

January 5, 2024

Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Decision Memo for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) CAG-00415R

Dear Ms. Syrek Jensen:

On behalf of the American Society of Hematology (ASH), the American Society for Transplantation and Cellular Therapy (ASTCT), the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), the Center for International Blood and Marrow Transplantation (CIBMTR), and the National Marrow Donor Program (NMDP), thank you for this opportunity to comment on the proposed decision memo for Allogeneic HSCT.

The Agency has proposed to remove the coverage with evidence development (CED) criteria for HSCT for patients with Myelodysplastic Syndromes (MDS), but note that important modifications are needed to the proposed decision memo to support appropriate medical indications and equitable access to care.

Allogeneic HSCT is the only curative therapy for patients with MDS, a group of blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. MDS primarily impacts older adults. The median age at diagnosis is approximately 75 years old.

For patients aged more than 10 years, the availability of HSCT through the CIBMTR and BMT CTN CED studies dramatically increased access among Medicare beneficiaries to levels that reflect the clinically appropriate need in the patient population, as demonstrated by the growth in annual volume from fewer than one hundred patients per year before 2010 and to more than seven hundred per year in 2022. We appreciate the Agency's work on this issue and appreciate the commitment to appropriate patient care.

The proposed decision memo requests comments on the nationally

Inclusion of Intermediate Risk MDS:

We believe the medical evidence demonstrates the benefits of allogeneic HSCT compared to currently available conventional therapy for patients with intermediate risk MDS and supports its inclusion in the indication. Enrollment criteria for BMT CTN 1102 included patients characterized as Intermediate-2 or High according to the IPSS criteria available when the study was designed. Overall results from the study for all patients show a survival advantage and overall benefits.

