November 1, 2020

Via Electronic Submission to www.regulations.gov
(Docket No. CMS-3372-P)

Seema Verma
Administrator
Center for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on the proposed Medicare Coverage of Innovative Technologies (MCIT) program and definition of "Reasonable and Necessary"

Administrator Verma,

The Medical Alley Association appreciates the opportunity to comment on the proposed creation of the Medicare Coverage of Innovative Technologies (MCIT) program, as well as defining the term "reasonable and necessary" to provide clarity and consistency in its use within the Medicare program.

As The Global Epicenter of Health Innovation and Care™, Medical Alley is home to world-leading care providers, payers, and health technology organizations that are bringing the future of healthcare forward. We were proud to host your visits here in late August to publicly announce the proposed MCIT program and in October 2019, along with HHS Deputy Secretary Eric Hargan, for the release of proposed changes to the Stark Law and Anti-Kickback Statute. These visits helped bring continued recognition to the central role Medical Alley plays leading the transformation of healthcare.

We commend this Administration's continued focus on increasing physician and patient access to innovative medical technologies. Too often, the promise and benefit these technologies provide are functionally unavailable due to onerous and outdated regulations hampering reimbursement or coverage determinations. Continuing the removal of bureaucratic obstacles to the safe, clinically appropriate use of new medical technologies to improve outcomes and lower the overall cost of care is a laudable goal and one strongly supported by the Medical Alley Association.

The Medical Alley Association supports the creation of the MCIT program and incorporating the use of the Food and Drug Administration's (FDA) Breakthrough Device designation for determining eligibility. This proposal takes significant strides towards increasing patient access to new, innovative medical technology and, combined with proper guard rails, will drive broader adoption and use in care plans around the country.

The Medical Alley Association urges that the proposed codification of the "reasonable and necessary" standard not be finalized. Existing sub-regulatory guidance is understood and provides needed flexibility in interpretation and use. Should CMS move forward with codifying this definition, we encourage further clarification that looking to coverage by commercial

insurers is only a mechanism to further CMS' stated goal of ensuring Medicare beneficiaries have access to technologies that improve health outcomes.

Continue Focus on Increasing Patient Access and Safety Through Creation of the Medicare Coverage of Innovative Technologies Program

The Medical Alley Association supports the creation of the proposed MCIT program and its use of the FDA's Breakthrough Device designation and receipt of market authorization as requirements for eligibility. Per CMS' request, we are providing feedback and input on several, separate pieces of the proposed program below.

Timelines for NTAP, TPT, and MCIT Should Be Aligned

Last year, CMS took important steps for breakthrough devices to qualify for both the New Technology Add-on Payment (NTAP) and Transitional Pass-Through Payment (TPT), via the Inpatient and Outpatient Rules respectively. The proposed MCIT rule is a logical next step for improving Medicare patients' access to innovative technologies. However, eligibility for NTAP and TPT are shorter than the proposed temporary coverage for MCIT devices, which could lead to inconsistencies in access for patients and disrupt ongoing research during the MCIT coverage period. Therefore, the Medical Alley Association supports extending the eligibility timeframe for NTAP and TPT in future rulemaking to match what is proposed for the MCIT program, as it will support consistency in access and evidence generation for qualifying devices.

Clarity is Necessary to Ensure that Diagnostic Devices are Eligible for the MCIT Pathway

The Medical Alley Association applauds the proposed use of the FDA Breakthrough Devices Program, as well as FDA marketing authorization, in determining eligibility for the MCIT program. Requiring a device to be designated as Breakthrough is a clear attempt to provide clarity and certainty in products eligible for this proposed coverage pathway. The proposed regulatory definition CMS put forward for "Breakthrough Device" indicates that diagnostic technologies would be eligible for the MCIT ("provides for more effective treatment or diagnosis…"). This definition contradicts statements earlier in the proposed rule that the MCIT pathway is limited to medical devices. CMS should clarify that diagnostic technologies can receive the Breakthrough designation and therefore are eligible for the MCIT pathway.

