October 30, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: New Technology Add-On Payment (NTAP) Approval Timeline Changes

Dear Administrator Brooks-LaSure,

The undersigned organizations, members of an informal working group focused on patient access to Chimeric Antigen Receptor (CAR) T-cell immunotherapies, are writing to express our appreciation for the Centers for Medicare & Medicaid's (CMS) continued leadership in supporting CAR T-cell therapies and to provide feedback on the recent changes to the New Technology Add-On Payment (NTAP) approval timeline updates, as outlined in the FY2024 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule. This feedback was also reflected in a prior letter submitted by this working group to CMS on June 9, 2023, during the FY2024 IPPS proposed rule comment period.

CAR T is a transformative therapy that substantially improves outcomes for patients with multiple forms of lymphoma, leukemia, and multiple myeloma and provides hope for many more with other hard-to-treat cancers. As more CAR T therapies are approved, patients are being treated with CAR T earlier, for new disease types, and in diverse settings.

We applaud CMS for recognizing this innovative treatment with the creation of the Medicare Severity-Diagnosis Related Group (MS-DRG) 018 in 2021. We also appreciate CMS's ongoing thoughtful consideration of the New Technology Add-On Payment and its impact to help to bring new, innovative therapies to patients that need them, but express concern around the recent documentation and timeline changes to NTAP.

Providers rely on NTAP to be able to provide patients access to new and innovative therapies. As of August 1, 2023, CMS now requires a complete and active FDA marketing application authorization at the time of submission. This new documentation requirement, in addition to the reduction in approval timeline from 3 years to 2 years, could have a negative impact on patients by restricting Medicare beneficiary access to innovative therapies.

Companies seeking to pursue NTAP status on behalf of patients depend on a clear and consistent application submission deadline. This sudden change in requirements and timeline is expected to have an immediate, real-world impact on a new CAR T indication that is expected to come to market in 2024.

In light of these recent changes and their immediate impact on patients, we encourage CMS to consider the following in order to maintain NTAP's role of improving patient access to new technologies available in the inpatient setting:

- Reverse course and reimplement the original approval timeline of 3 years for New Technology Add-On Payments
- Provide a grace period or waiver of the new requirement for a complete and active FDA marketing application authorization for this first year of implementation

Our organizations encourage CMS to consider the items raised above and we look forward to working with CMS to further support novel treatments for unmet medical needs among cancer patients. For any questions, please contact ckoski@signaldc.com.

Sincerely,

American Society of Gene and Cell Therapy

BMT InfoNet

Cancer Support Community

HealthTree Foundation