



March 11, 2024

Dear Colleagues:

We are pleased to inform you the Centers for Medicare & Medicaid Services (CMS) released its National Coverage Determination (NCD) for allogeneic hematopoietic cell transplant (HCT) for patients with myelodysplastic syndrome (MDS) on March 6, 2024. The full text of the NCD can be found [here](#).

Briefly, per the decision memo: "CMS is expanding Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood, or umbilical cord blood stem cell products for Medicare patients with myelodysplastic syndrome who have prognostic risk scores of:

- ≥ 1.5 (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or
- ≥ 4.5 (high or very high) using International Prognostic Scoring System – Revised (IPSS - R), or
- ≥ 0.5 (high or very high) using the Molecular International Prognostic Scoring System (IPSS - M)."

This represents a substantial improvement in payor policy. The studies performed by CIBMTR (10-CMS-MDS) and the Blood and Marrow Transplant Clinical Trials Network (BMT CTN 1102) generated important evidence supporting CMS's decision. These studies under CED have provided access to allogeneic HCT for more than 6,000 patients over 65 years with MDS. Much credit should go to the strong advocacy efforts of the American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT) in collaboration with CIBMTR and NMDP over more than 14 years.

The effective date of CMS' new coverage policy is Wednesday, March 6, 2024. Patients receiving allogeneic HCT with Medicare insurance and **meeting the above criteria outlined by CMS** after this date should receive coverage based on the NCD. There is no further role for a CED for this disease, patients whose allogeneic HCT begins after March 6, 2024 will no longer need to participate in our MDS CED observational study (NCT01166009) initiated in December 2010. **Coverage decisions about patients with MDS who do not meet the criteria outlined by CMS in the NCD will require a decision from local Medicare Administrative Contractors.**

CIBMTR will begin taking steps to close the study and new patients should no longer be asked to sign specific consent for the MDS CED study as of March 6,

2024. Understanding potential lags in reporting to the CIBMTR, **tools to enroll patients with MDS who received an alloHCT before March 6, 2024, and not yet reported to CIBMTR will remain available until March 25, 2024.** Of course, all centers should continue to consent patients to participate in CIBMTR's observational database protocol and continue to provide data for transplant recipients including those who participated in the MDS CED.

CIBMTR is very appreciative of the collaborative efforts of the broad cellular therapy community in serving older Americans with MDS who have benefited from allogeneic HCT over the last 14 years.

Please feel free to contact [CIBMTR center support](#) with any questions.