

# United States Senate

WASHINGTON, DC 20510

May 7, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma,

We write regarding Medicare's proposed coverage decision for chimeric antigen receptor (CAR) T-cell therapies released on February 15, 2019. We appreciate your agency's efforts to ensure that Medicare coverage for these novel medicines reflects an evidence-based understanding of the safety and efficacy of these therapies. Given the goal of patient access to this evolving form of cancer care, we ask for your consideration of changes to the proposed coverage decision that can accommodate both FDA-approved and future CAR T-cell therapies and ensure patient access to this technology.

Precision and personalized medicine, such as cellular therapy, is a rapidly advancing field that holds promise for many patients diagnosed with life-threatening disease. As a result, appropriate data collection to ensure the quality and efficacy of such treatments is an important issue that must be carefully considered. We therefore support the Centers for Medicare and Medicaid Services' (CMS) desire to collect additional data on the clinical outcomes of Medicare patients who receive CAR T-cell therapy given that this population is not traditionally well represented in clinical trials. However, the proposed collection of clinical data may be repetitive and unnecessarily burdensome since much of this information is already being collected as part of the Center for International Blood and Marrow Transplant registry. With this concern in mind, we urge CMS to develop policy that will support and increase the exchange and collection of important clinical data while also eliminating unnecessary barriers to new therapies and new methods of administering these treatments.

As CMS determines Medicare coverage criteria on patient eligibility and facility, we ask your agency to consider the following modifications to the Medicare's coverage decision:

- 1. Establish patient eligibility criteria that ensures patient access to all FDA-approved indications for CAR-T** – While currently approved therapies are only indicated for patients whose diseases have either relapsed or for patients whose previous treatments have failed, clinical trials show promise for CAR-T as a front-line therapy in other aggressive cancers. When clinically appropriate according to FDA guidance, Medicare beneficiaries should have access to these treatments.
- 2. Cover CAR T-cell therapies in appropriate sites of care that meet FDA and CMS safety standards** – We suggest that CMS ensure patient access to CAR T-cell therapies administered in all sites that meet the specific safety protocols outlined in Medicare's proposed coverage decision and the FDA's requirements.

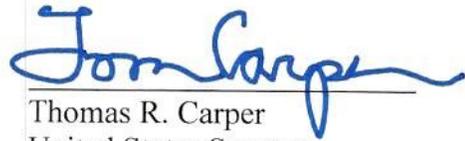
Lastly, we want to highlight the importance of ensuring that there is no unnecessary delay in patient access as a result of collecting clinical data and evidence. We understand that in order to achieve this objective, CMS must approve at least one patient registry that can be operational by May 17, 2019 when this coverage decision is finalized. If not, we ask you to provide an extension of the compliance deadline for the new patient registry until it is fully operationalized. Patients that may benefit from CAR T-cell therapy have often exhausted every other available treatment option and are already suffering greatly from the burden of their disease. We urge CMS to work quickly and transparently with stakeholders to avoid any disruption in patient access to these treatments.

Thank you for your consideration of these issues. We appreciate CMS' efforts to bring the best possible care to Medicare beneficiaries, and want to work together with you and your team to ensure patient access to the most effective therapies.

Sincerely,



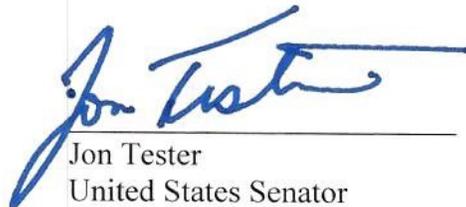
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