Dear Dr. Capehart,

The American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT) are very appreciative that Noridian Healthcare Solutions has proposed the draft local coverage determination (LCD), DL39396, Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin. 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 are prime candidates, allo-HCT is their only option for curative intent therapy, making this LCD critically important.

The Societies have reviewed Noridian’s proposed LCD and are concerned that the wording is somewhat different from Palmetto GBA’s L39270 on the same topic. In order to avoid regional differences in interpretation, ASH and ASTCT ask that Noridian use the same language as Palmetto in its LCD. The Societies believe consistent language across the Medicare Administrative Contractors (MACs) will help ensure consistent coverage.

The proposed Noridian LCD (DL39396) includes the following language:

It is the intention of this Local Coverage Determination to formally notify Medicare enrolled providers of Noridian Medicare’s coverage and allowance for reimbursement of services related to Allogeneic Stem Cell Transplantation in compliance with NCD 110.23. Covered indications for allogeneic stem cell transplant of hematopoietic cells extracted from healthy donor matched peripheral blood and/or bone marrow for infusion as treatment of primary refractory or relapsed Hodgkin’s and non-Hodgkin’s lymphoma, B-cell or T-cell origin, is limited to Medicare beneficiaries for whom the primary disease is refractory to standard-of-care treatment or for those whose disease has relapsed and are without alternative potentially curative options.

The highlighted language is similar, but different from the language used in Palmetto LCD L39270. ASH and ASTCT have concerns that this language could result in more restrictive coverage for allo-stem cell transplant for Medicare beneficiaries with lymphoma. The standard of care is evolving in this ever-changing field and new potentially curative options are becoming available. The Societies would not want Noridian to be in a position of restricting access because of the language referenced above.

ASH and ASTCT request that the Noridian LCD mirror the language below from Palmetto’s L39270 below:

This policy describes additional locally covered indications for allo-HSCT for primary refractory or relapsed Hodgkin’s and non-Hodgkin’s lymphomas with B-cell or T-cell origin that are medically necessary in patients for whom there are no other curative intent options.
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.

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