



August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: File Code: CMS-3421-NC: Medicare Program; Transitional Coverage for Emerging Technologies

Dear Administrator Brooks-LaSure:

The undersigned members of the Cancer Early Detection Alliance (“CEDA”) appreciate the opportunity to provide comments on the Transitional Coverage for Emerging Technologies (“TCET”) Notice. This letter focuses on the importance of early cancer detection and improving the TCET pathway to allow greater access to early cancer detection technologies for Medicare beneficiaries.

CEDA represents a diverse group of national organizations including patient advocacy organizations, healthcare professional societies, and industry leaders, all with significant expertise in cancer care and early detection. CEDA’s mission is to promote and expand access to quality, equitable early cancer detection and care, with a specific focus on reaching underserved communities and addressing racial and ethnic disparities.

Cancer is the second leading cause of death in the U.S. after heart disease. In 2020, more than 600,000 Americans died from cancer.¹ Each year, more than 1.9 million new cancer cases are diagnosed.² Many cancers can be found early before the disease progresses to a more serious stage, and early detection screening tools have proven essential for preventing deaths from late-stage cancer diagnoses. Early detection of cancer saves lives, lowers costs for treatment, and increases the quality of life for patients and their communities.

The White House’s Cancer Moonshot set a goal to prevent more than four million cancer deaths by 2047. Early cancer detection is critical to accomplishing this goal and expanding access to cancer screenings is the first step. Several federal agencies have expanded programs and funding to facilitate increased access to early cancer detection. Already, the Centers for Medicare & Medicaid Services (“CMS”) has moved to improve access to lung and colon cancer screenings. We enthusiastically applaud CMS’s efforts to improve access to early cancer screenings and encourage continued work to ensure that all Medicare and Medicaid enrollees have access to critical early diagnostic tools.

The risk of cancer increases with years of life lived, and Medicare beneficiaries comprise the majority of individuals diagnosed with cancer. Medicare covers several cancer screenings as preventative services including for breast, cervical, colorectal, prostate, and lung cancers. Among Medicare beneficiaries, not all racial, ethnic, and socioeconomic groups have equal access to these early detection screenings, due

¹ Centers for Disease Control and Prevention (CDC) (2023). Cancer Data and Statistics. <https://www.cdc.gov/cancer/dcpc/data/>

² American Cancer Society (2022). Cancer Facts and Figures. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf>

to barriers such as transportation, negative experiences or mistrust of the medical industry, or long travel distances to care, leading to lower early cancer diagnosis rates and higher prevalence of cancer deaths in underserved communities. These disparities in early cancer diagnosis increased during the COVID-19 pandemic and resulted in increased late-stage diagnoses and death according to a 2023 cross-sectional study in *The Lancet*.³

New technologies in early cancer diagnostic tests that increase access and improve early cancer diagnosis rates for underserved or rural communities would greatly benefit Medicare beneficiaries and decrease the morbidity and mortality due to late-stage cancer diagnosis. CEDA actively supports and promotes increasing access to early cancer diagnosis for underserved communities and coverage of existing and new technologies that accomplish that goal.

TCET and Early Cancer Diagnostic Tests

CEDA is pleased to provide comments on CMS's published notice on how to improve the design of TCET to achieve more timely and predictable access to breakthrough technologies for Medicare beneficiaries. The new TCET pathway uses current national coverage determination ("NCD") and coverage with evidence development ("CED") processes to expedite Medicare coverage of certain "Breakthrough Devices," deemed as such by the Food and Drug Administration ("FDA"). For a medical technology to be designated a "Breakthrough Device" by the FDA, it must meet two criteria: 1) the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and 2) the device must either represent a new technology with no approved alternative or it offers significant advantage over existing alternatives.