CMS Should Preserve Flexibility for Manufacturers of Devices Eligible for MCIT

The timeline for coverage under the proposed MCIT pathway creates questions at two key inflection points, and the Medical Alley Association believes that CMS should ensure qualifying device manufacturers retain flexibility in decision making at each. The first is whether participating in the MCIT pathway should be a voluntary "opt-in" as originally proposed; we believe this is appropriate, and that CMS should ensure the start of the eligibility clock takes market availability into account, similar to what is done under NTAP and TPT. This is also helpful for smaller companies that, without a stream of revenue, would likely be cost-prohibited from conducting evidence generation studies. The second is if CMS should automatically initiate a National Coverage Determination (NCD) process at the conclusion of coverage through the MCIT pathway. The Medical Alley Association does not support this and urges CMS to allow the manufacturer to determine which coverage process, if any, is best suited to the particular device.

Further Clarity Needed in Coding Processes and Medicare Benefit Categories

The Medical Alley Association strongly supports efforts to better integrate new and effective technologies into clinically appropriate patient-care plans. Far too often, innovation is deemed to occur primarily in technology – whether it be device, digital, or drug – and not in the actual delivery of care to the patient. Organizations located in Medical Alley are leading the transformation of healthcare by not only developing and manufacturing new technologies, but also in the design and implementation of more effective ways to care for patients – often incorporating these new technologies – that result in lower costs and improved outcomes.

Through the proposed MCIT pathway, CMS does not clearly outline how a Breakthrough Device will receive appropriate coding. Completing this process is critical for the tracking and collection of evidence and ongoing research, as well as ensuring proper payment to the provider and manufacturer. It is critical that CMS provide clarity on the process by which Breakthrough Devices receiving coding, so that proper research and evidence collection can occur and that any innovative care plans are not interrupted due to lack of anticipated access to the breakthrough device.

We also urge CMS to provide clarity to existing policies and use its existing regulatory authority to include certain breakthrough technologies, such as those where digital technology defines its uniqueness, within existing Medicare benefit categories. The development and implementation of digital health tools – including those that use algorithms, artificial intelligence, or software as a medical device – have brought significant changes to healthcare delivery. Tools similar to these are being integrated more frequently as part of innovative care plans, including those designed using value-based care arrangements, as they can result in significant improvement in patient adherence, lower the overall cost of care, and improving outcomes for patients of all disease state and conditions. We recognize that CMS does not have the ability to unilaterally create new benefit categories; however, it should look to use existing authority to include breakthrough digital technologies within existing benefit categories where appropriate.

It is appropriate to note here that closely monitoring the MCIT pathway for potential waste, fraud, and abuse is critical to the success of the program. The Medical Alley Association is, as evident throughout this comment, a strong supporter of creating the MCIT pathway and making adjustments to ensure it achieves the desired outcome. We also know that any new program must be carefully scrutinized in its formative years, when processes and guardrails are still being implemented. Cooperation and collaboration to confront suspected waste, fraud, and abuse is critical for the MCIT pathway to achieve its goal of increasing patient access to new medical technologies.

Effectiveness Data is Important to the Long-Term Success of MCIT

The Medical Alley Association believes that patient safety is, and should be, of the utmost importance in all aspects of healthcare. The proposed MCIT pathway is no different. For example, as CMS notes in the proposed rule, manufacturers that are required by FDA to collect post-market data will not see that mandate changed by this new pathway. We also believe that the MCIT provides a new and beneficial opportunity for CMS and the FDA to work closely together on post-market surveillance and the Medical Alley Association supports the use of existing or new resources to ensure this cooperation to continue ensuring patient safety can be as successful as possible.

MCIT provides a critical opportunity to generate clinical evidence needed for long-term coverage under Medicare. Additionally, we agree that additional evidence will likely be necessary to make a longer-term coverage decision after MCIT coverage has concluded. For this reason, it is important that manufacturers understand CMS' expectations regarding the evidence necessary to support coverage beyond the MCIT program period and that feedback and communication happen in a clear and transparent manner.

To this end, the Medical Alley Association believe that CMS should provide additional incentives for participants in the MCIT program to gather additional evidence during the coverage period. Flexibility is important in the methods and type of evidence generation, and CMS should allow for the potential to use real-world data as appropriate, while evaluating the study design, data, outcomes, and other metrics by using generally accepted scientific standards for good observational research practices. While we do not support a requirement of additional evidence collection, MCIT provides a tremendous opportunity to gather this evidence, and so an appropriate incentive would help achieve a high degree of participation and potentially result in broader and richer set of data for making future coverage determinations.

