MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: CMS-3421-NC— Medicare Program: Transitional Coverage for Emerging Technologies

Dear Administrator Brooks-LaSure:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the referenced notice proposing the Transitional Coverage for Emerging Technologies (TCET) program.

MITA Member companies continue to develop innovative technologies—including advanced digital health technologies powered by artificial intelligence (AI) and machine learning (ML). The pathway from FDA marketing authorization to Medicare beneficiary access must keep pace with innovation, which is expected to only accelerate. Otherwise, novel technologies will languish in bureaucratic review, creating unnecessary barriers to Medicare beneficiary access and stifling innovation.

In a previously finalized rule, CMS created a Medicare coverage pathway that would expedite beneficiary access to innovative medical devices with Food and Drug Administration (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.

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 medical technology developers to have access to expedient, transparent, and predictable pathways in order to bring innovative products to Medicare beneficiaries. We also urged that the MCIT program be expanded beyond just "Breakthrough" technologies given that not all innovative products earn this designation.

We stand by these comments and were disappointed in the repeal of the MCIT program. The MCIT program as proposed would have implemented better policies for bringing innovative medical solutions from FDA marketing authorization to CMS coverage. It would have also more generally clarified the Medicare coverage determination process by codifying a definition of the "reasonable and necessary" coverage criteria.

While we believe that the TCET proposal would be a modest step in the right direction, we have concerns about the scope and utility of the program as proposed. We are concerned that TCET will not address certain

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

fundamental coverage, coding, and payment issues facing innovative technologies and will not adequately support the volume of new products coming to market.

TCET Proposal

Under the proposed TCET coverage pathway, CMS will coordinate with FDA and manufacturers of Breakthrough Devices as those devices move through the FDA premarket review processes to ensure timely Medicare coverage decisions following any FDA marketing authorization. The Agency's goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after FDA marketing authorization.

Current CMS policy considers all new technologies as experimental (i.e., not covered) until CMS or the Medicare Administrative Contractors (MACs) determine that they are reasonable and necessary. We urge CMS to reverse this policy for breakthrough technologies, i.e., deem breakthrough technologies to be reasonable and medically necessary until they are determined to be experimental by CMS or the MACs using current coverage policy and processes. This approach to covering breakthrough technologies would accelerate beneficiary access to breakthrough technologies as defined by FDA:

"The device- provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and

- Represents breakthrough technology; or
- No approved or cleared alternatives exist; or
- Offers significant advantages over existing approved or cleared alternatives; or
- Device availability is in the best interest of patients." [2]

In addition, CMS should expand the TCET eligibility criteria. CMS is proposing that certain devices will be candidate for the TCET pathway, including those that meet the following criteria:

- FDA-designated Breakthrough Devices,
- Determined to be within a Medicare benefit category,
- Not already the subject of an existing Medicare NCD, and
- Not otherwise excluded from coverage through law or regulation.

We are concerned that these criteria are overly narrow and will result in numerous innovative medical devices languishing without appropriate Medicare reimbursement. Only a handful of devices have received "Breakthrough" marketing authorization by the FDA. Over reliance on this criterion will still leave numerous medical solutions in limbo.

The very limited scope of this proposal is particularly concerning for medical imaging given the small number of imaging products that currently have "Breakthrough" status. Our industry continues to innovate and has numerous advanced AI/ML solutions in development that may not quality for "Breakthrough" designation and have an uncertain pathway to appropriate coverage, coding, and payment. CMS should expand its criteria for TCET candidacy and develop more expansive criteria for inclusion in the program to ensure efficient market access for advanced imaging solutions and software, novel radiopharmaceuticals and contrast agents, and high intensity focused ultrasound therapies.

Further, CMS should "grandfather" into the TCET program those products that would have been eligible for MCIT but lost the opportunity to engage in that pathway when the program was rescinded.

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[2] US Food and Drug Administration. Breakthrough Devices Program. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#:~:text=The%20Breakthrough%20Devices%20Program%20is,irreversibly%20debilitating%20diseases%20or%20conditions. Accessed August 2, 2023.

We are also concerned that that this proposal will not align with other payment policy timelines (e.g. NTAP) and will not adequately address ongoing coding and payment issues. Gaining coverage for innovative products is only one step on the longer pathway to Medicare beneficiary access. Unless these products also have a transparent, predictable, and expedient pathway to appropriate coding and payment, they will continue to face serious challenges to adoption.

In the TCET proposal, CMS anticipates the program only handling a limited number of products per year. This is highly concerning given ongoing advances across the medical technology field. We do not anticipate any major volume challenges given that not all innovative 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, meaning that these products may not receive marketing authorization for some time.

We urge CMS to continue to work with medical technology innovators, healthcare providers, patients, and others to improve and expedite the path from FDA marketing authorization to CMS coverage. CMS should swiftly issue a new proposed rule to seek solutions to these challenges and move forward with improvements to the Medicare coverage process.

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If you have any questions, please contact Peter Weems, Senior Director of Policy & Strategy, at 703-841-3238 or by email at pweems@medicalimaging.org.

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.