While CEDA commends CMS for releasing a pathway for expedited Medicare coverage, the coalition has concerns regarding device eligibility and that by narrowing or excluding certain devices, such as cancer diagnostic tests, the TCET pathway falls short in achieving more timely access to early cancer diagnostic devices. As we know from data, cancer diagnoses improve when individuals reach the age of 65 and have access to Medicare, earlier diagnosis tools will be more critical for supporting Medicare enrollees in identifying cancer early and receiving earlier intervention to support a five-year survival rate.⁴ For these reasons, **CEDA urges CMS to consider including early cancer diagnostic tools that are FDA-designated Breakthrough devices in the TCET pathway rather than, as the notice indicates, carving out lab diagnostic tools from the pathway and instead leaving the majority of those coverage decisions up to Medicare Administrative Contractors ("MACs").**

The TCET notice defines appropriate candidates for the TCET pathway as including those devices that are:

- Certain FDA-designated Breakthrough Devices;
- Determined to be within a Medicare benefit category;
- Not already the subject of an existing Medicare NCD; and
- Not otherwise excluded from coverage through law or regulation.

Several early cancer diagnostic tests have been granted a Breakthrough Device designation by the FDA and would qualify as an appropriate candidate for the TCET pathway according to that definition. Some

³ Han, Xueson et al. (2023). Changes in cancer diagnoses and stage distribution during the first year of the COVID-19 pandemic in the USA: a cross-sectional nationwide assessment. *The Lancet*. vol. 24, issue 8, August 2023. doi.org/10.1016/S1470-2045(23)00293-0

⁴ Patel, D; He, H; Berry, M; et al. Cancer diagnoses and survival rise as 65-year-olds become Medicare-eligible. *American Cancer Society Journals*. <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.33498>

of these early cancer diagnostic tests fit into the five Medicare benefit categories for cancer screenings while others are categorized under the lab diagnostic test benefit category.

Lab diagnostic tests, unlike any other Breakthrough Devices fitting into a benefit category, according to the notice, would mostly be deferred to the MACs instead of achieving accelerated national coverage through the TCET pathway. The TCET Notice states, “We believe that the majority of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by the MAC through existing pathways.” Lab diagnostic tests are the only category of FDA-designated Breakthrough Devices which are specifically referenced in the TCET notice as significantly less likely for TCET eligibility. While this statement indicates that CMS *can* consider diagnostic lab tests for the TCET pathway to coverage, it implies that it is unlikely that lab diagnostic tests would be selected. It becomes even less likely considering that CMS plans to accept no more than five TCET candidates per year because of resource limitations.

CEDA is concerned that deferring coverage decisions to the MACs could result in later coverage decisions and inconsistent reimbursement across different regions that would complicate and disincentivize innovation and implementation. Those delays and regional inconsistencies would reduce access to early cancer diagnostic tests which could reduce cancer morbidity and mortality.

CEDA is concerned that the TCET pathway is not designed to accept current and future early cancer diagnostic technologies that would be covered under diagnostic lab tests. As the notice is now written, it discourages innovators in early cancer diagnostic technology whose devices do not fit in the five cancer screening benefit categories from pursuing the TCET pathway. Opening the TCET pathway to encourage coverage of early diagnostic lab tests, such as early cancer diagnostic technology, could ensure that Medicare individuals are receiving more timely access to early cancer screening and reducing cancer related deaths as in-line with the President’s Moonshot goal. **We ask CMS to clarify when diagnostic lab tests would be selected for the TCET pathway and consider amending the TCET pathway notice to allow lab diagnostic tests eligibility for TCET in the same manner as other Breakthrough Devices instead of largely excluding them from TCET.**

We appreciate your consideration of our comments. CEDA welcomes the opportunity to engage in further dialogue with CMS on this issue and any issues related to early cancer detection. Please contact CEDA Coalition coordinators at Peggy.Tighe@PowersLaw.com, Taryn.Couture@PowersLaw.com, and Natalie.Keller@PowersLaw.com or by phone at 202-466-6550.

Sincerely,

The Undersigned Members of CEDA

◆ *Colon Cancer Coalition*

FORCE: Facing Our Risk of Cancer Empowered ◆

◆ *LUNgevity Foundation* ◆ *Ovarian Cancer Research Alliance*

◆ *Prevent Cancer Foundation* ◆ *ZERO Prostate Cancer*