Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Acute Myelogenous Leukemia (AML): Policy No. 119

Last Approval: 2/14/2024
Next Review Due By: February 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

The National Marrow Donor Program (NMDP) describes acute leukemias as a heterogeneous group of neoplastic disorders that arise from malignant transformation of blood-forming, or hematopoietic, stem cells. Malignant transformation typically involves chromosomal rearrangements (translocations), deletions, or additions, which disturb the normal control of cell division, allowing affected cells to multiply without restraint. Clones, or leukemic cells, arising from such transformation particularly influence the development of white blood cells (WBCs), or leukocytes, and rapidly proliferate in the bone marrow, replacing normal cells and causing anemia, thrombocytopenia, and granulocytopenia. After release into the blood stream, leukemic cells can infiltrate any organ or site and often spread to the liver, spleen, lymph nodes, central nervous system, and gonads, where they continue to grow and divide, resulting in small tumors, inflammation, and/or organ damage and failure. Acute myeloid leukemia (AML) is also called acute myeloblastic leukemia, acute myelogenous leukemia, and acute nonlymphocytic leukemia. AML is an aggressive disease in which too many myeloblasts or immature white blood cells that are not lymphoblasts are found in the bone marrow and blood. Two methods are commonly used to classify AML. The French American British Cooperative Group classification is based on morphological-histochemical cell characteristics and identifies eight subtypes of AML and categorized as M0-M7 ([1-6]NMDP date unknown).

The World Health Organization (2022) Classification System incorporates clinical, morphologic, immunophenotypic, cytogenetic and molecular markers that can be used to direct treatment that include five major subcategories of AML:

1. AML with recurrent genetic abnormalities;
2. AML with multilineage dysplasia;
3. Therapy-related AML and myelodysplasia (MDS);
4. AML not otherwise categorized; and
5. Acute leukemia of ambiguous lineage.

The National Cancer Institute ([1-2] NCI 2024) notes that certain gene and cytogenetic abnormalities have been identified as high-risk for a poor prognosis with chemotherapy. These include internal tandem duplication of the FLT3 gene, mutation of the tp53 gene, deletions of the long arms or monosomies of chromosomes 5 or 7; translocations or inversions of chromosome 3, t(6;9), t(9;22) and abnormalities of chromosome 11q23, t(10;11) translocation, t(1;22)(p13;q13) translocation, trisomy 8, and certain antigens/glycoproteins. Most children and adults with newly diagnosed AML undergo systemic multiagent chemotherapy designed to induce disease remission (induction therapy). These aggressive treatment approaches produce severe bone marrow aplasia and suppression of the hematopoietic system, which may lead to morbidity and mortality from infection or hemorrhage; therefore, therapy is combined with appropriate supportive care involving early recognition and treatment of infection and, when necessary, red blood cell and platelet transfusions. With effective anticancer agents and appropriate supportive care, complete remission (CR) occurs in 75% to 90% of the children and 60% to 70% of the adults with AML. Even with treatment most patients relapse and die from leukemia. Among those who achieve first CR (CR-1), disease-free survival has averaged only 40% at 5 years in children and overall survival with or without disease has averaged only 25% at ≥ 3 years in adults.

Since undetected minimal residual disease is a major cause of relapse, patients in CR usually undergo a second phase

and, often, a third phase of multiagent chemotherapy known as consolidation therapy and intensification therapy, respectively, which frequently employ different agents and/or higher doses than used in induction therapy in an attempt to eradicate residual disease. High-dose chemotherapy may be administered for this purpose but also ablates normal marrow (myeloablation), thereby destroying the hematopoietic system.

