HFSA
HEART FAILURE SOCIETY OF AMERICA
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October 15, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Submitted electronically via www.regulations.gov

Re: CMS-3372-P2; Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Dear Administrator Brooks-LaSure:

On behalf of the Heart Failure Society of America (HFSA), I am writing to voice concern about CMS' proposed rule to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule, which was published on January 14, 2021, with an original effective date of March 15, 2021, but subsequently delayed until December 15, 2021. HFSA is a multidisciplinary organization working to improve and expand heart failure care through collaboration, education, research, innovation, and advocacy. The vision of the HFSA is to significantly reduce the burden of heart failure. As such, we strongly support policies that would enhance patients' access to devices that are critical for diagnosing and treating conditions that could be life threatening, and that help close the gap in inequities that persist in healthcare.

In previous comments to your agency, the HFSA expressed support for the underlying goals of the MCIT rule, which aims to establish a new Medicare coverage pathway for devices designated as breakthrough by the Food and Drug Administration (FDA).

The HFSA strongly supports providing Medicare beneficiaries with faster access to new, innovative medical devices and urges CMS to revisit, without delay in 2022, a pathway that would grant more immediate CMS coverage for critical FDA-approved breakthrough devices. Patients who need access to breakthrough devices have, by definition, debilitating or life-threatening chronic conditions with limited or no treatment options. For example, patients with heart failure and recalcitrant congestion and/or low cardiac output despite guideline-directed medical therapy have an average mortality of >50% at 6-12 months. Additionally, readmission rates and costs are high for these patients. Novel interventions that may help reduce mortality, readmission rates and costs among these patients are highly supported by the HFSA. When a device that treats these unmet clinical needs achieves FDA approval, clinicians should be empowered to analyze the underlying evidence of efficacy and safety and make decisions based on individual patients' needs.

Currently, Medicare Administrative Contractors (MACs) continue to make decisions one-by-one about whether to cover procedures utilizing FDA designated breakthrough devices. This results in a process that is unnecessarily duplicative, undermines the medical authority of licensed providers, and most importantly, limits access to Medicare beneficiaries. The MCIT pathway would alleviate that concern, providing both clinicians and their patients clear access to technologies that the FDA has deemed safe and effective.

HFSA also urges CMS to ensure that devices that are eligible for entrance into the MCIT pathway based on the original March 15, 2021, effective date are not rendered ineligible

based on timing provisions in past versions of this rule. We encourage CMS to draft a rule such that all technologies able to opt-in to MCIT are eligible for the full 4-year coverage period instead of a truncated portion of it or no coverage at all.

In summary, HFSA supports providing Medicare beneficiaries with timely access to life-changing therapies and urges CMS to finalize such a pathway as soon as possible.

Thank you for the opportunity to comment. If you have questions or require additional information, please contact Sue Ramthun at sramthun@hfsa.org.

Sincerely,

Mark Drazner, MD, MSc, FHFSA
President
Heart Failure Society of America