The American Society of Hematology (ASH) represents over 17,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related disorders. These disorders encompass malignant hematologic disorders, such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions, such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. ASH members currently treat patients with leukemia and lymphoma with Kite’s Yescarta and Novartis’ Kymriah. In full disclosure, ASH receives commercial and medical education support from both Kite and Novartis.

The Society respectfully disagrees with the preliminary coding recommendations offered by CMS for Yescarta, code Q2041 and Kymriah, code Q2040. The significant issue of concern is the inclusion of clinical services, such as leukapheresis, with the payment for delivery of a CAR-T drug. The Society asks that CMS consider the following:

- Patients receiving CAR-T therapy are the sickest of the sick and have typically exhausted all other treatment options, including chemotherapy, radiation, or stem cell transplant. Unfortunately, because of this, there will likely be many instances when leukapheresis and dose preparation services will take place, but the infusion does not. CMS must release guidance on how hospitals are to bill for the services rendered.

- Additionally, if CMS’ intention is to include the leukapheresis service and dose preparation with the actual product in the Q-code, it is unclear when providers should drop the charges for the services provided. Do providers need to hold charges until the CAR-T infusion service is rendered? If so, this could mean holding charges for weeks, and possibly months. Holding charges like this would require a different workflow than is typical for hospitals, and will require additional administrative oversight to ensure accuracy. Again, CMS must release guidance on this in order to prevent confusion.

As CMS moves to create permanent HCPCS codes for these products, we are advocating for separation of the leukapheresis and other patient care and hospital services from the finished product itself. This therapy has the potential to save the lives of individuals who have exhausted all other treatment options. But unfortunately, because our current reimbursement systems and payment rates fall short of covering the costs for the services associated with CAR-T therapy, institutions are forced to make difficult choices on whether to provide the treatment, resulting in long waiting lists for patients to receive the therapy. It is imperative that we get the coding and associated billing procedures for the new and innovative treatments right the first time. With more CAR-T therapies for other conditions expected to receive FDA approval in the near future, the precedent set here will influence patient access to this entire class of treatment.