COLLEGE of AMERICAN PATHOLOGISTS

November 2, 2020

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

Subject: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-3372-P entitled "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary.'" As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Like the Administration, the CAP is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. The CAP has continually advocated for regulatory frameworks that enhance patient safety and maintain quality laboratory testing and innovation without creating a significant regulatory burden on laboratories. We have also regularly worked with Centers for Medicare & Medicaid Services (CMS) on coverage issues ranging from National Coverage Determinations (NCDs) to Program Integrity Manual (PIM) updates. Here, we provide comments on CMS's proposal to define "reasonable and necessary," as well the proposal for a new coverage pathway for breakthrough devices. The CAP's goal is to ensure that coverage decisions are made by qualified health experts through a transparent process that is based on sound medical evidence. These decisions affect millions of Medicare beneficiaries and impact critical access to innovative technologies and procedures.

Defining "Reasonable and Necessary"

As CMS explains, the factors used in making "reasonable and necessary" determinations based on section 1862(a)(1)(A) of the Act have not been established in regulations for Medicare coverage purposes. However, Chapter 13 of the Medicare PIM includes such factors as instructions for Medicare contractors in establishing local coverage policy. Under this proposed rule, CMS is proposing to codify in regulation, the PIM definition of "reasonable and necessary" with modifications including adding a reference to commercial health insurer coverage policies. These regulatory standards would be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B.

The CAP generally supports CMS's proposal to codify the existing PIM definition of reasonable and necessary, including the proposed modification. However, we contend that predicating Medicare coverage policy on commercial insurance coverage demands increased transparency in developing national and local coverage determinations. Specifically, CMS and its Medicare Administrative Contractors (MACs), must identify each of the commercial coverage policies it considered and

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provide a detailed rationale for the commercial policy on which it chose to base Medicare coverage, all of which should be subject to notice-and-comment by public stakeholders. In terms of how CMS would identify these coverage policies, we are aware of proprietary subscription-based software programs that provide information on private insurance policies. Alternatively, CMS may consider encouraging private insurers to incorporate their coverage policies into CMS' Documentation Requirements Lookup Services (DRLS).

In addition, coverage policies of commercial insurers – even the least restrictive policy – may not consider the uniqueness of the Medicare population. Commercial policies sometimes consider coverage for only a subset of its population, which may not be relevant to seniors or disabled beneficiaries. As part of its analysis, CMS and MAC analysis should ensure that adoption of the least restrictive coverage policy of a commercial plan does not inadvertently limit coverage or impede access for Medicare patients, and when it is clinically relevant.

Further, we urge CMS to clarify that the revised definition of reasonable and necessary, which requires that an item or service be considered "safe and effective," does not imply a requirement for an item or service to have FDA clearance or approval. This clarity is important to ensure continued access to new and innovative laboratory developed tests (LDTs) which are required to meet standards for analytical validity under the Clinical Laboratory Improvement Amendments (CLIA) process and clinically validated by the CLIA lab, itself.

Finally, as our members have and continue to face a multitude of challenges under the current Medicare coverage paradigm, we urge CMS to grandfather current policies, including those that were included as part of negotiated rulemaking. This revised definition should not put our prior efforts to ensure meaningful coverage for key items and services in jeopardy. Equally important, we would not support allowing MACs to develop alternate approaches to address any or all of the considerations outlined above, parallel to their current practice of making coverage decisions in the absence of an NCD or national policy. Instead, we urge CMS to continue to work with public stakeholders, including the CAP and the rest of the medical community, to improve the process for developing local coverage policy, which continues to deteriorate despite CMS' recent efforts to address long standing concerns.

MCIT Pathway

According to the proposed rule, the statutory timeframes for the NCD process limit CMS's ability to institute immediate national coverage policies for new, innovative medical devices. CMS also points to "coverage uncertainty between the period of FDA market authorization and CMS finalization of an NCD or a Medicare Administrative Contractor's (MACs) finalization of a local coverage determination (LCD)," as well as variation in coverage from one jurisdiction to another. Therefore, CMS believes that a new coverage pathway is needed that would provide for "immediate national Medicare coverage of any FDA-market authorized breakthrough device if the device meets criteria outlined in this proposal." According to CMS, the proposed MCIT pathway would improve health care for Medicare beneficiaries "by providing national Medicare coverage for devices receiving the FDA breakthrough device designation." Given the major advances in medical technologies that can provide for earlier and more accurate diagnoses and effective treatments, the proposed voluntary pathway can help ensure patients have access to these innovative technologies without the lengthy process Medicare coverage.

While the CAP strongly believes that the quality of care provided to Medicare beneficiaries depends on access to treatments appropriate to their needs, including new technologies, we have concerns about the creation of new coverage pathways that may undermine or circumvent the current

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processes. As CMS explains, the current coverage pathways include: (1) NCD; (2) LCD; (3) claim-by-claim adjudication; (4) Clinical Trial Policy (CTP); and (5) Parallel Review. In this proposed rule, CMS acknowledges the multiple coverage pathways that are currently available, but states that "at this time none are readily available to provide immediate national coverage for new breakthrough devices with a Medicare benefit category at the same time as FDA market authorization." However, as new technologies advance with the accumulation of scientific evidence through ongoing clinical trials by manufacturers and others, national coverage policies should be flexible enough to allow for new technologies as they are developed. Further, any coverage decisions by CMS should not preclude MACs from determining coverage for new technologies at the local level as they become available. In fact, MACs should have the flexibility to reasonably choose to cover new technologies not yet reviewed by the FDA, by applying a rigorous review process per national guidelines. Local MAC decisions remain an important pathway for coverage, and a well-functioning LCD should be reflective of the circumstances, needs, and capabilities of the patients and practice in the jurisdiction for which it is developed. Finally, as we have expressed before, we believe the coverage with evidence development (CED) process has historically taken years to result in a coverage or non-coverage decision, which is too slow to provide reasonable access to new technologies, and only offers treatment to a limited population of patients who have access to trials and registries.

We are also concerned that an additional coverage pathway has the potential to arbitrarily decide which technologies receive a head start or other advantage in the traditional coverage process and, as emphasized above, we strongly urge CMS to include robust transparency in any process providing coverage for Medicare beneficiaries. In particular, more transparency and detail must be provided regarding coding and reimbursement aspects of the MCIT, as well as how this process would interact with the current coverage pathways.

The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions related to the "reasonable and necessary" definition to Nonda Wilson nwilson@cap.org / (202) 354-7116 and the MCIT pathway to Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

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