NATIONAL HEALTH COUNCIL

August 28, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

RE: Transitional Coverage for Emerging Technologies

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide input to the Centers for Medicare and Medicaid Services' (CMS') notice on Transitional Coverage for Emerging Technologies (TCET)

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable, equitable health care. Made up of more than 150 national health- related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC has supported efforts to create a coverage pathway for new and emerging medical devices and technologies. Without coverage, advances in technology will not benefit patients. We appreciate that CMS has taken this important step to creating a program to advance coverage for emerging devices. For many patients, technology is an area where advances are making tremendous progress in increasing health and wellbeing. The NHC supports efforts to get emerging technology to patients as efficiently and safely as possible. We particularly note that this notice was issued in parallel to new guidance to improve the coverage with evidence development (CED) pathway. Since a strong CED pathway is critical to increasing access to breakthrough technologies, we submit our comments on TCET as an addition to our comments on the new CED guidance.

Our specific recommendations are below.

Scope of the Proposal

New technologies generally fall into three categories. Some devices meet the reasonable and necessary criteria and are appropriate subjects for a national coverage

determination. Some are promising, but need more evidence relevant to the Medicare population and may not yet meet the “reasonable and necessary” standard, and thus can only be covered under CED. Finally, some are reasonable and necessary, but additional data from real world use of the technology is needed to formulate a long-term national coverage policy. CMS currently defers coverage decision-making on items and services in this latter category to its local Medicare Administrative Contractors (MACs). This results in a patchwork approach to access that does not serve patients well. We request that the TCET program be designed in a way to minimize these geographic variations in coverage.

One concern is the limited number of devices that will enter the program. CMS projects that resources will support approximately five devices a year entering this program. This small scope could present barriers to patients accessing needed technologies. In addition, there is no way to predict at what point new products may be nominated for entering the program. If the available slots are full when an extremely promising technology is nominated, we may need to delay consideration of that device solely on timing and capacity issues. There needs to be a way of assuring that the system can expand and contract to address need and opportunity. We encourage CMS to work with advocates and industry to increase capacity. To do that, CMS needs to be transparent about what resources are needed to achieve a higher capacity.

Need to Include Diagnostics

In the notice, CMS states that “Diagnostic lab tests are a highly specific area of coverage policy development, and CMS has historically delegated review of many of these tests to specialized MACs. 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." Diagnostic advances can be impactful for patients, particularly those with rare diseases for whom a diagnosis may be one of the most difficult parts of their patient journey. The NHC believes that CMS should clarify that diagnostics should be eligible for the TCET program when appropriate and work with advocates to increase resources to help include as many as possible.

Patient Engagement

In our comments on the proposed CMS guidance on CED, the NHC offered the following recommendation on patient engagement. We think that this level of engagement should be built into the TCET program as well.

> *“CMS currently seeks input on proposed coverage policies through the National Coverage Determination (NCD) process, but patients do not have a way to directly engage with the agency on the choice to apply CED requirements. As with all health care decisions that CMS and others in the health care ecosystem influence, the NHC recommends that CMS consult patients on how imposition of CED might impact:*

- *Beneficiary access to treatment (e.g., geographic barriers)*
- *Beneficiary health and outcomes (e.g., from delayed access to care)*
- *Beneficiary and caregiver experience (e.g., quality of life and other factors).*

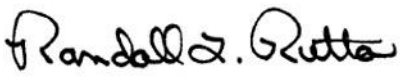
If CMS determines that it will utilize CED, it should also consult patients on study design protocols and outcomes of relevance to transitioning to full coverage for the product or service.

The need for patient engagement in trial design, choice of outcomes most important to patients, and other parts of the CED decision making process is not directly addressed in this guidance. In the past, the primary role of patients has been limited to their role as study subjects. Understanding their ability and willingness to participate in studies is critical. We need to make sure that study design is as least burdensome as possible and supports the patient's successful participation in trials. If there are issues with participation, the patient perspective can also identify barriers that can be overcome. In both examples, engaging patients both in study design and implementation will result in better outcomes. In addition, when designing studies, identifying measures and outcomes that matter to patients is another key area of engagement. Over the past two decades, stakeholders have collaborated to develop best practices for identifying concepts important to patients and developing corresponding patient-centered outcome measures. The NHC urges CMS to make sure that all aspects of the CED process properly engage patients."

Conclusion

Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
Chief Executive Officer