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) from a donor into a patient. HSCs are immature cells that can develop into any of the three types of blood cells (red cells, white cells or platelets). HSCs are created in the bone marrow and are found in the bone marrow and peripheral blood. There is also a high concentration of HSCs in umbilical-cord blood. Hematopoietic stem-cell transplantation (HSCT) can be either autologous (using the person's own stem cells) or allogeneic (using stem cells from a donor). In allogeneic HSCT, it is preferable for donors to have a human leukocyte antigen (HLA) type that is identical to the recipient. Matching is performed on the basis of variability at three of more loci of the HLA gene (e.g., HLA-A, HLA-B, HLA-DRB1). As HLA variability increases, transplant-related morbidity and mortality, including graft rejection and graft-versus-host disease, also increase. For patients who lack an HLA-matched sibling, alternative sources of donor grafts include suitably HLA-matched adult unrelated donors, umbilical cord blood stem cells, and partially HLA-mismatched, or HLA-haploidentical, related donors ([1-6] NMDP date unknown; [1-2] NCI 2024).

COVERAGE POLICY

All <u>transplants</u> 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.

<u>Transplant Evaluation</u>

Please see *MCP-323 Pre-Transplant Evaluation* for additional criteria and information.

Components of the transplant evaluation include:

1. History and physical examination
2. Psychosocial evaluation and clearance:
   a. Absence of any history of medical treatment non-compliance
   b. Member understands surgical risk and post procedure follow-up required
   c. Adequate family and social support
   d. No behavioral health disorder by history or psychosocial issues
      i. If history of behavioral health disorder, no severe psychosis or personality disorder may be present
      ii. Mood/anxiety disorder must be excluded
3. EKG
4. Chest x-ray
5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers
   b. Members > 50 years age
   c. Those with a clinical or family history of heart disease or diabetes.
6. Pulmonary clearance if evidence of pulmonary artery hypertension or chronic pulmonary disease
7. Neurological exam and clearance for transplant including **ONE** of the following:

a. Normal neurologic exam
b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g. diabetic peripheral neuropathy)
c. Abnormal neurological exam with positive findings including **ONE** of the following:
   - Lumbar puncture normal cytology
   - Lumbar puncture with cytological exam abnormal: central nervous system disease treated prior to clearance.

8. A Performance Status that includes **ONE** of the following:
   a. Karnofsky score 70-100%
   b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: Human immunodeficiency (HIV); Epstein Barr virus; Hepatitis virus B (HBV); Hepatitis C; cytomegalovirus (CMV); rapid plasma reagin (RPR) and/or fluorescent treponemal antibody:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months
        ii. Human immunodeficiency virus 1 (HIV-1) ribonucleic acid undetectable
        iii. On stable anti-retroviral therapy >3 months
        iv. No other complications from acquired immunodeficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
   c. Urine drug screen if Member has a history of and/or current drug abuse.

10. Colonoscopy (if indicated or if Member is age ≥ 45) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

11. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy or a total vaginal hysterectomy) within the last three years with complete workup and treatment of abnormal results as indicated.*

12. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problem pre- or post-transplant within the last 12 months

13. One of the following tests:
    a. Mammogram for women if indicated or > age 40, with complete workup and treatment of abnormal results as indicated;*
    b. Prostate specific antigen for men if history of prostate cancer or previously elevated prostate specific antigen with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Criteria for Hematopoietic Allogenic Stem Cell Transplantation (HSCT) for Acute Myelogenous Leukemia

Hematopoietic Allogeneic Stem Cell Transplantation (HSCT) ablative or non-myeloablative from a human leukocyte antigen (HLA)-matched donor (e.g., at least six out of eight match of the HLA-A, HLA-B, HLA-C and HLA-DRB1 markers) **OR** from cord blood when there are no matched sibling or unrelated donors (e.g., at least four out of six match of the HLA-A, HLA-B and HLA-DRB-1 markers) **OR** haploidentical related donor **may be considered medically necessary** for the treatment of Acute Myelogenous Leukemia when **ALL** of the following criteria are met:

1. All transplant criteria are met

2. In **adults** who are > age 18 with **ANY** of the following:
   a. History of myelodysplastic syndrome (MDS)

b. Failed induction therapy: presence of leukemia blasts in the blood, bone marrow or any extramedullary site after 4-6 weeks of chemotherapy
c. High white blood cell count (WBC) > 100,000 at diagnosis
d. AML after first relapse
e. Extramedullary disease outside the bone marrow especially affecting central nervous system
f. Requiring > one cycle to achieve remission
g. Complete first remission (CR-1);**
h. Poor to intermediate risk stratification^^

