August 28, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

On behalf of the millions of patients suffering from serious, life-threatening, and chronic diseases that our organizations represent, we write to thank you for your leadership and commitment to making innovative medical treatments and technologies more accessible and available to Medicare beneficiaries. Access to the latest safe and effective medical treatments and technologies is critical to Medicare beneficiaries and their families, all deserving to live longer, healthier lives.

We appreciate that the Centers for Medicare and Medicaid Services (CMS) recently issued the proposed Transitional Coverage for Emerging Technologies (TCET) procedural notice. TCET represents a good first step toward fostering patient access to new devices and technologies that can save lives and improve patient health outcomes. We are concerned, however, that the proposed TCET notice does not go far enough in making available innovative new treatments to Medicare beneficiaries.

We believe significantly more needs to be done to ensure patients have timely access to new technologies, soon after they are approved by the Food and Drug Administration (FDA). CMS should establish a separate, predictable, and transparent pathway for Medicare coverage of all innovative devices and technologies that can improve health outcomes and prolong life. Without continued action, many patients will continue to face challenges when attempting to access new lifesaving and life-enhancing technologies. We stand ready to work with CMS on creating more accelerated options for patients in need in addition to the proposed TCET program.

We kindly request that CMS take into consideration the following key modifications to improve access to new technologies under TCET.

First, the proposed TCET guidance potentially expands patient access to only a very small number of new medical technologies and would exclude many technologies and treatments that have the potential to extend life expectancy and improve outcomes in patients. Under the proposal, the Agency expects that no more than five devices with Breakthrough designation would be eligible to go through the TCET process annually, citing resource constraints. We believe CMS could use more resources in many areas, including within the Coverage and Analysis Group that will implement the TCET policy. We are committed to helping CMS receive those resources. However, we believe that if a product meets TCET eligibility criteria, it should have the option to pursue the pathway, with no restrictions on the number eligible annually.

Secondly, the TCET policy would not include diagnostic tests, claiming that they are a highly specific area of policy that historically had been delegated to specialized Medicare Administrative Contractors (MACs). Diagnostic lab tests are no more specific than other areas of medicine, and diagnostic lab tests

are not the only area where, historically, review has occurred under the local jurisdictions of MCMS should not exclude clinical diagnostic lab tests from TCET eligibility.

The third area of concern is with process. TCET lacks clarity on certain processes, such as the determination of Medicare benefit categories, coding, and payment. Better defining these steps and holding CMS to specific timelines would help ensure TCET achieves the goal of being an accelerated pathway for patient access to novel and innovative devices.

Additionally, we would like to see better transparency in the nomination process. Within TCET, there is no public tracking of TCET requests until the NCD process is initiated, and a tracking sheet is posted online. This means the nomination process, including the number of requestors and the number accepted into the pathway each year, would not be public. We believe CMS must provide greater transparency regarding the nomination process and urge that this be included in the final TCET notice.

Lastly, we urge CMS to continue to refine and expand TCET after implementation to include certain devices that do not have a breakthrough designation but still can confer clinically meaningful benefits to patients, including devices that save and extend lives, and those that address unmet patient needs. The current proposal is an incremental approach, but more must be done by CMS to meaningfully accelerate access and foster innovation. If CMS is truly committed to accelerating beneficiary and physician access to promising new technologies, CMS must–in addition to the proposed CED improvements under TCET–create a temporary, transitional national coverage policy for important new technologies.

Medicare beneficiaries with serious and life-threatening illnesses simply should not have to face unnecessary hurdles to accessing the treatments they need to extend their lives and improve their overall health and well-being. We thank you for your attention to this critically important issue and stand ready to work with you to ensure the implementation of these changes.

Sincerely,

American Cancer Society Cancer Action Network
COPD Foundation
GO2 for Lung Cancer
HealthyWomen
LUNGevity Foundation
National Brain Tumor Society
National Pancreas Foundation
Ovarian Cancer Research Alliance
Partnership to Advance Cardiovascular Health
Preventive Cardiovascular Nurses Association
StopAfib.org/American Foundation for Women's Health
The Lustgarten Foundation