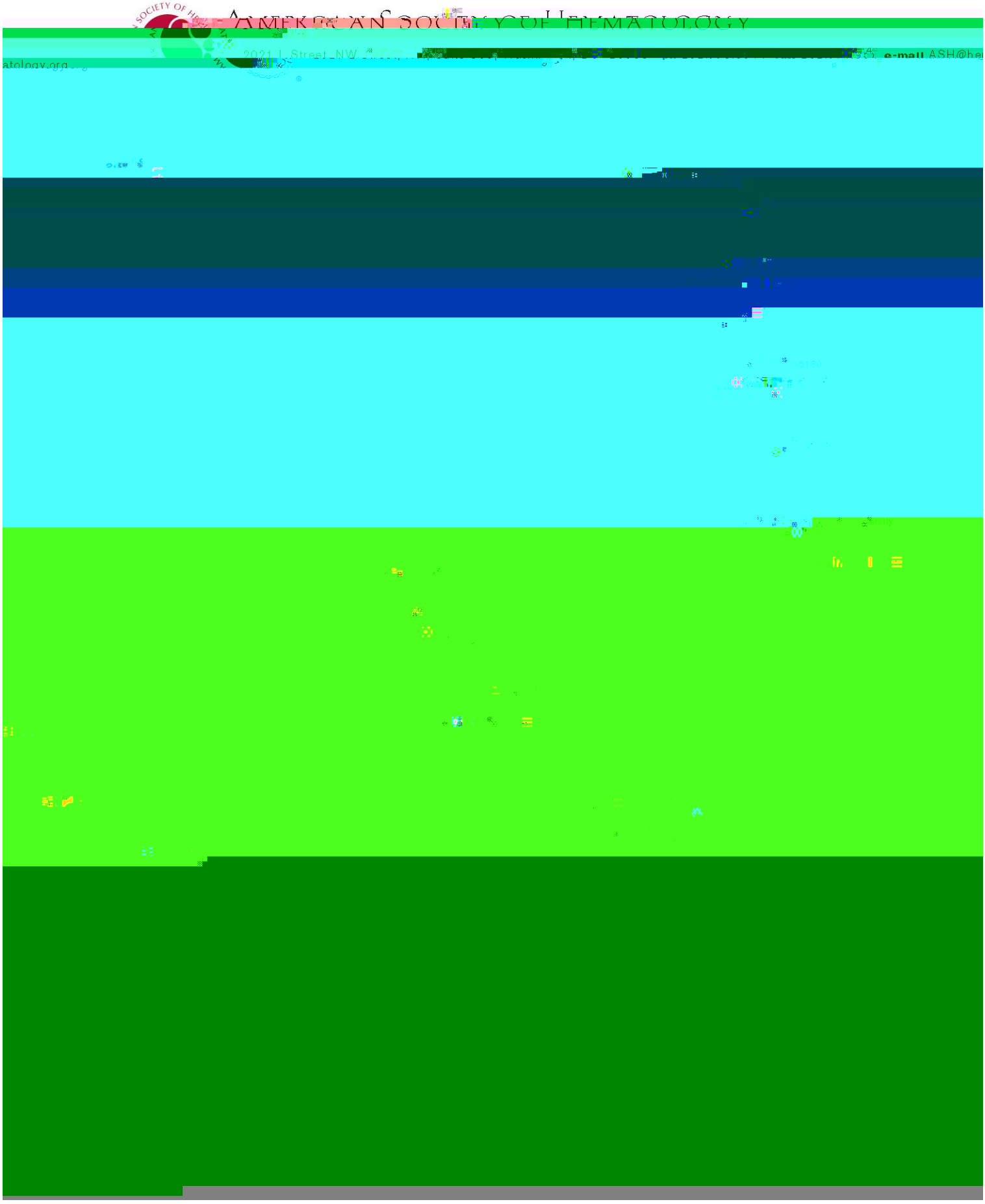

Patients receiving CAR T-cell therapy have typically exhausted all other treatment options, including chemotherapy, radiation, and stem cell transplant. Successful treatment with CAR T-cell therapy improves quality of life and increases survival for these patients. ASH has strong concerns that, as written, the proposed decision memo will narrow the already limited access to this therapy. The Society recommends that CMS eliminate the CED requirement and instead implement a National Coverage Determination (NCD) with a registry reporting requirement which will allow the agency to collect additional data on this therapy while mitigating the access concerns raised by the current policy.

CMS proposes to cover autologous treatment with T-cells expressing at least one chimeric antigen receptor (CAR) through CED when prescribed by the treating oncologist, performed in a hospital, and all of the outlined requirements are met. ASH recommends revising "autologous" to "FDA approved," thereby removing the tie to cell source. Kymriah® and Yescarta®, the two approved CARs, are the first therapies of their kind to be approved; however, there are numerous CARs currently under development that employ a different method of action. Because ASH recognizes that CMS prefers not to reopen its NCDs on a regular basis, this recommended change will provide a pathway to coverage for therapies ASH expects to be approved in next five years.

The patient requirements as proposed by CMS require a patient to have "relapsed or refractory cancer." ASH recommends CMS change this to cover patients with "FDA label indications." Although the two currently approved FDA products are approved for individuals with relapsed and refractory cancers, current clinical trials are underway

For collecting and analyzing patient reported outcomes (PROs), ASH recommends that CMS work closely with CIBMTR to implement a system that is least burdensome for providers and patients. ASH members recognize the importance of collecting and analyzing PROs; however, they have also noted the additional burden this places on the provider and the added difficulty in this particular patient population, due to high rates of adverse events. Additionally, developing the necessary infrastructure and protocols, all of which have to be approved by Institutional Review Boards (IRBs) of all participating centers, to collect PROs, will take time. Therefore, ASH recommends that CMS allow for additional time for this process while allowing patients to enroll on CED studies to evaluate clinical outcomes.

ASH wants to ensure that patients who have already begun the process of CAR-T therapy prior to the final proposed decision memo will not have a delay in care, and that patients not be denied appropriate life-saving care while an acceptable data collection trial is undergoing CMS selection, IRB approval, and widespread national deployment. For example, CMS must clarify how coverage will or will not be applied to patients who already underwent leukapheresis but have not yet been infused. The agency should implement this policy in a manner consistent with providing coverage.

Thank you for the opportunity to provide comments on the Proposed Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Martha Liggett, Esq.

Executive Director