3. In **children** who are < age 18 with any of the following:
   a. in children who are < 2 years at diagnosis
   b. failed induction therapy: presence of leukemia blasts in the blood, bone marrow or any extramedullary site after 4-6 weeks of chemotherapy
   c. high white blood cell count (WBC) > 100,000 at diagnosis
   d. AML after first relapse
   e. extramedullary disease outside the bone marrow especially affecting central nervous system
   f. requiring > one cycle to achieve remission
   g. Abnormality of chromosome 5 or 7
   h. Complete first remission (CR-1);**
   i. Poor to intermediate risk stratification^^

** Complete First Remission (CR-1) is defined by bone marrow biopsy as bone marrow is normocellular with no more than 5% blasts **AND** no signs or symptoms of the disease (NCI 2024; NCCN 2023).

^^ Risk Status of AML Based on Cytogenetic and Molecular Factors (NCI 2024)		
Risk Status	**Cytogenetic Factors**	**Molecular Abnormalities**
Favorable Risk	Core binding factor: Inv(16), t(8;21), t(16;16) or t(15;17)	Normal cytogenetics: NPM1 mutation in the absence of FLT3-ITD or isolated biallelic CEBPA mutation
Intermediate Risk	Normal cytogenetics: +8 alone, t(9;11) or Other non-defined	c-KIT mutation in patients with t(8;21), inv(16) or t(16;16)
Poor Risk	Complex (3 or more abnormalities) -5, -7, 5q-, 7q-, +8, Inv3, t(3;3), t(6;9), t(9;22) Abnormalities of 11q23,excluding t(9;11)	Normal cytogenetics with FLT3-ITD mutation TP53 mutation

4. Second or subsequent complete remission (CR-2) following complete first remission (CR-1) defined by bone marrow biopsy including **BOTH:**
   a. Bone marrow is normocellular with no more than 5% blasts
   b. No signs or symptoms of the disease.

5. The requesting transplant recipient should not have any of the following absolute contraindications:
   a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer)
   c. Systemic and/or uncontrolled infection
   d. AIDS (CD4 count < 200cells/mm3)
   e. Unwilling or unable to follow post-transplant regimen:
      - Documented history of non-compliance
      - Inability to follow through with medication adherence or office follow-up
   f. Chronic illness with one year or less life expectancy
   g. Limited, irreversible rehabilitation potential
   h. 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:
      i. A reasonable expectation that the member can adequately comply with a complex, post-transplant plan of care
      ii. The member is free from addiction for at least 6 months
   i. Inadequate social/family support

6. The requesting transplant recipient is carefully evaluated and potentially treated for **ANY** of the following relative contraindications (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
   a. Smoking, documentation supporting free from smoking for 6 months
   b. Active peptic ulcer disease
   c. Active gastroesophageal reflux disease
   d. Cerebrovascular Accident (CVA) with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months
   e. Obesity with body mass index of >30 kg/m^2
   f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis requires consultation by a gastroenterologist or hepatologist
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Additional Criteria for Hematopoietic Autologous Stem Cell Transplantation (HSCT) for Acute Myelogenous Leukemia

Hematopoietic Autologous Stem Cell Transplantation (HSCT) **may be authorized** when the following criteria are met:

1. Member has Acute Myelogenous Leukemia (AML) in complete first remission (CR-1)
2. All pre-transplant criteria are met
3. Member does not have an allogeneic donor or has medical contraindications to an allogeneic transplantation procedure
4. Member is in complete morphologic and cytogenetic complete remission (CR) at the time of stem cell harvest
5. Member does not have myelodysplastic syndrome (MDS)
6. Member does not have any of the absolute contraindications and should be evaluated for any relative contraindications listed above.

