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RE: Proposed Local Coverage Determination (LCD): Palmetto GBA: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (DL39270)

Dr. Garrett and Dr. Banker,

The American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT) are very appreciative of Palmetto GBA's leadership in drafting the local coverage determination (LCD), DL39279, Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin. Our Societies support this LCD, as written, and believe it will have a positive impact on the health of Medicare beneficiaries living with certain types of lymphoma by providing access to allogeneic hematopoietic cell transplantation (allo-HCT).

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. 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. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

The ASTCT is a professional membership association of more than 3,000 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. The clinical teams in our society have been instrumental in developing and implementing clinical care standards and advancing

cellular therapy science, including participation in trials that led to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

Our Societies understand that the LCD will expand coverage for allogeneic stem cell transplant for Medicare beneficiaries with primary refractory or relapsed Hodgkin and non-Hodgkin lymphomas with B-cell or T-cell origin, for whom there are no other curative intent options when it is deemed medically necessary. The scientific evidence referenced in the draft LCD is recognized by our Societies as demonstrating the effectiveness in general and the comparable success of the procedure regardless of age, providing the justification for this coverage decision. The Medicare National Coverage Determination (NCD) for Allogeneic Stem Cell Transplantation (110.23) does not specifically include lymphoma as a covered indication, leaving Medicare beneficiaries with lymphoma without nationally consistent access to this potentially curative treatment and creating a different standard of care under Medicare than what is afforded to patients with commercial insurance. For the subset of lymphoma patients who need it, allo-HCT is their only option for curative intent therapy, making this LCD critically important.


ASH and ASTCT strongly support this LCD and are grateful to Palmetto GBA for addressing this gap in coverage and allowing our patients to access this life-altering treatment.

Should you have questions, please contact Suzy Leous (sleous@hematology.org), ASH's Chief Policy Officer, or Alycia Maloney (amaloney@astct.org), ASTCT's Director of Government Relations.

Sincerely,



Jane N. Winter, MD
ASH President



Brenda M. Sandmaier, MD
ASTCT President