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VIA ELECTRONIC DELIVERY

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-3772-P, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

Dear Administrator Verma:

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 the proposed rule on the “Medicare Coverage of Innovative Technology (MCIT)” program.

In this proposed rule, CMS proposes the creation of a Medicare coverage pathway that would expedite beneficiary access to innovative medical devices with FDA “breakthrough” designation. This proposed rule would also update the definition of the “reasonable and necessary” criteria under which CMS determines whether or not to cover a product or service.

MITA supports periodic reexamination of the regulations which grant patients access to medical products and services. As medical technologies mature and proliferate, MITA believes that manufacturers and innovators should have access to expedient, transparent, and predictable pathways to bring their products to patients. Modern regulatory approaches make sense for modern medical device technologies.

Reasonable and Necessary

CMS is proposing to update its policies to consider items or services “reasonable and necessary” if they are:

1. Safe and effective;
2. Not experimental or investigational; and
3. Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Policy changes that improve the transparency, accountability, and predictability of the Medicare national coverage determination process will improve beneficiary access to innovative medical technologies and services. Historically, CMS has made coverage determinations based on internal review of available evidence. Given limited Agency resources, the ability of Medicare beneficiaries to gain timely access to innovative technologies has been limited.

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, including establishing expectations for such things as:

- Criteria for assessment
- Evaluation methods
- Timelines
- Appropriate endpoints
- Types of evidence to be considered, including non-traditional sources such “real world evidence”

Further, CMS needs to establish consistent targets for evidence requirements, both in terms of kind, amount, and appropriate and relevant outcomes measures.

Use of Commercial Insurance Policies

CMS is also proposing to create a separate basis under which an item or service would be considered “appropriate” 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 factor criteria defining “appropriate” for Medicare patients but fulfills safe and effective and not experimental or investigational.

In this proposed rule, CMS proposes utilizing private payer coverage policies as inputs to support or augment its own decision-making. This may not be appropriate in all cases and CMS should be cautious in broad adoption of private payer policies without engagement of interested and affected parties in a transparent and collaborative process.

Private payer coverage policies are widely varied in the medical solutions and populations they cover and often rely on a variety of data sources and analysis methodologies. In some cases, these policies are significantly more or less expansive in terms of the use cases or populations covered. Further, private payers often use proprietary health care technology assessment processes that are not transparent in their data sources or analysis methods. The policies under consideration must be developed based on publicly available, transparent and high-quality data sources and evaluation methods. There may not in all cases be a simple crosswalk between these policies and a unitary CMS coverage determination. These policies, however, may be useful resources in development of CMS coverage policies.

As a general matter, we would support the Agency’s use of commercial coverage policies to expand Medicare beneficiary access to safe and effective items and services. Such a policy would align with the goal in Executive Order No. 13890 of “streamlining the approval, coverage, and coding process so that innovative products are brought to market faster...consistent with the principles of patient safety, market-based policies, and value for patients.”

We would note that we understand CMS intent, with this proposal, as being to provide for coverage where either 1) CMS or a MAC does its own review and determines that the item or service is reasonable and necessary under the existing standards, or 2) CMS or a MAC becomes aware of a commercial coverage policy that supports Medicare coverage of the item or service. MITA does not support a policy to allow CMS or a MAC to deny coverage based on a negative commercial policy if CMS or the MAC determines that the item or service is appropriate for Medicare beneficiaries based on the Manual criteria.

The proposed regulations should not authorize CMS or the MAC to narrow Medicare coverage analysis, based on commercial coverage policy.

We also recognize that commercial payers may not have the specific patient experience due to the nature of the product/service and their insured populations. In the event their coverage policy is restricted or offers no coverage, we would recommend CMS not select the most restrictive or non-coverage commercial payer policy.

We look forward to working with the Agency to establish a formal, collaborative, transparent process with opportunity for comment from all interested and affected parties in a public process, to evaluate publicly available private payer coverage policies for the Medicare population at both the national and local level.

We also welcome clarity in more general coverage definitions and standards for Medicare coverage. The proposed criteria, particularly its alignment with FDA terminology and commercial coverage is a positive step in Medicare beneficiaries having access to the newest technologies, and for innovators to have a clear outline of what they must meet for coverage.

MCIT Pathway

CMS is proposing to grant national Medicare coverage under the MCIT pathway to medical devices with FDA “breakthrough” status beginning immediately on the date of FDA marketing authorization. Under this program, Medicare coverage would continue for four years unless the Agency determines that the device does not have a Medicare benefit category as defined by statute.

Medical imaging technologies are being rapidly innovated and MITA supports a modernized regulatory and reimbursement framework to facilitate timely market access for innovative medical solutions. The proposed MCIT pathway would address the coverage uncertainty manufacturers of certain innovative devices face as they wait for a National Coverage Determination (NCD) or Local Coverage Determination (LCD) and would enable expedient Medicare beneficiary access to “breakthrough” technologies as they become available.

The MCIT program as proposed by in this rulemaking 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 advanced imaging solutions and software, novel radiopharmaceuticals and contrast agents, and high intensity focused ultrasound therapies. CMS should also consider extending the coverage period to five years or longer.

CMS requests comment on whether “diagnostics” should be included in the MCIT pathway, which we understand may be inclusive of diagnostic imaging agents such as radiopharmaceuticals for PET or SPECT. Diagnostic imaging agents play a crucial role in informing appropriate treatment for patients with oncologic, cardiac, neurologic, and other health conditions. In many cases diagnostic imaging agents afford the clinician adjunctive diagnostic information not available through other diagnostic procedures. Given that CMS specifically references *in vitro* clinical laboratory tests as examples of devices to which the MCIT pathway would apply, we believe that the agency should also make the MCIT pathway available to diagnostic imaging agents to the extent they serve a similar clinical function.

Additionally, many medical solutions that have CMS coverage still face adoption challenges due to low reimbursement rates. CMS should make sure that it is collecting and analyzing cost data during the four-year coverage period to ensure that items and services are appropriately paid.

CMS should also ensure that this and any new future coverage pathways maximize collaboration between innovators and policymakers. Ideally, both parties will be working together to bring new medical solutions to Medicare beneficiaries.

We would not necessarily support CMS automatically opening a National Coverage Analysis if a MAC has not issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period. This timeframe is arbitrary and would not account for work that may already be in progress.

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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.