Criteria for Subsequent Hematopoietic Allogenic Stem Cell Transplantation (HSCT)

Hematopoietic Allogeneic Stem Cell Transplantation (HSCT) (ablative or non-myeloablative) **may be authorized after the first prior stem cell transplantation has occurred** only one time for members with AML who meet all of the above criteria for transplant and have **ANY** of the following:

1. Bone marrow relapse (defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after a complete remission as indicated by a peripheral blast count of 5,000 or greater)
2. Primary graft failure indicated by no signs of engraftment*** by 42 days after the transplant
3. Failure to engraft***
4. A suitable allogeneic donor has been identified.

A second or repeat Hematopoietic Autologous or Allogeneic Stem Cell Transplantation (ablative or non-myeloablative) **may be authorized** only one time for Members with AML who meet **ALL** of the above criteria for transplant and have **ANY** of the following:

1. Primary graft failure indicated by no signs of engraftment* by 42 days after the transplant
2. Failure to engraft.***

*** Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 0.5 x 10^9/L or > ANC 500 at any time after transplantation ([1-6]NMDP date unknown).

Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
   a. Presence of no absolute contraindication as listed above

b. History and physical within the last 12 months
c. Kidney profile within the last 12 months
d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age)
e. Psychosocial evaluation or update within the last 12 months
f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
   a. Authorization letter/documentation from previous insurer
   b. Presence of no absolute contraindication as listed above
   c. History and physical within the last 12 months
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age)
   e. Psychosocial evaluation or update within the last 12 months
   f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

Limitations and Exclusions

1. Allogeneic (ablative or non-myeloablative) stem cell transplantation or autologous stem cell transplantation when the above criteria are not met
2. A second or repeat autologous or allogeneic (myeloablative or non-myeloablative) transplant due to persistent, progressive, or early relapsed disease.
3. Hematopoietic stem cell collection, storage and freezing for a future unplanned transplant.

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

In individuals with intermediate or unfavorable prognosis acute myelogenous leukemia (AML) hematopoietic stem cell transplantation is the preferred treatment, especially for those < 60 years of age. In cases where a suitable donor can be identified, allogenic HCT is preferred to autologous HCT or consolidation chemotherapy alone (Kolitz 2023). For patients with relapsed or refractory AML, HCT provides the greatest change of attaining a cure (Larson 2023).

Masetti et al. (2022) conducted a meta-analysis of studies comparing allogeneic hematopoietic stem cell transplantation (allo-HSCT) in first complete remission (CR1) with chemotherapy alone in high-risk pediatric acute myeloid leukemia (AML). Nine studies were included in the meta-analysis with a total of 1448 patients; 522 patients in the allo-HSCT group and 926 in the chemotherapy group. Outcomes measured included overall survival (OS), reduced relapse risk (RR), and disease-free survival (DFS). The allo-HSCT group showed significantly improved overall survival ($p = 0.0006$). Two of the nine studies reported RR with a total of 606 patients. The RR was significantly high in the chemotherapy group compared to the allo-HSCT group ($p = 0.006$). DFS was reported in three studies with a total of 861 patients. The results showed improved DFS in the allo-HSCT group ($p = 0.0001$). A limitation of this study is the follow up period as allo-HSCT can be complicated by severe long-term toxicity and salvage rate after relapse is lower in transplanted patients. Another limitation is the differences in chemotherapy protocols and consolidation strategies in the chemotherapy groups. The analysis concluded that allo-HSCT offers significant improvement in OS and DFS for high-risk pediatric AML in CR1.

Brissot et al. (2019) compared the outcomes of acute myeloid leukemia patients with active disease who received allogeneic stem cell transplantation from a haploidentical donor with post-transplant cyclophosphamide (Haplo PTCy) (n=199) versus an unrelated 10/10-matched donor (UD 10/10) (n=1111) and versus an unrelated 9/10-mismatched donor (UD 9/10) (n=383). Outcomes measured included overall survival, leukemia-free survival (LFS), non-relapse

mortality, relapse incidence, and graft-versus-host, relapse-free survival (GFRS). OS at two years did not differ significantly between the three groups of patients with 29.3% in the Haplo PTCy group, 34.7% in the UD 10/10 group, 27.6% in the UD 9/10 group. LFS rate at 2 years was 22.8% in the Haplo PTCy group versus 28% in the UD 10/10 group and 22.2% in the UD 9/10 group. No significant difference in non-relapse mortality, relapse incidence, or GFRS were reported between the three groups. The study concluded a haploidentical donor may be used when an HLA-identical sibling donor is not available for patients with AML.

