



COLLEGE of AMERICAN PATHOLOGISTS

April 14, 2020

The Honorable Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Acting Administrator Richter:

The College of American Pathologists (CAP) appreciates the opportunity to comment further on the Final Rule CMS-3372-F 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’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.

Under the final rule, CMS will 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 will 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 Appreciates CMS’ consideration of commercial coverage policies to broaden coverage and make new technologies more widely available by bringing together the expertise of private payers and CMS. However, we continue to urge CMS and its Medicare Administrative Contractors (MACs), to make public each commercial coverage policy it considers and provide a detailed rationale for the commercial policy on which it chose to base Medicare coverage. Furthermore, when coverage is afforded on the basis of commercial policy, CMS and MACs should adopt the least restrictive coverage policy so as not to inadvertently limit coverage or impede access for Medicare patients.

We continue to 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 do not support allowing MACs to develop alternate approaches to address any or all of the considerations outlined in the final rule. Coverage should continue to be based on the steps outlined in Chapter 13 of the PIM regarding the process for attaining an LCD.



The CAP strongly believes that the quality of care provided to Medicare beneficiaries depends upon access to treatments appropriate to their needs, including new technologies. We appreciate CMS' efforts to increase beneficiary access to newly FDA market-authorized treatments and to accelerate the process to gain coverage under the new voluntary pathway without the lengthy process of traditional Medicare coverage pathways. We would like to emphasize that as new technologies advance with the accumulation of scientific evidence through ongoing clinical trials by manufacturers and others, national coverage policies themselves 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.

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, we again strongly urge CMS to include robust transparency in any process providing coverage for Medicare beneficiaries. In particular, greater 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 these 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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