Molina Clinical Policy
Haploidentical Allogeneic Hematopoietic Cell Transplantation in Blood Cancers: Policy No. 362

Last Approval: 4/10/2024
Next Review Due By: April 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Haploidentical allogeneic hematopoietic cell transplantation is becoming a viable alternative for patients in need of a bone marrow transplant but lack a fully matched donor of stem cells. In general, allogeneic hematopoietic cell transplantation (HCT) may cure a broad variety of malignant and non-malignant hematologic disorders. The hematopoietic stem cells required are obtained from a related or unrelated donor's bone marrow or peripheral blood. For best outcomes, the stem cell donor is a human leukocyte antigen (HLA)-matched sibling. However, there is only a 25 percent chance a sibling will be a full match for a patient in need of a stem cell transplant. When there is not an HLA-matched sibling alternative sources of donor grafts may be used including, but not limited to suitably HLA-matched adult unrelated donors, umbilical cord blood stem cells, and partially HLA-mismatched, or HLA-haploidentical, related donors. This alternative donor source may be especially relevant for minority ethnic groups for which well-matched unrelated donors are less common (NCCN 2023).

Haploidentical related donors have a 50% match for important HLA markers. There are advantages and disadvantages of HLA-haploidentical HCT. Advantages include the rapid availability of donor stem cell source from family and graft versus leukemic effect which may improve overall survival. Haploidentical family members are available much faster than the many months it takes to conduct a nationwide search for unrelated donors. The disadvantages of haploidentical allogeneic HCT is alloreactivity leading to graft rejection and graft-versus-host disease (GVHD). This was a major problem early on in the history of haploidentical HCT. Graft engineering (depletion of alloreactive T cells to help reduce GVHD) and pharmacologic prophylaxis of GVHD (post-transplantation cyclophosphamide), have reduced some of the risk of graft failure and GVHD (Fuchs & Luznik 2021).

Haploidentical allogeneic HCT has been used successfully in the treatment of Acute Myeloid Leukemia (AML), Aplastic anemia and other bone marrow failure disorders as well as Hodgkin's lymphoma. AML has several subtypes that are grouped by the maturity of the primary cancer cell population. The disease is categorized as untreated, in remission, refractory, or recurrent; there is no staging system for AML. The median age at diagnosis of AML is 68 years. Overall survival (OS) rate at five years is 30% however this can vary by age group; younger patients have an OS of nearly 50% while it is less than 10% in patients over age 60. The OS may be improving due to the FDA approval of over 40 drugs or drug combinations. Research has also advanced with respect to the evolution, progression, and resistance mechanisms of AML that will aid in the diagnosis, classification, and monitoring of patients (Shimony 2023).

Treatment for AML may include chemotherapy, chemotherapy with stem cell transplant, radiation therapy, targeted therapy, or other drug therapy. HCT is preferred in individuals less than 60 years of age with intermediate or unfavorable prognoses. When a donor is available, allogeneic HCT is preferred over autologous HCT. Recipients should be monitored for signs or symptoms of acute or chronic GVHD (Vakiti & Mewawalla 2023).

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other

transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.
Haploidentical allogeneic HCT **may be considered a medically necessary** option when there are no matched sibling or unrelated donors for the following blood cancers:

1. Acute Myelogenous Leukemia (AML)
2. Aplastic Anemia and other Bone Marrow Failure Disorders
3. Hodgkin's Lymphoma
4. Non-Hodgkin's Lymphoma

HLA-haploidentical donor selection criteria include **ALL** of the following:

1. Donor must be medically, socially, and psychologically fit to donate

2. Donor age <40 years preferred over donor age ≥40 years

3. No major ABO incompatibility between donor and recipient; major ABO incompatibilities include:
   a. Recipient blood type O: Donor type A, B, or AB
   b. Recipient blood type A: Donor blood type B or AB
   c. Recipient blood type B: Donor blood type A or AB
   d. Recipient blood type AB: No major ABO incompatibilities

4. Matched CMV IgG serologic status between donor and recipient include:
   a. For a recipient who is CMV IgG negative, use a CMV IgG negative donor
   b. For a recipient who is CMV IgG positive, use a CMV IgG positive donor

AND

5. Use an ABO compatible donor over a minor ABO incompatible donor (ABO compatible transplants are O→O, A→A, B→B, or AB→AB).

*Note: Please see the specific MCP for clinical criteria for each of the above diagnoses

For Members with Significant or Daily Cannabis Use

1. Active, untreated substance abuse or misuse (including daily significant cannabis use) requires documentation of a formal substance use disorder evaluation with clear and unambiguous documentation of **ALL** of the following:
   a. A reasonable expectation that the member can adequately comply with a complex, post-transplant plan of care
   b. The member is free from addiction for at least 6 months

Limitations and Exclusions

Absolute contraindications to the use of a specific HLA-haploidentical donor include:

1. Donor is medically or psychologically unfit
2. Recipient has anti-donor HLA antibodies of sufficient strength to result in a positive crossmatch result by flow cytometry or by complement-dependent cytotoxicity assay

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of

its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Yang (2019) published a systematic review and meta-analysis of haploidentical versus matched donor stem cell transplantation for patients with hematologic malignancies. 25 studies enrolling 11,359 patients were included (haploidentical HCT n = 2677; Matched HCT n = 8682). Matched HCT and haploidentical HCT had similar risks for all primary endpoints including acute and chronic GVHD, nonrelapse mortality, and 1-year cumulative incidence of relapse. The authors concluded that haploidentical HCT is a safe and effective transplant option for those that lack a matched donor, however a caveat was noted with regard to its suitability for patients who receive reduced intensity chemotherapy.

