Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms Surgery

Policy ID:	HHO-DE-MP-1097
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	N/A
Annual Approval Date:	10/2022
Last Revision Date:	10/08/2021
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Allogeneic hematopoietic cell transplantation (allo-HCT) – Involves the intravenous (IV) infusion of allogeneic (donor) stem cells to reestablish hematopoietic function in individuals whose bone marrow or immune system is damaged or defective. They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates.

PROCEDURES

A prior authorization is required.

Myeloablative allo-HCT may be considered medically necessary as a treatment of EITHER of the following conditions:

- Myelodysplastic syndromes; or
- Myeloproliferative neoplasms.

Reduced-intensity conditioning allo-HCT may be considered medically necessary as a risk-adapted treatment in individuals, who for medical reasons would be unable to tolerate a myeloablative conditioning regimen as a treatment of EITHER of the following conditions:

- Myelodysplastic syndromes; or
- Myeloproliferative neoplasms.

Myeloablative allo-HCT or reduced-intensity conditioning allo-HCT for myelodysplastic syndromes and myeloproliferative neoplasms not meeting the criteria as indicated in this policy is considered experimental/investigational (E/I) and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service: Inpatient/Outpatient

Experimental/investigational (E/I) services are not covered regardless of place of service.

Allogeneic HCT for myelodysplastic syndromes and myeloproliferative neoplasms is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

Table	Style
38230	Bone marrow harvesting for transplantation.
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

National Comprehensive Cancer Network (NCCN)-2019

Current National Comprehensive Cancer Network clinical guidelines for myelodysplastic syndromes (v.1.2020) make the following general recommendation about allo-HCT: “For patients who are transplant candidates, an HLA [human leukocyte antigen]-matched sibling, or HLA-matched unrelated donor can be considered. Results with HLA-matched unrelated donors have improved to levels comparable to those obtained with HLA-matched siblings. With the increasing use of cord blood or HLA-haploidentical related donors, HCT has become a viable option for many patients. High-dose conditioning is typically used for younger patients, whereas RIC [reduced-intensity conditioning] for HCT is generally the strategy in older individuals.”

American Society for Blood and Marrow Transplantation-2015

The American Society for Blood and Marrow Transplantation (2015) categorized the Indications for HCT into five areas as follows:

- Standard of care (S), where indication for HCT is well defined and supported by evidence:
    - This category includes indications that are well defined and are generally supported by evidence in the form of high quality clinical trials and/or observational studies (e.g., through CIBMTR or EBMT).
- Standard of care (C), clinical evidence available, where large clinical trials and observational studies are not available but HCT has been shown to be effective therapy:
    - This category includes indications for which large clinical trials and observational studies are not available. However, HCT has been shown to be an effective therapy with acceptable risk of morbidity and mortality in sufficiently large single- or multi-center cohort studies. HCT can be considered as a treatment option for individual patients after careful evaluation of risks and benefits. As more evidence becomes available, some indications may be reclassified as “Standard of Care.”
- Standard of care (R), rare indication, for rare diseases where HCT has demonstrated effectiveness but large clinical trials and observational studies are not feasible:
    - Indications included in this category are rare diseases for which clinical trials and observational studies with sufficient number of patients are not currently feasible because of their very low incidence. However, single- or multi-center or registry studies in relatively small cohorts of patients have shown HCT to be effective treatment with acceptable risks of morbidity and mortality. For patients with diseases in this category, HCT can be considered as a treatment option for individual patients after careful evaluation of risks and benefits.
- Developmental (D), for diseases where pre-clinical and/or early phase clinical studies show HCT to be a promising treatment option:
    - Developmental indications include diseases where pre-clinical and/or early phase clinical studies show HCT to be a promising treatment option. HCT is best pursued for these indications as part of a clinical trial. As more evidence becomes available, some indications may be reclassified as “Standard of Care, Clinical Evidence Available” or “Standard of Care.”
- Not generally recommended (N), where available evidence does not support the routine use of HCT:
    - Transplantation is not currently recommended for these indications where evidence and clinical practice do not support the routine use of HCT. The effectiveness of non-transplant therapies for an earlier phase of a disease does not justify the risks of HCT. Alternatively, a meaningful benefit is not expected from the procedure in patients with an advanced phase of a disease. However,

this recommendation does not preclude investigation of HCT as a potential treatment and transplantation may be pursued for these indications within the context of a clinical trial.

