April 9, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G 200
Independence Avenue, SW
Washington, DC 20201

**Re: Increased Reimbursement for Use of Chimeric Antigen Receptor T Cell Therapies**

Dear Administrator Verma:

We understand the Centers for Medicare & Medicaid Services (CMS) is currently addressing a range of difficult challenges related to the coronavirus response and we thank agency staff for their tireless efforts to support patients and providers as we navigate this unprecedented crisis. In the midst of these circumstances, we are cautious to raise additional issues, knowing that agency attention is rightly focused on this national emergency. But with an eye toward the future, and the needs of people with cancer, we wish to raise another issue for your consideration and are grateful for consideration at the appropriate time.

On behalf of our organizations, which collectively represent hundreds of thousands of people diagnosed with serious and life-threatening illness, we write to urge CMS to ensure patient access to Chimeric Antigen Receptor (CAR) T cell therapies and establish adequate, permanent Medicare reimbursement. CAR T therapy represents transformative treatment that has the potential to substantially improve outcomes for some patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL), B-cell acute lymphoblastic leukemia (ALL), and provides hope for many patients with other cancers. It is with these affected patient populations in mind that we urge CMS to ensure that beneficiaries' access to this potentially life-saving therapy is not compromised.

As you are aware, CMS' existing new technology payment for the current CAR T therapy will expire on September 30, 2020. To ensure American seniors can seek and receive CAR T treatment after the current fiscal year expires, we urge CMS to once and for all ensure reimbursement for hospital providers. A solution, such as a new Medicare Severity-Diagnosis Related Group (MS-DRG) for fiscal year 2021, can be formulated in a manner which reflects the true expenses associated with the administration of this novel therapy outside of the context of a clinical trial.

Of important note, according to a study published in the Journal of the American Medical Association (JAMA), adults with B-cell lymphoma not only have shown higher rates of survival when treated with CAR T, but evidence suggests health system costs are reduced when CAR T therapy is used earlier in treatment versus chemotherapy.[1] Additional data demonstrate that

1 Whittington MD, McQueen RB, Ollendorf DA, et al. Long-term Survival and Cost-effectiveness Associated With Axicabtagene Ciloleucel vs Chemotherapy for Treatment of B-Cell Lymphoma. JAMA. 22 Feb. 2019.

some patients may experience dramatic increases of life expectancy, gaining an average 12 years of life, following CAR T therapy.[2] Patients must be afforded the opportunity to access the most effective treatments recommended by their healthcare providers. Inadequate reimbursement can limit an institution's ability to offer CAR T cell therapy, thereby limiting patient access.

To ensure life-saving treatments are available to all those in need, our systems must evolve to reflect a rapidly changing healthcare landscape. Please support long-term solutions that protect patient access and adequately reimburse providers when developing the Fiscal Year 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule.

Sincerely,

American Cancer Society Cancer Action Network

Blood & Marrow Transplant Information Network

Cancer Support Community

CLL Society

Cutaneous Lymphoma Foundation

International Myeloma Foundation

Leukemia & Lymphoma Society

Lymphoma Research Foundation

Myeloma Crowd / CrowdCare Foundation

2 The Fast Pace of CAR T-Cell Innovation Caused an Array of Challenges in Treatment. AJMC Nov. 2019.