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Dear Ms. Syrek Jensen and Drs. Szarama and Paserchia:

The Association of American Cancer Institutes (AACI) represents 98 National Cancer Institute (NCI)-designated and academic-based cancer research programs that excel in cancer research, clinical care and education. AACI cancer centers and their regional community-based networks provide care for an estimated 700,000 newly diagnosed patients with cancer, representing as much as 40 percent of the nation's cancer burden. Cancer therapies have improved dramatically over the last several years, due to the development of novel therapies resulting from research conducted at the AACI cancer centers.

AACI appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the fiscal year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule outlining how CMS proposes to pay for chimeric antigen receptor T-cell (CAR T) therapies administered on an inpatient basis. CAR T therapies represent a critical advancement in treating malignancies. Evidence shows these therapies provide innovative ways to treat cancer by genetically reprogramming the patient's white blood cells to attach to their tumor cells and induce cancer cell death, resulting in significant increases in complete remission and survival compared to conventional chemotherapy.

In August 2017, CAR T immunotherapy tisagenlecleucel (Kymriah®) was approved by the Food and Drug Administration (FDA) for the treatment of pediatric and young adult acute lymphoblastic leukemia. A one-time infusion costs \$475,000. In October 2017, the FDA approved a second product, axicabtagene ciloleucel (YESCARTA®) for adult patients with certain types of large B-cell lymphoma. The cost of the YESCARTA® product has been widely reported as \$373,000 per treatment. In May 2018, a second approval for CAR T was granted to expand the Kymriah® treatment to adults with relapsed large B-cell lymphoma.

Nearly half of AACI's cancer centers are approved to offer CAR T therapies, however, there are

reimbursement obstacles associated with treating patients with CAR T on an inpatient basis. The cost for patient infusion ranges from \$350,000 to \$500,000. This may not include additional costs associated with the preparation and administration of the therapies. This also does not consider instances where patients must be monitored closely to ensure that side effects are not life-threatening.

AACI is encouraged that CMS is considering a number of reimbursement alternatives in its FY19 Proposed Rule that would ensure access to CAR T therapies. Despite the higher reimbursement rate proposed in this rule, and given the current DRG options, reimbursement would still be less than one-ninth of the cost of the list prices for these therapies. This reimbursement challenge could cause cancer centers to not offer Medicare patients life-saving blood and bone marrow transplants due to hospital reimbursement shortfalls.

In most cases, inpatient administration is necessary due to the intensity of post-administration care, but we expect that with more product experience, our cancer centers will be able to shift to providing these therapies as outpatient care. In addition, the personalized products offered to providers do not include opportunities for discounts or incentives for bulk purchases and carry limited product sourcing. This results in the cost of CAR T cells not varying by hospital or locality, putting pricing beyond providers' control.

Reimbursement rates currently do not cover additional procedures associated with CAR T therapy implementation, such as the cost of acquiring cells. In most cases, once the cancer center is reimbursed it is unable to cover the full cost associated with cell procurement, patient care, supplies, staff time, and other costs associated with administering these therapies. AACI requests that CMS collect and analyze data on total treatment costs, and use these data to formulate a payment structure that fully reimburses hospitals for the cost of administering these therapies, whether treatment is delivered in an inpatient or outpatient setting.

Additionally, it is essential that a long-term payment solution be established so that new gene therapies and combination therapies do not face the same reimbursement barriers. As new and innovative therapies are discovered and implemented, the potential high costs for these therapies need to be addressed. While there may not be a one-size-fits-all solution for ensuring full reimbursement, it is imperative that a payment structure be established that results in maximum access to CAR T treatment for Medicare patients.

Thank you for considering our views.

Sincerely,

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AACI President

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