COALITION OF
Wound
Care
Manufacturers

April 16, 2021

Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-3372-IFC
200 Independence Ave., S.W.
Washington, DC 20201

Submitted electronically

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ‘‘Reasonable and Necessary’’ [CMS–3372–IFC]

Dear Acting Administrator Richter:

On behalf of the Coalition of Wound Care Manufacturers (“Coalition”), I am pleased to submit comments in response to the Interim Final Rule (IFC) regarding Medicare Coverage of Innovative Technology (MCIT) and the Definition of “Reasonable and Necessary”. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Many of our members continue to create innovative technologies to treat patients with wounds and as such we are very interested in this proposal.

GENERAL COMMENTS

The Coalition applauds CMS for the MCIT pathway rule which gets innovative technologies to market faster. Providing automatic, national coverage for FDA-designated breakthrough technologies for four years streamlines a very lengthy process once a product is approved by the FDA. The Coalition believes that with respect to the MCIT portion of the IFC, CMS provided ample time for stakeholder feedback and adequately addressed issues raised by stakeholders. While there are still some operational issues that will need to be addressed, these issues can be resolved through future rulemaking or sub-regulatory guidance. The Coalition recommends that the Agency move forward without further delays in implementing the final MCIT rule.

The Coalition however does not believe that the Agency addressed the concerns of stakeholders adequately with respect to the new definition of reasonable and necessary. The issues surrounding the reasonable and necessary definition are numerous and complex. Stakeholders addressed many of their concerns in the comments submitted and yet there is still much confusion surrounding this portion of the proposal. This portion of the rule should have been issued as a stand-alone proposal as the nature of it is separate from the MCIT rule and applies more broadly in the Medicare program. As such, we recommend that the definition of reasonable and necessary be removed from

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the MCIT final rule so as to not further delay the implementation of the MCIT pathway. Then CMS can issue a stand-alone proposed rule to address the complexities of the reasonable and necessary definition by providing more clarification and addressing all the gaps that were contained in this proposal.

SPECIFIC COMMENTS

The Agency specifically requested feedback from stakeholders on a number of different issues. The Coalitions response to some of those issues follows.

Operational Issues Relating to the MCIT Pathway

CMS determined that "a detailed description of coding and payment is beyond the scope of the MCIT rule and resides in other payment rules". The Coalition agrees. The Agency has already identified that some of the operational issues are outside the scope of the MCIT rule and it has recognized that they already have the authority to address these issues within other payment rules. Through the inpatient new technology add on payment process as well as the hospital outpatient transitional pass through payment status process, CMS already has experience with expediting coding and payment for medical devices with and even without the designation of "breakthrough". Furthermore, manufacturers often meet with CMS prior to FDA approval to educate the Agency on their new product, discuss the evidence surrounding it and answer the Agency's questions. These meetings will continue after the MCIT rule goes into effect.

We submit that CMS should move forward with implementing the MCIT final rule without further delay. The Agency effectively issued a proposed rule, received feedback from a diverse group of stakeholders and addressed the issues in the final rule. We believe that if the Agency needs to address any operational issues related to the MCIT rule, it can be done through future rulemaking or sub regulatory guidance.

Considerations in Connection With Potentially "Overlapping Rules,"

CMS is concerned that there might be overlapping rules with respect to benefit category determinations and payment policies for durable medical equipment which would not allow for public input on benefit category determinations (BCDs) before there is national coverage and that this possible overlap is an obstacle to implementation. The Alliance disagrees.

There is precedent since the Agency has issued overlapping proposals in the past and has still moved forward in the implementation of those rules. In this situation, the Agency is concerned with potentially overlapping provisions within the DMEPOS rule dealing with BCDs. The Coalition is not concerned nor do we believe that it has any bearing on the MCIT rule for the following reasons:

- The DMEPOS rule is specific to the class/category of products contained in the DMEPOS rule and is more limited in scope.
- The DMEPOS proposed rule stated that BCDs can be made on a case by case basis as claims are adjudicated.
- Benefit Category Determinations are not usually controversial and are usually straightforward.
- Both CMS and the Medicare Administrative Contractors (MACs) already routinely make benefit category determinations both with and without the opportunity for public notice and comment.

- Both CMS and the MACs make benefit category decisions when they pay claims for new technologies that are not the subject of an explicit coverage determination.
- In a majority of circumstances, the BCD for a particular item or services is either implied or assumed and BCDs are not made.

The possible overlap with the DMEPOS rule and specifically with respect to BCDs should not be an issue. In both cases: stakeholders were afforded ample time to provide feedback, the DMEPOS rule is more limited in scope, and CMS already has mechanisms in place to make BCDs when needed – but is not always necessary. Furthermore, the Agency followed the appropriate process and procedures in its establishment of the MCIT rule. Decisions regarding specific items and services should not rise to the level of warranting additional rulemaking and the provision of notice and comment. The MCIT rule should be implemented without further delay.

New Information Reflecting Increased Volume of Breakthrough Devices

CMS is concerned that it received new information once the comment period closed which reflects the increased volume of breakthrough devices and the effect the increased volume has on the impact analysis contained in the rule.

Our concerns include the following regarding this portion of the IFC:

1. In the IFR, the Agency cited the FDA information and a recent New England Journal of Medicine article which was provided and considered by CMS **AFTER** the comment period closed. As a matter of procedure, stakeholders were afforded ample time and opportunity to submit comments and accompanying information to the Agency for its consideration during the initial comment period. It is not appropriate for the Agency to now utilize data received after the fact. That said, the data submitted to the Agency also appears to be flawed in multiple ways. The fact that that 400 devices have been designated as breakthrough devices is irrelevant. The relevant information to be considered is how many of those 40O devices were actually **approved** by the FDA and of those approved how many would be **eligible** for the MCIT pathway. Those numbers are not contained in the article or in the data provided to the Agency by the FDA.

