commercial health insurer coverage provision would not prevent the ability of existing commercial policies to be incorporated and considered during coverage policy development. Commercial coverage policies are already reviewed as part of the existing national and local coverage development processes. Additionally, AMP fears that addition of this provision within the definition may lead to instances where a product or service 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 proposed 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,

Karen E. Weck, MD FCAP
President, Association for Molecular Pathology