COALITION OF

Wound Care Manufacturers

October 15, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS – 3372-P2
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary''

Dear Administrator Brooks-LaSure:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am submitting comments in response to the proposed rule repealing the final Medicare Coverage of Innovative Technology (MCIT) and the Definition of "Reasonable and Necessary" rules. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. As manufacturers, we have a vested interest in this proposed rule and offer the comments below.

The Coalition is disappointed with CMS's decision to repeal the MCIT final rule. CMS has many tools at its disposal that it could have employed– including coverage with evidence development as well as sub regulatory guidance – to move forward with implementing MCIT which would not only have expedited access to breakthrough diagnostic and therapeutic devices for Medicare beneficiaries but would have helped address health inequities that the Agency has indicated in several rules they are interested in tackling.

One of the reasons the CMS cited for repealing the final rule was because some stakeholders were concerned that clinical evidence of safety and efficacy was not specific to the Medicare population. We do not agree with this concern. 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 Agency further stated in previous rulemaking, "We note that our rule provides for the termination of MCIT coverage in instances where a medical device safety communication or

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

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 that CMS is able to terminate MCIT coverage under certain circumstances, the Agency demonstrated that they thought out the issue of clinical benefits and instituted protections for Medicare beneficiaries – thus creating a check and balance. 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 these concerns issued by those submitting comments in previous rulemaking.

The collection of evidence does not stop at the FDA. Based on the MCIT final rule, CMS would have encouraged manufacturers to continue developing and collecting additional evidence that could have been used after the MCIT pathway term expired 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' concerns regarding evidence gaps and the development of additional clinical evidence could be minimized if CMS, through sub regulatory guidance were to:

1. Establish a process that would expedite coverage of innovative technologies,
2. Use and build upon successful elements of existing CMS processes and
3. Seek an agreement on an evidence development plan for the MCIT period so that the Agency has received assurances that clinical evidence supports improved outcomes for Medicare beneficiaries.

CMS adequately and accurately addressed the concerns of clinical benefit, safety and efficacy to the Medicare population in previous rulemaking. As identified by the Agency, there are ample checks and balances already in place to protect Medicare beneficiaries. The Coalition does not agree with the issues recently cited in the proposed rule to justify the repeal and as a result recommends the Agency should implement the MCIT rule – it should not be repealed.

The Agency was also seeking feedback on existing pathways for innovative technology. Current pathways exist for new technology add-on payments in the FY 2020 Inpatient Prospective Payment System (NTAP) and outpatient transitional pass-through (TPT) payments in the Outpatient Prospective Payment System as well as the National Coverage Determination (NCD) process, Local Coverage Determination (LCD) process, Coverage with Evidence Development (CED), and Parallel Review claim-by-claim adjudication. However, most of these pathways are insufficient to address the different types of new technologies coming into the marketplace. NCDs, and NCDs with CED, are developed only for technologies that could have a large impact on Medicare, leaving out many types of technologies that could better address health disparities or provide a significant benefit to a smaller Medicare patient population, including minority and underserved populations where no, or limited, alternatives exist.

Furthermore, a significant amount of time can elapse between marketing authorization of an innovative medical device by the Food and Drug Administration (FDA) and the issuance of coverage policies providing access to the device for Medicare beneficiaries. This "coverage gap" is significant as it is difficult to predict the time it will take to navigate the Medicare coverage process or the evidence that will be required. Medicare beneficiaries often face difficulty accessing the new technologies, including denials of coverage by Medicare Administrative Contractors (MACs) and

Medicare Advantage plans based on a general finding that the technology is "experimental or investigational" without any evidentiary review. As a result, beneficiaries must pay the full cost out of their pocket for such new therapies which further creates disparities and inequities in treatment within the Medicare population. Additionally, while Medicare Advantage plans are required to cover all Part A and Part B covered services, many MA plan policies do not align with traditional Medicare coverage, exacerbating the coverage gap for those beneficiaries enrolled in those plans.

The MCIT pathway is meant to guarantee Medicare coverage only for breakthrough diagnostic and therapeutic devices, which, by definition, are devices that provide more effective treatment or diagnostics options for those with life-threatening or irreversibly debilitating human conditions. Because breakthrough devices address unmet needs for patients, it is critical that patients with serious conditions have immediate access to them. Without timely coverage, Medicare beneficiaries would likely not be able to benefit from innovative advances until a significant period of time has elapsed after authorization from the FDA, creating preventable delays in access.

CMS has been very focused on addressing health inequities and disparities in treatment. Yet when given the opportunity to bring these types of innovative technologies to market quicker – CMS has determined that this rule should be repealed – despite the fact that these technologies could possibly address the very health inequities and disparities in minority and underserved populations the Agency is trying to correct.

The Coalition requests that CMS not repeal the MCIT final rule. The Agency has at its disposal the ability to move forward with the implementation and make enhancements to the MCIT program through sub regulatory guidance and already established coverage with evidence development protocols. We appreciate the ability to provide our comments and hopes that the Agency adopts our recommendations. If you have any additional questions or would like further information, please do not hesitate to contact me.

Sincerely,

Karen Ravitz, JD
Health Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296
Karen.ravitz@comcast.net