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Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: **Proposed National Coverage Determination for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)**

Dear Ms. Syrek Jensen and respective colleagues:

The Society for Immunotherapy of Cancer (SITC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) proposal for national coverage of CAR-T therapies approved by the U.S. Food and Drug Administration (FDA) under "Coverage with Evidence Development" (CED). With nearly 2,400 members representing 17 medical specialties, SITC is the world's leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. SITC aims to make cancer immunotherapy a standard of care.

SITC commends CMS for evaluating strategies towards providing Medicare/Medicaid coverage for lifesaving CAR-T therapies. Advances in immunotherapy are changing the face of cancer care. Ensuring all cancer patients have equal access to these lifesaving therapies is of the utmost importance. SITC membership wants to ensure the proposed NCD process involving CED, as well as any subsequent policies implemented at the conclusion of the National Coverage Analysis (NCA), does not hinder patient access or measurably slow the development of innovative, new treatments. ***We, therefore, urge CMS to consider the following key points as it goes through the review process relative to the unique aspects of CAR-T therapy.***

- **Consideration should be made upon any implementation of CED policies that the results of such policies do not hinder the future development of innovative immunobiologics.**
    - Descriptions of how the data will be collected through the CED mechanism should be more clearly articulated.
    - CMS should also clarify that the data collected via CED will not impact current or future policy coverage decisions. Instead, final clinical trial results should dictate these decisions.
    - The CED policy should also be flexible enough that in the event expansions are granted for immunobiologics that are currently approved by the FDA, that each new on-label use is deemed covered under the NCD.

- **If CMS deems that CED is necessary, then SITC recommends the agency take steps to use existing infrastructures of data reporting. This could streamline the reporting and data collection process and reduce the administrative burden on hospitals.**
    - As an example, the FDA has already mandated post-marketing studies of both of the currently approved CAR-T therapies. These observational studies require manufacturers of such CAR-T products to assess long-term safety by following at least 1,500 patients for 15 years after product administration. This infrastructure could be used if a CED is necessary.
    - Additionally, both CAR-T manufacturers require administering hospitals to be accredited by the Foundation for Accreditation in Cellular Therapy (FACT) prior to offering patients treatment. In turn, hospitals accredited by FACT must submit data to the Center for International Blood and Marrow Transplant Research (CIBMTR).
        - CIBMTR is currently collecting long-term data on patients receiving cellular therapy in the United States for on-going research within the field. CIBMTR has extensive experience collecting and analyzing data described under the current proposal and does so in a way to adjust for differences in patient populations and sites of care. Their current registry platform is widely considered to be the most streamlined and efficient for cellular therapy providers.

SITC actively supports on-going efforts to better study and define the value of CAR-T therapy, including a deeper understanding of the economic impact on patients, payers, industry and other stakeholders. We also welcome the opportunity to work with CMS to serve as a professional resource to CMS during this time of rapidly developing advances in the field.

We again appreciate the opportunity to submit our comments and urge CMS to consider the above key points.

Should you have any questions, please do not hesitate to contact SITC Executive Director, Tara Withington, at twithington@sitcancer.org.

Sincerely,

Tara Withington

Tara Withington, CAE,
Executive Director, Society for Immunotherapy of Cancer