Haploidentical HCT in AML and Lymphoma
Brissot (2019) compared outcomes of patients with active AML treated with either haploidentical HCT (n=199) or unrelated 10/10 matched donors (n=1111) or unrelated, 9/10 mismatched donors (n=383). This was a retrospective analysis utilizing the European Society for Blood and Marrow Transplantation Registry. To control for differences in disease risk between the groups a propensity score weighted analysis was used. Outcomes between the three groups were not significantly different in a multivariate analysis. The outcomes evaluated included leukemia free survival, overall survival, relapse incidence, non-relapse mortality, GVHD-free relapse-free survival. Based on this data the authors concluded that use of a haploidentical donor was a viable option for AML patients with active disease.

For patients with acute leukemia in complete remission or with lymphoma, the United States Blood and Marrow Transplant Clinical Trials Network conducted a phase III, randomized trial of reduced intensity conditioning and transplantation of either double unrelated donor umbilical cord blood or HLA-haploidentical bone marrow (BMT CTN 1101; NCT01597778). The key results of this trial are below (Fuchs 2021). The primary endpoint was progression free survival at 2 years.

Cell Source / Endpoint	Progression free survival at 2 years	Non-Relapse mortality at 2 years	Overall Survival at 2 years
Umbilical cord blood (double unrelated)	35% (CI 28-42%)	18% (CI 13-24%)	46% (CI 38%-53%)
Haploidentical Bone marrow	41 % (CI 34-48)	11% (CI 6-16%)	57% (CI 49%-64%)

Overall, data appear to favor haploidentical HCT over double unrelated cord blood. Other data regarding outcomes are mostly from retrospective analyses and large multi-institutional studies comparing post-transplant GVHD, transplant related mortality, disease-free survival, or relapse.

Haploidentical HCT in severe Aplastic Anemia
Dezern (2023) reported results from a phase 2 trial (NCT02833805). The trial design was a single arm, single center, prospective, bone marrow transplantation for patients with severe aplastic anemia who do not have a fully matched HLA donor. This phase 2 trial used non-Myeloablative conditioning and transplantation of partially HLA-Mismatched/Haploidentical related or matched unrelated donor bone marrow. The median patient age was 25 years and median follow-up time was 40.9 months. The protocol for the HLA-haploidentical HCT included post transplantation cyclophosphamide based GVHD prophylaxis and reduced intensity conditioning. The haploidentical HCT group that received 400cGy of total body irradiation had 100% overall survival with minimal GVHD in 20 consecutive patients.

Haploidentical HCT in Hodgkin Lymphoma
Some studies of Hodgkin's lymphoma patients have reported comparable outcomes between post-transplant cyclophosphamide haploidentical HCT and HLA matched HCT, while other recent studies have shown notable differences in outcomes. Castagna's 2020 retrospective comparison of haploidentical versus HLA matched HCTs for chemosensitive Hodgkin lymphoma indicated superior results for haploidentical HCT for 2-year progression free

survival without significant difference in overall survival.

A retrospective analysis published in 2024 compared outcomes in HLA-matched and haploidentical donor transplantations in Hodgkin's lymphoma (Montoro 2024). While there were no significant differences between the two groups in relapse, progression free survival or GVHD-relapse free survival, the HLA matched group did significantly better in overall survival and nonrelapse mortality as compared to the haploidentical donor group.

In review of the CTN 1101 trial results, Ramsey 2023 concluded that haploidentical bone marrow transplant is a "fair value choice for commercially insured patients with high-risk leukemia and lymphoma who require HCT".

A phase 3 trial (NCT03275636) looking at overall survival of haploidentical donors in AML, ALL and MDS is still underway and will be completed in April of 2024. For additional peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

National and Specialty Organizations

The **National Comprehensive Cancer Network (NCCN)** published *Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia.* The guidelines note that haploidentical transplantation may be considered a treatment option if no appropriated matched sibling donor is found and the patient is a candidate for HCT.

The **NCCN** also published *Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation* focus on the management of adult patients with malignant disease. The guidelines provide guidance on HCT, including pretransplant recipient evaluation, hematopoietic cell mobilization, and treatment of GVHD to enable the patient and provider to assess management options pertinent to each individual patient's condition.

The **American Society for Transplantation and Cellular Therapy (ASTCT)** recommends preferential use of myeloablative conditioning in eligible patients. A haploidentical related donor marrow graft is preferred over a cord blood unit in the absence of a fully HLA-matched donor (Dholaria et al. 2021).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38230	Bone marrow harvesting for transplantation; allogeneic
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/10/2024	Policy reviewed, added non-Hodgkin's lymphoma to indications. Updated Overview and Summary of Medical Evidence sections. AMR review completed 4/3/2024.
04/13/2023	Policy reviewed, no changes to criteria. Replaced "marijuana" with "cannabis". Updated Overview and Summary of Medical Evidence sections.
04/13/2022	Policy reviewed; included marijuana use under absolute contraindications; updated Summary of Medical Evidence and Reference sections.
04/05/2021	Policy reviewed, no changes to criteria, updated references.
04/23/2020	New policy.

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