2. The number of devices that would be eligible and approved under the MCIT pathway are not as significant as CMS cited in the IFC. Just because a device is designated as breakthrough does not mean it will be approved, or if approved, would be eligible under the MCIT pathway – or that the manufacturer will opt into the MCIT pathway. In fact, the number is very small. Only 23 of the 400 technologies that have been approved as breakthrough devices by the FDA would have been eligible under the MCIT pathway. The designation as a breakthrough device is only the first step in a rather long and arduous process which includes: conducting analytical studies, conducting clinical studies, producing safety and efficacy data, submitting to the FDA for review multiple times along the way and ultimately gaining FDA clearance or approval. We believe that the measurement that should have been addressed is the rather under estimated number of breakthrough devices that will actually get approved and of those, which will be eligible and then opt into the MCIT pathway.

3. Finally, even CMS in its impact analysis, recognized that there would not be any effect on Medicare spending. In addition, while there could be a temporary cost for innovations, the new technology may also mitigate ongoing chronic health issues or improve efficiency of services and therefore reduce some costs to the Medicare program. While there may be an

increase in the future of the number of designated breakthrough devices, the number of those that are approved by the FDA that are eligible and actually opt in to the MCIT pathway will continue to be a rather small number.

All in all, the information received after the comment period closed which appears to reflect an increase in the volume of breakthrough devices is flawed and should not have an impact on the MCIT pathway moving forward. The volume of devices that the Agency suggests could impact the analysis is greatly overestimated as it used the number of devices that are designated as breakthrough devices and NOT those that are actually approved and eligible under this pathway. As stated above, the number of devices that may be approved and eligible is actually very small and as such should not impact CMS's decision to move forward in implementing the final MCIT rule without further delay.

Clinical Benefit/Protections and Medicare Beneficiaries

Manufacturers conduct significant research and clinical trials in order to bring products into the marketplace. All of their data is reviewed extensively by the FDA. If the FDA believes - based on its review - that a product is not safe or effective, the FDA would not provide approval or clearance for that particular product to enter the marketplace. The Agency considered this issue carefully and addressed stakeholders adequately. In fact, the Agency stated "the FDA requirements for demonstrating safety and efficacy are sufficient in determining whether to grant coverage to a breakthrough device under MCIT." The Coalition agrees with CMS.

The Agency further stated, "We note that our rule provides for the termination of MCIT coverage in instances where a medical device safety communication or warning letter is issued by the FDA, or if the FDA revokes market authorization for a device. These provisions will help protect beneficiary safety while ensuring that beneficiaries have more rapid access to new and innovative technology". In recognizing that not only the FDA requirements are sufficient but also providing for a check and balance at CMS so that the Agency is able to terminate MCIT coverage under certain circumstances demonstrates that the Agency thought out the issue of clinical benefits and instituted protections for Medicare beneficiaries. The FDA has been and will continue to be evaluating and making decisions with respect to the safety and efficacy of a given device for a particular population. This evaluation process has been in place and will continue to provide protections to Medicare beneficiaries while at the same time allowing for more rapid access to valuable technologies. CMS addressed all of the concerns issued by those submitting comments.

The collection of evidence does not stop at the FDA. In the IFC, the Agency encourages manufacturers to continue developing and collecting additional evidence that can be used after the MCIT pathway term expires in order for a product to receive permanent coverage. As a result, there is a very strong incentive for manufacturers to continue evidence development and collection in the Medicare population. All of this ultimately benefits the patient and the benefit of gaining access to these breakthrough technologies should not be delayed.

CMS adequately and accurately addressed the concerns of clinical benefit, safety and efficacy to the Medicare population. As identified by the Agency, there are ample checks and balances already in place to protect Medicare beneficiaries. The Coalition recommends that the concerns raised related to the clinical benefit and protections for the Medicare population have been adequately addressed and therefore the MCIT rule should be implemented and not be further delayed.

Definition of "Reasonable and Necessary"

Unlike the MCIT rule, the Agency did not adequately address the rule regarding codification of the definition of "reasonable and necessary". There are still significant concerns and gaps in the rule.

The Coalition maintains that the IFC contains two very distinct and severable rules – the MCIT pathway and the codification of the definition of "reasonable and necessary" for determining Medicare coverage. The Coalition submits that the codification of the new definition of "reasonable and necessary" is broader in its application than just to the technologies subject to the MCIT rule. The definition of reasonable and necessary will have significant implications in the Medicare program with respect to Medicare benefits and therefore it should have been issued as a separate rule.

The Coalition had significant concerns with the codification of the definition of reasonable and necessary which are outlined in our letter submitted to the Agency on November 2, 2020. We continue to be extremely concerned that the Agency will use commercial insurers to deny or restrict coverage for the Medicare population.

The Coalition recommends that CMS sever the rule addressing the definition of "reasonable and necessary" from the MCIT rule. CMS should issue another proposed rule with respect to the definition of reasonable and necessary – which would not only be more appropriate it could also be issued with more information being placed within it to address the commercial payer issue which was not codified, the significant gaps as well as the concerns of stakeholders.

Conclusion

The Coalition recommends that the Agency move forward with the MCIT final rule without further delay. The Coalition further recommends that the portion of the rule that addresses the definition of reasonable and necessary be severed from the IFC and be issued in a separate rulemaking process affording stakeholders a new opportunity for notice and comment. We appreciate the opportunity to provide our comments on the MCIT IFC. If you have any questions or would like further information, please feel free to contact me.

Sincerely

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