



March 29, 2024

On behalf of the American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT), and the National Marrow Donor Program (NMDP) we are writing regarding the revised National Coverage Determination (NCD) for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS), which was finalized by the Centers for Medicare & Medicaid Services (CMS) on March 6, 2024. We extend our thanks to CMS for removing the coverage with evidence development (CED) criteria and for creating revised coverage indications for MDS. While we appreciate the agency's work, these revisions, which were effective upon publication, have implications for local coverage of HSCT for MDS of which we want you to be aware.

The NCD expands coverage for “allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with myelodysplastic syndromes.” Coverage under the NCD is dependent on prognostic risk scores outlined in the policy. Prior to the release of the NCD, coverage for allogeneic stem cell transplant for MDS patients was provided under the less stringent CED policy. However, the elimination of the CED creates a potential coverage gap during the transition period, which could affect many patients within your jurisdiction.

We want to alert you that your organization may be experiencing an influx of HSCT cases that were previously covered under the CED, and that the MACs have the discretion to cover these cases. The NCD specifically states that “coverage of all other indications for stem cell transplantation not otherwise specified above as covered or non-covered will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A).” Our organizations respectfully request that you review these cases expeditiously to ensure that appropriate cases are covered at the local level. This will allow patients and providers to proceed with treatment as centers adjust their practices to meet the NCD's requirements.

HSCT is typically planned at least six to eight weeks in advance to schedule acquisition of cells from the donor, arrange inpatient admission, and otherwise coordinate complex care. An overnight change in coverage is particularly problematic since some centers already scheduled transplants prior to March 6. Caregivers, and donors may have already made the difficult arrangements for time off from work, travel, accommodations, and other pertinent logistical arrangements. Depending on the patients' clinical status and risk scores, some patients already scheduled for HSCT before March 6 had their coverage based on the CED may now experience a coverage shift and could be left without coverage which would have been determined at the federal level and will now be left for adjudication locally.

Thank you for consideration. We would like to offer our societies as resources to you and would be happy to identify subject matter experts or provide the names of hematology Carrier Advisory

Committee representatives, should you need their assistance. We also have resources available that can be provided to you during this period of transition. If you have questions or would like to discuss the revised NCD and other coverage issues, please use Suzanne Leous, ASH Chief Policy Officer ([sleous@hematology.org](mailto:sleous@hematology.org); 202-292-0258), as your point of contact.

Sincerely,



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