

Congress of the United States
Washington, DC 20515

October 29, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Dear Administrator Verma:

As Members of the House Ways & Means Committee with jurisdiction over the Medicare Program, we have a responsibility to ensure that Medicare beneficiaries have access to high quality health care. It is with this responsibility in mind that we are writing to highlight the need for continued work on Medicare reimbursement for Chimeric Antigen Receptor Therapies (CAR T) that are currently used in the treatment of relapsed and refractory cancers. We urge CMS to continue to engage the public and work with providers to determine solutions to ensure Medicare beneficiaries have access to CAR T therapies both now and looking ahead at future immunotherapy innovation.

The Food and Drug Administration (FDA) approvals of CAR T therapies in 2017 marked a milestone in the way cancer is treated and open up a new treatment option for thousands of patients for whom traditional cancer therapies have failed. Patients with leukemia and lymphoma receiving CAR T therapy have typically exhausted all other treatment options, including chemotherapy, radiation or stem cell transplant. Clinical trial data shows that these innovative therapies can produce dramatic and lasting results in patients.

CAR T holds the potential to revolutionize cancer treatment. Each treatment is individual to the patient by genetically engineering a patient's T-cells to target a specific tumor-associated antigen. Cells are collected from patients and then delivered to the manufacturer where the molecularly engineered receptors are inserted into the cells and then reproduced. The new CAR T cells are then returned to the hospital where they are infused into the patient. This infusion requires close oversight and care by healthcare providers both during and after the treatment. Most patients experience adverse side effects in the days following the infusion and often require prolonged inpatient hospital stays. This results in high costs for both the services associated with CAR T therapy and the drug.


Medicare inpatient reimbursement for these life-saving therapies has proven to be a challenge. We appreciate that the Centers for Medicare and Medicaid Services (CMS) in rulemaking for the Inpatient Perspective Payment System (IPPS) has acknowledged the challenges facing patients and CAR T therapy providers and has expressed a willingness to work


with the community to address concerns with access to CAR T therapy. We appreciate that CMS has expressed an interest in exploring new payment options, including value-based arrangements, for drugs administered in the outpatient setting. However, we urge CMS to similarly examine payment options within the inpatient setting. CMS should also focus on the setting of care where CAR T is almost always administered: IPPS hospitals and PPS-exempt cancer hospitals.

While we appreciate that CMS engaged with a variety of stakeholders throughout the rulemaking process, we believe there is a lot more work to be done to improve access to CAR T therapies currently available, while also paving the way in the Medicare program for future CAR T therapies. CAR T marks the beginning of the pipeline of many innovative therapies. There are currently over 400 clinical trials testing the effectiveness of these therapies across a wide variety of blood cancers and solid tumors. This is just the tip of the iceberg when looking at the innovation that is occurring across all immunotherapy and gene therapy. It is critical that the Medicare program keep up with this exciting innovation so Medicare beneficiaries can access these ground-breaking treatments and, in some cases, life-saving therapies.

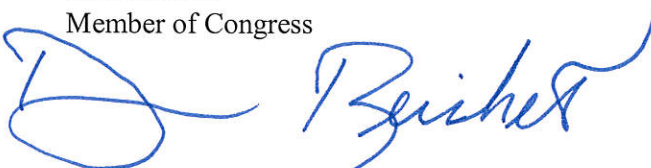
We recommend that CMS quickly bring together all of the relevant stakeholders including PPS hospitals and PPS exempt cancer centers, physician groups, patient representatives, scientific experts and CAR T manufacturers for a formalized and collaborative technical expert panel (TEP) to work towards improving reimbursement for CAR T therapies in the inpatient and cancer hospital setting in order to promote greater access to such therapies both now and in the future. We encourage the TEP to develop unique payment options that would pave the way for innovative immunotherapy treatments for years to come.

Sincerely,



Suzan K. DelBene
Member of Congress

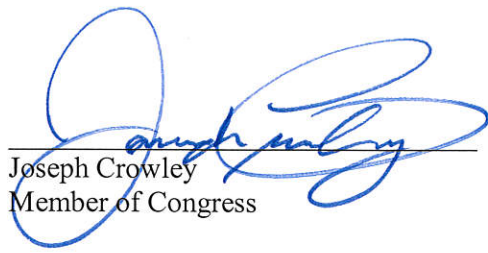

Erik Paulsen
Member of Congress


Terri A. Sewell
Member of Congress

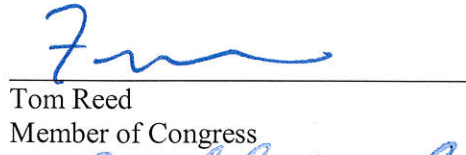

Dave Reichert
Member of Congress


Judy Chu
Member of Congress

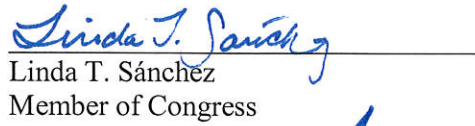

Vern Buchanan
Member of Congress



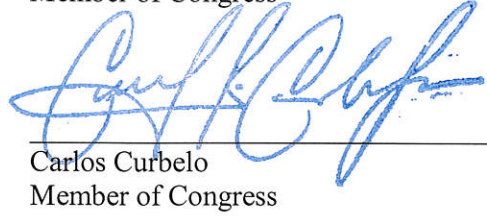
Joseph Crowley
Member of Congress



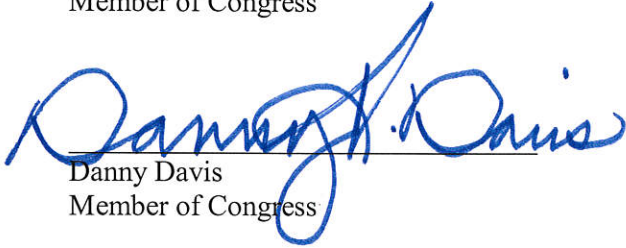
Tom Reed
Member of Congress



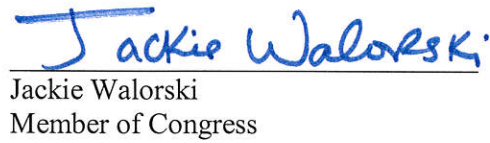
Linda T. Sánchez
Member of Congress



Carlos Curbelo
Member of Congress



Danny Davis
Member of Congress



Jackie Walorski
Member of Congress



Brian Higgins
Member of Congress



George Holding
Member of Congress



Ron Kind
Member of Congress