References

InterQual® Level of Care Criteria 2019. Acute Care Adult. McKesson Health Solutions, LLC.

Aoki K, Ishikawa T, Ishiyama K, et al. Allogeneic haematopoietic cell transplantation with reduced-intensity conditioning for elderly patients with advanced myelodysplastic syndromes: a nationwide study. Br J Haematol. 2015; 168(3): 463-466.

Basquiera A, Rivas M, Remaggi G, et al. Allogeneic hematopoietic stem cell transplantation in adults with myelodysplastic syndrome: Experience of the Argentinean Group of Bone Marrow Transplantation (GATMO). Hematology. 2016; 21(3): 162-169.

Kroger NM, Deeg JH, Olavarria E, et al. Indication and management of allogeneic stem cell transplantation in primary myelofibrosis: a consensus process by an EBMT/ELN international working group. Leukemia. 2015;29(11):2126-2133.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms, Version 1.2020.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes, Version 2.2020.

Artz AS, Logan B, Zhu X, et al. The prognostic value of serum C-reactive protein, ferritin, and albumin prior to allogeneic transplantation for acute myeloid leukemia and myelodysplastic syndromes. Haematologica. 2016; 101(11):1426-1433.

Yew PY, Alachkar H, Yamaguchi R, et al. Quantitative characterization of T-cell repertoire in allogeneic hematopoietic stem cell transplant recipients. Bone Marrow Transplantation. 2015; 50(9):1227-1234.

Koenecke C, Göhring G, de Wreede LC, et al. Impact of the revised International Prognostic Scoring System, cytogenetics and monosomal karyotype on outcome after allogeneic stem cell transplantation for myelodysplastic syndromes and secondary acute myeloid leukemia evolving from myelodysplastic syndromes: a retrospective multicenter study of the European Society of Blood and Marrow Transplantation. Haematologica. 2015; 100(3):400–408.

Basquiera AL, Pizzi S, Correas AG, et al. Allogeneic hematopoietic stem cell transplantation in pediatric myelodysplastic syndromes: A multicenter experience from Argentina. Pediatr Blood Cancer. 2015; 62(1):153-7.

Symeonidis A, van Biezen A, de WreedeL, et al. Achievement of complete remission predicts outcome of allogeneic haematopoietic stem cell transplantation in patients with chronic myelomonocytic leukaemia. A study of the Chronic Malignancies Working Party of the European Group for Blood and Marrow Transplantation. Br J Haematol. 2015; 171(2); 239-246.

Pohlen M, Groth C, Sauer T, et al. Outcome of allogeneic stem cell transplantation for AML and myelodysplastic syndrome in elderly patients (>60 years). Bone Marrow Transplant. 2016; 51(11); 1441-1448.

Heidenreich S, Ziagkos D, de Wreede LC, et al. Allogeneic stem cell transplantation for patents age ≥70 years with myelodysplastic syndrome: A retrospective study of the MDS subcommittee of the chronic malignancies working party of the EBMT. Biol Blood Marrow Transplant. 2017; 23(1):44-52.

Kröger N, Giorgino T, Scott BL, et al. Impact of allogeneic stem cell transplantation on survival of patients less than 65 years of age with primary myelofibrosis. Blood. 2015; 125(21):3347–3364.

Majhail NS, Farnia SH, Carpenter PA, et al. Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2015; 21(11):1863–1869.

Beelen DW, Trenschel R, Stelljes M, et al. Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic haemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): a randomised, non-inferiority, phase 3 trial. Lancet Haematol. 2020;7(1):e28-e39.

Scott BL, Pasquini MC, Logan BR, et al. Myeloablative Versus Reduced-Intensity Hematopoietic Cell Transplantation for Acute Myeloid Leukemia and Myelodysplastic Syndromes. J Clin Oncol. 2017;35(11):1154-1161.

Kröger N, Iacobelli S, Franke GN, et al. Dose-reduced versus standard conditioning followed by allogeneic stem-cell transplantation for patients with myelodysplastic syndrome: A prospective randomized phase iii study of the EBMT (RICMAC Trial). J Clin Oncol. 2017;35(19):2157-2164.

POLICY UPDATE HISTORY

<Date>	<Event>