



April 2, 2020

The Honorable Seema Verma  
Administrator, Centers for Medicare and Medicaid Services  
Hubert Humphrey Building  
200 Independence Avenue, S.W. 445-G  
Washington, D.C. 20201

Dear Administrator Verma:

As the Centers for Medicare and Medicaid Services (CMS) works on proposed payment rules for FY 2021, the Healthcare Leadership Council (HLC) is writing to express support for patient access to life-saving Chimeric Antigen Receptor (CAR) T-cell therapies. Innovation in the treatment of cancer has led to transformative, lifesaving therapeutic options for patients whose care needs were previously unmet by contemporary treatments. CAR T-cell therapies represent a marked advancement in the field of cancer care and have proven to be lifesaving in the treatment of patients with certain types of refractory or relapsed cancers.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Medical centers, including both Prospective Payment System (PPS) Hospitals and PPS-exempt cancer hospitals, have been providing these innovative therapies which hold promising outcomes for patients that have few effective therapeutic options. We were encouraged that the FY 2020 Hospital Inpatient Prospective Payment (IPPS) Final Rule continued new technology add-on payments (NTAPs) through FY 2020 for the two CAR T-cell therapies approved by the Food and Drug Administration. Additionally, CMS' 2020 National Coverage Decision for CAR-T treatment was a significant step to expand access for Medicare beneficiaries in facilities closer to their homes. However, medical centers continue to face significant challenges related to reimbursement and temporary add-on payments are set to expire on September 30, 2020. It is critical that CMS develop appropriate reimbursement models to ensure that Medicare beneficiaries who require CAR T-cell therapies continue to have access to it, while also not negatively impacting reimbursement for or access to other valuable inpatient hospital services that may result from any budget neutral reweighting.

The current reimbursement model is unsustainable for institutions providing CAR T-cell therapies and has led to access barriers particularly among Medicare beneficiaries. These

access barriers have resulted in a two-tiered system in which commercially insured patients have greater access compared to Medicare beneficiaries. In FY 2019, CMS's payment policy for PPS hospitals left providers absorbing significant losses when administering CAR T-cell therapies to Medicare patients. While the FY 2020 new technology add-on payment offset up to 65 percent of the cost of the therapy, PPS hospitals faced an average loss of \$50,000 per case. When NTAPs expire this year, losses could more than double absent a stable payment mechanism. Additionally, for PPS-exempt cancer hospitals, which are ineligible for new technology add-on payments, the cap imposed by the Tax Equity Fiscal Responsibility Act of 1982 has proven inadequate to cover the actual direct costs of care for patients who receive CAR T-cell therapies. If medical centers continue to absorb substantial financial losses on a per-patient basis to treat Medicare beneficiaries with CAR T-cell therapies, the ability to provide them access to this lifesaving treatment is at risk.

We respectfully request CMS provide medical centers that deliver CAR T-cell therapies with a stable reimbursement model that adequately reimburses both PPS and PPS-exempt cancer hospitals for product acquisition and clinical care costs so they may continue to deliver innovative, lifesaving cancer therapies.

HLC appreciates this opportunity to provide these comments. Please contact Tina Grande at 202-449-3433 or [tgrande@hlc.org](mailto:tgrande@hlc.org) if there are any comments or questions about this letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary R. Greal".

Mary R. Greal