PIPC Partnership to Improve Patient Care

August 28, 2023

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

Dear Administrator Brooks-LaSure:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to comment on the Transitional Coverage for Emerging Technologies (TCET) notice.

Since its founding, the Partnership to Improve Patient Care (PIPC) has been at the forefront of applying principles of patient-centeredness to the nation's health care system – from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that achieves value to the patient. Having driven the concepts of patient-centeredness and patient engagement in the conduct of research, PIPC looks forward to bringing the voices of patients and people with disabilities to the discussion of how to advance patient-centered principles throughout an evolving health care system.

PIPC is aligned with CMS' goal of making innovative medical technologies more accessible and available to patients. It is imperative that as new technologies are developed and approved, patients are able to quickly and easily access them without delays and barriers that can lead to further declines in their health. With this in mind, we would encourage CMS to consider the following comments to strengthen the TCET pathway and encourage more robust patient access to innovative technologies.

There should be a more robust and formalized process for the patient perspective to be incorporated through the TCET process.

Input from impacted patient populations will be critical to CMS throughout this process. CMS should lean on patient experts as they develop their NCD criteria and refine what evidence will be collected throughout the CED process. While CMS recognizes the importance of stakeholders in the proposed rule, we recommend personalized avenues for patient and disability communities to provide feedback about their lived experience. PIPC suggests that CMS formalize a more robust process for stakeholder feedback with a goal of prioritizing patient and disability engagement throughout the TCET process. As proposed, CMS provides one public comment period for the NCD and suggests that if stakeholder groups miss the formal opportunity to comment, they may post feedback on their public websites and make CMS aware of this. PIPC encourages CMS to take a step beyond this and incorporate additional formal opportunities for feedback from impacted patients and people with disabilities.

Ultimately the TCET pathway will greatly impact which technologies patients are able to access when, so it is imperative that CMS incorporate outcomes that matter to patients in its decision-making process. It would be beneficial for CMS to host a patient listening session for each NCD under consideration to assess the outcomes that matter to impacted patients and people with disabilities. It would also be useful to convene advisory committees made up of relevant experts from the patient, disability, and provider communities to advise CMS throughout the entire TCET process, enabling CMS to receive relevant feedback earlier. We would encourage CMS to build on the engagement best practices of entities such as the Patient-Centered Outcomes Research Institute (PCORI).[1] Similar to PCORI, CMS and sponsors of data collection activities should establish a predictable process for engagement in the CED process and the TCET pathway. This includes meaningful roles for patients and people with disabilities throughout the process, including in MEDCAC deliberations and in the implementation of data collection.

CMS should clearly acknowledge and abide by the laws barring use of QALYs and similar measures as it refines the CED process.

CMS acknowledges in the TCET notice that the TCET pathway would build upon CMS and AHRQ's ongoing collaboration on the CED NCD process and that it is likely that many NCDs conducted under the TCET pathway will result in CED decisions. CMS notes that it will be working with AHRQ to improve CED. As it works through that process, PIPC would like to ensure that CMS acknowledges that, by law, CMS cannot reference measures of effectiveness that devalue disabled lives or discriminate to determine whether a treatment will be subject to CED. We are concerned that the MEDCAC has referenced studies utilizing the quality-adjusted life year (QALY) in the past as part of its National Coverage Decision process, twice leading to a decision to subject a treatment to CED,[2,3] despite enactment of the Affordable Care Act (ACA) barring use of QALYs in Medicare coverage decisions.[4] As CMS and AHRQ work to build a more systemic framework for CED, we look forward to CMS acknowledging current law and its ban on using QALYs and similar measures to make Medicare decisions, including those related to coverage through CED.

---

[1] PCORI, "Engagement Rubric for Applicants," *Patient-Centered Outcomes Research Institute*, last modified June 6, 2016, https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf.

[2] Tamra Syrek Jensen, et. al., "Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers," Medicare Coverage Database, Centers for Medicare and Medicaid Services, August 7, 2019, https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=291.

[3] Tamra Syrek Jensen, et. al., "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease," Medicare Coverage Database, Centers for Medicare and Medicaid Services, January 11, 2022, https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=305.

[4] House of Representatives, Congress. 42 U.S.C. 1320e - Comparative clinical effectiveness research. U.S. Government Publishing Office, https://www.govinfo.gov/app/details/USCODE-2010-title42/USCODE-2010-title42-chap7-subchapXI-partD-sec1320e

The TCET pathway should strive to make as many innovative technologies available to patients as possible.

It is imperative that patients and their doctors are able to make decisions as to the best course of treatment. Once a therapy or technology is approved by FDA, additional barriers should not keep patients from being able to access the treatment course deemed best for them by their physician. With this in mind, we would urge CMS to utilize the TCET pathway to bring as many innovative technologies to patients as possible. In the current TCET notice, CMS indicates that it anticipates that no more than five devices would be eligible to go through the TCET pathway annually. We would encourage CMS to reconsider this decision and open the pathway to a greater number of devices. If a product meets all the TCET criteria, we believe it should be given the option to pursue the pathway, as this will facilitate the availability of more technologies to patients with fewer barriers faster. This is also another example of how patient engagement is vital – if CMS limits the TCET pathway, patient input should be given significant weight in determining the products that will have the most impact.

In conclusion, PIPC appreciates CMS establishing the TCET pathway and taking steps to make innovative devices available to patients with fewer barriers to access. We would encourage CMS to consider more robust avenues to meaningfully engage patients and to ensure this pathway provides broad meaningful access to novel technologies.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care