Existing Guidance for Determining "Reasonable and Necessary" Is Sufficient and Modifications Should Be Made Only to Continue Increasing Access

As part of the introduction to the proposed rule, CMS reiterates the Administration's commitment to ensuring Medicare beneficiaries have access to new cures and technologies that improve outcomes. To that end, CMS is proposing to codify into regulation the longstanding Program Integrity Manual (PIM) definition of "reasonable and necessary," along with an alternative pathway for satisfying the "appropriateness" prong of this standard through the analysis of the commercial insurance market. The Medical Alley Association appreciates this proposal, but does not support it for the reasons that follow.

Existing Sub-Regulatory Guidance is Understandable and Retains Needed Flexibility

The proposed rule from CMS seeks to codify the existing sub-regulatory definition of "reasonable and necessary." We believe this is unnecessary and will not move CMS forward toward its goal of ensuring beneficiary access to new technologies that improve outcomes. Stakeholders and CMS both have a clear understanding of this language and keeping it at a sub-regulatory level preserves greater flexibility in its interpretation. Further, the long history of its use within the Medicare statute, and previous failed attempts to define it, further illustrate why this permanent change should not be made without extensive and thoughtful stakeholder discussion and input that cannot be achieved solely through comments on a proposed rule.

Any Codification Should Ensure Commercial Insurance Coverage Is Only Used If Other Criteria for Appropriateness Are Not Met

The current PIM standard for "reasonable and necessary" requires a product or service to be:

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
    a. 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;

b. furnished in a setting appropriate to the patient's medical needs and condition;
c. ordered and furnished by qualified personnel;
d. one that meets, but does not exceed the patient's medical need; and
e. at least as beneficial as an existing and available medically appropriate alternative.

As part of codifying this standard, CMS proposes to add a part (f) that reads:

f. covered by commercial insurers unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.

The Medical Alley Association is strongly supportive of efforts to ensure that the use of any product or service be appropriate for the patient. Continuing to reduce the overall cost of care, improving access and outcomes for patients, and ensuring patient safety, must be the primary drivers in healthcare. We do not oppose adding commercial coverage as a positive proxy for appropriateness, where a product or service would satisfy criteria numbers (1 – safe and effective) and (2 – not experimental or investigational), but not (3 – appropriateness). We do not, however, support looking to commercial insurance coverage to the base review of the appropriateness criteria.

There are several reasons we believe this is the proper approach. Beneficiaries covered by commercial payers are different than Medicare and, all else being equal, a different analysis of appropriateness is required. Additionally, CMS is statutorily prohibited from considering cost-effectiveness in Medicare determinations, while — and we believe, rightfully so — this is often a key consideration for commercial payers. One significant area where the analysis of commercial insurance coverage, and where the current definition of "appropriateness" may fall short, is in minimizing the disruption to those transitioning to Medicare coverage, especially in the treatment and care of chronic diseases. Using commercial insurance coverage in this way is one example of how it could result in CMS achieving its stated goal of ensuring Medicare beneficiaries have greater access to new medical technologies.

Again, the Medical Alley Association does not support codifying the current PIM standard. However, if CMS moves forward in doing so, we do support allowing an analysis of commercial insurance coverage as a positive proxy for satisfying "appropriateness," but do not support adding to the base criteria for meeting it.

Clarify That MCIT Coverage is Available to Non-Implantable Devices

Under the regulatory language put forward in the proposed rule, it is not clear that non-implantable devices are eligible for the MCIT coverage pathway. The Medical Alley Association urges CMS to modify this language to provide clarity that non-implantable devices are indeed eligible. This can be done by adding the words "or use" after "to implant," so that the regulatory language at 405.605(b) would read: "any reasonable and necessary procedures to implant or use the breakthrough device."

The end goal of this rule — as with the rest of the agency's work — is to improve the health and longevity of people on Medicare and Medicaid; medical devices play a critical role in that work, as does the agency's focus on patient safety. Bringing the best devices forward the moment we know which patients will benefit most from them and which patients are best served by other therapies will help all parties reach this ambitious goal.

Thank you again for the opportunity to comment on these proposed changes. We look forward to continuing to work with CMS on this and other proposed rules in the future.

Sincerely,

Shaye Mandle
President & CEO
Medical Alley Association