

June 25, 2018

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

RE: FY 2019 Medicare Hospital Inpatient Prospective Payment System and Coverage of Transformative Therapies

Dear Administrator Verma:

The undersigned organizations write to express our feedback and appreciation to the Centers for Medicare and Medicaid Services (CMS) on proposals in the Medicare Inpatient Prospective Payment System (IPPS) proposed rule that can help ensure timely and appropriate patient access to new innovations in treatments for some of Medicare's most vulnerable beneficiaries. It is the aim of our organizations to help ensure that coverage and reimbursement policies do not serve as a barrier to treatment for patients.

Innovations in treatments continue to revolutionize and deliver more personalized medicines for patients. New treatments are available or being developed that represent significant clinical advances and value for patient health outcomes – addressing serious diseases or high unmet medical need; serving small patient populations, including rare and orphan diseases; and providing substantial, durable health outcomes for patients. These so called “Transformative Therapies”, including cellular and gene therapies, are revolutionary and target treatment to specific patient populations or subsets of patient populations.

Our goal is to ensure that coverage and reimbursement policies keep pace with advances in medicines, allowing for patient access to the highest standard of treatment in the most appropriate site of care. For these reasons, we thank the Agency for proposing potential updates to the current inpatient payment structure to ensure patients and their providers have continued access to CAR T therapies.

While each of the undersigned organizations might, in individual comment letters, wish to provide additional clarity and detail around the proposals outlined in the IPPS proposed rule, we collectively urge the Agency to ensure that the reimbursement pathway chosen:

- Provides adequate provider and subsequent patient access in a manner that allows the selection of the most appropriate site of care and treatment product;
- Appropriately considers both the short-term and long-term implications of the reimbursement structure chosen;
- Creates flexibility for the adoption of future innovations into the IPPS reimbursement structure; and
- Continues to engage stakeholders to refine these reimbursement solutions in order to improve patient health outcomes while appropriately managing healthcare costs.

It is critical that the program adapt to support new innovations and continue to work with interested parties to meet the continuing needs of Medicare beneficiaries. Again, we urge the Agency to make updates consistent with the themes outlined above for Transformative Therapies. We look forward to continuing to work with the organization to address the shared goals of providing quality, patient-centric treatment that improves health outcomes and recognizes the substantial benefit of new and innovative therapies for patients.

Sincerely,

Alliance for Regenerative Medicine
Biotechnology Innovation Organization
Friedreich's Ataxia Research Alliance
Hemophilia Federation of America
Lupus and Allied Diseases Association, Inc.
Personalized Medicine Coalition