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April 16, 2021

VIA ELECTRONIC DELIVERY

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

RE: CMS–3372–IFC, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period

Dear Acting Administrator Richter:

As the leading trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices the Medical Imaging & Technology Alliance (MITA) is responding to interim final rule with comment period concerning the delay and request for additional information on the Medicare Coverage of Innovative Technology (MCIT) program and the codification of the definition of the "reasonable and necessary" criteria for Medicare coverage.

In these comments, we (1) urge CMS to implement the MCIT program as soon as possible; (2) offer recommendations for operationalization of this program; (3) express confidence in products brought to market with FDA breakthrough designation.

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In this rule, CMS created a Medicare coverage pathway that would expedite beneficiary access to innovative medical devices with FDA "breakthrough" designation. This rule also updated the definition of the "reasonable and necessary" criteria under which CMS determines whether or not to cover a product or service. CMS delayed implementation of this rule for 60 days in order to assess the legality and validity of this rulemaking and to seek additional input on operational concerns regarding the rule.

MITA expressed support for the MCIT program as well as the codification of "reasonable and necessary" in comments submitted to the docket on the proposed rule.[1] In our comments, we discussed the need for product developers to have access to expedient, transparent, and predictable pathways in order to bring innovative products to Medicare beneficiaries.

[1] https://www.regulations.gov/comment/CMS-2020-0098-0182

In particular, we argued that, in addition to the proposed changes, CMS should further update its coverage process to include provisions that allow the Agency and the requestor to develop a formal, written agreement for how coverage or an item of service can be achieved and to establish consistent targets for evidence requirements, both in terms of kind, amount, and appropriate and relevant outcomes measures.

We also argued that the MCIT program as proposed would approximate an ideal pathway for bringing innovative medical solutions through FDA marketing authorization and CMS coverage determination. As discussed in the proposed rule, only a handful of devices have received "breakthrough" marketing authorization by the FDA. This will still leave numerous medical solutions in limbo. CMS should expand this program and develop more expansive criteria for inclusion in the program to ensure efficient market access for diagnostic imaging solutions and software, diagnostic radiopharmaceuticals and contrast agents, and high intensity focused ultrasound therapies. We also argued that CMS should also consider extending the coverage period to five years or longer.

We note that CMS previously requested comment on whether "diagnostics" should be included in the MCIT pathway, which we understand to refer to diagnostic imaging agents like radiopharmaceuticals for PET. Diagnostic imaging agents play a crucial role in informing appropriate treatment for patients with oncologic, cardiac, neurologic, and other health conditions. In particular, in many cases diagnostic imaging agents are required for on-label use of breakthrough-designated therapeutics, much like clinical laboratory tests that are approved as companion diagnostics. Given that CMS specifically references such clinical laboratory tests as examples of devices to which the MCIT would apply, we believe that the agency should make the MCIT pathway available to diagnostic imaging agents to the extent they serve a similar clinical function. Specifically, we urge CMS to include diagnostic imaging agents in the MCIT when required for on-label use of a breakthrough-designated therapeutic.

We stand by these comments and urge swift implementation of the MCIT program and look forward to continued collaboration on updating the definition of "reasonable and necessary."

In the Federal Register notice delaying implementation of the MCIT program, CMS correctly identifies that while the rule would eliminate coverage uncertainty early after FDA market authorization and automates coverage so that innovative products are brought to market faster, the rule did not directly address operational issues, such as how the Agency would establish coding and payment levels for particular devices, which are both central to prompt market access. We share this concern and suggest that CMS look to programs such as Passthrough and the New Technology Add-on Payment policies as models for resolving these operational concerns. We also suggest that CMS establish a process by which a product developer can start sharing information with CMS in advance of FDA marketing authorization, so that coding, coverage, and payment can be determined advance of clearance or approval. However, determinations of coding and payment are issues that are not new to the reimbursement process and should not delay the implementation of the MCIT program.

CMS also raises concerns that the volume of devices with FDA breakthrough designation may overburden the MCIT program once it is operational. We do not anticipate any major challenges given that not all breakthrough devices will come to market at once, some may fall outside of existing benefit categories, and some would already be covered under existing National Coverage Determinations (NCDs). Further, a device having breakthrough status does not necessarily mean that it has been cleared or approved by the FDA. FDA suggests that product sponsors request the Breakthrough Device designation by submitting a "Designation Request for Breakthrough Device" Q-Submission,[2] meaning that these products may not receive marketing authorization for some time.

[2] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

CMS also raises concerns about the benefits of breakthrough devices for Medicare patients. Given that the FDA reviews medical devices for safety and efficacy, we believe that any product in the MCIT program will have reasonable assurances of benefit to the Medicare population.

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If you have any questions, please contact Peter Weems, Senior Director, Strategic Operations and Policy, at pweems@medicalimaging.org or 703-841-3228.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.