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July 16, 2018

Maria Ellis

Executive Secretary for MEDCAC  
Centers for Medicare & Medicaid Services  
Center for Clinical Standards and Quality, Coverage and Analysis Group  
S3-02-017500 Security Boulevard  
Baltimore, MD 21244

Email: [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov)

Re: Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—August 22, 2018

Dear Executive Secretary Ellis:

The Alliance of Dedicated Cancer Centers (ADCC) welcomes the opportunity to submit comments for this meeting on the state of evidence for Chimeric Antigen Receptor (CAR) T-cell therapies, specifically seeking the MEDCAC's recommendations regarding collection of patient reported outcomes (PRO) in cancer clinical studies. In particular, we wish to comment on the use of evidence-based PRO assessments to provide information that impacts patients, their providers and caregivers after a CAR T-cell therapy intervention for the patient's cancer.

The ADCC is comprised of 11 of the nation's premier cancer hospitals; we are at the forefront of cutting-edge research and the translation of breakthroughs from the bench to the bedside. Many of our member hospitals participated in the clinical trials related to CAR T-cell therapies, and all our member hospitals are among the select few academic medical centers in the nation that are currently qualified to offer such therapies to patients.

The ADCC is a strong advocate of the use of PROs in quality measurement for several reasons. They provide outcome measurement in a timely manner. By definition, they are sensitive to the patients' perspective. Furthermore, PROs have been shown to improve symptom control, enhance communication, and increase patient satisfaction and sense of well-being. Recent studies have also reported a relationship between the administration of PROs and increased survival. Nevertheless, despite our strong support for the use of PROs in quality measurement, we do not believe that it would be appropriate to adopt PROs as a requirement for coverage of CAR T-cell therapies at this time.

The reasons for our opposition include the following:

- Systems and processes for administering and collecting PRO data are immature and not yet widely adopted across organizations. While the potential exists for PROs to yield rich and meaningful data for improving patient care, an unfunded mandate at this time creates a risk that patients will be denied access to centers that lack the infrastructure to develop and implement workable PROs data collection processes; moreover, introducing this mandate prematurely could create an incentive for centers to initiate less than rigorous data collection processes that impact the validity and reliability of results.
- As CAR-T cell therapy is an entirely new therapeutic intervention, evidenced-based interventions designed to address issues identified using PRO data are still under development
- The acute toxicity profile of CAR-T cell therapy, particularly the neurotoxicities, will make PRO data collection challenging, especially during the acute treatment phase
- There are several emerging PRO tools and there is not sufficient evidence to support which PRO instrument is best suited for this novel therapeutic intervention

We are sincerely appreciative for the opportunity to submit our perspective on this issue. Our clinicians and other technical experts are available as a resource for you; please do not hesitate to reach out whenever we may be of assistance. Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Karen Bird".

ADCC Executive Director