A systematic review and meta-analysis were performed to assess the role of a second allogenic hematopoietic cell transplantation (allo-HCT) in patients with AML. Twelve studies (n=1586 patients) involved a mixed population of patients in both pediatric and adult age groups and 8 studies (n=1186 patients) restricted to the adult age group were included in the review. Studies were included if they included > 10 patients, were published in full manuscript form, and evaluated the use of a second allo-HCT for the sole purpose of treating relapsed AML. Outcomes measured include compete hematologic remission (CR), overall survival (OS), progression-free/disease-free survival (PFS/DFS), acute and chronic graft-versus-host disease, non-relapse mortality (NRM), and relapse.

In the mixed population group (n=126) the CR rate was 47%. In the adult population group (n=190) the CR rate was 67%. The OS rates for the mixed population group (n=1524) was 28% and 34% in the adult population (n=1186). PFS/DFS rates in the mixed population group (n=419) was 27% and 30% in the adult population group (n=1117). Acute GVHD rates were 35% and 29% in the mixed population group (n=104) and adult population group (n=951), respectively. Chronic GVHD rates were 27% in the mixed population group (n=104) and 58% in the adult population group (n=398). In the mixed population group (n = 1253), the NRM rate was 40% and in the adult population group (n=1149), the NRM rate was 27%. The relapse rate in the mixed population group (n=314) was 40% and 51% in the adult population group (n=1157). The analysis concluded that a second allo-HCT is an acceptable treatment choice for AML patients relapsing after a first allo-HCT (Kharfan-Dabaja et al. 2022).

National and Specialty Organizations

The **National Marrow Donor Program (NMDP)** has published the following guidance: *Disease-Specific HCT Indications and Outcomes Data; Engraftment; HLA Matching; Patient Eligibility for HCT; Transplant Consultation Timing; and Treatment Before Transplant* ([1-6] NMDP date unknown). These indicate SAA and other bone marrow failure (including Fanconi anemia, Diamond-Blackfan anemia and others) as indications for HSCT.

The **National Comprehensive Cancer Network (NCCN)** Guidelines for Acute Myelogenous Leukemia recommend allogeneic SCT for treatment of individuals in first complete remission (CR-1) with HLA matched sibling donor, AML after relapse, and second complete remission. The NCCN has outlined risk stratification to guide individual treatment recommendations and prognosis based upon risk status. Transplant indications include intermediate or poor risk stratification (NCCN 2023).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
	Collection Codes
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
	Cell Processing Services
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor

38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
	Cell Infusion Codes
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38242	Allogeneic lymphocyte infusions
38243	Hematopoietic progenitor cell (HPC); HPC boost
	Histocompatibility Codes
86812	HLA typing; A, B, or C (e.g., A10, B7, B27), single antigen
86813	HLA typing; A, B, or C, multiple antigens
86816	HLA typing; DR/DQ, single antigen
86817	HLA typing; DR/DQ, multiple antigens

HCPCS (Healthcare Common Procedure Coding System) Codes

Code	Description
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood derived stem-cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including pheresis and cell preparation / storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical / surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre-and post-transplant care in the global definition

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

2/14/2024	Policy reviewed, no changes to criteria. Updated summary of medical evidence and references.
2/8/2023	Policy reviewed, no changes to criteria, included section on cannabis use.
12/8/2021	Policy reviewed, no changes to criteria, updated references.
12/9/2020	Policy reviewed, no criteria changes. Updated references.
12/10/2019	Policy reviewed; clarified that haploidentical transplants may be considered medically necessary when there are no matched sibling or unrelated donors.
6/19/2019	Policy reviewed, criteria and Summary of Medical Evidence sections condensed – no changes to criteria. Updated risk stratification table based on NCCN 2019 guidelines; updated references.
9/13/2018	Policy reviewed, no criteria changes; updated references.
6/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
9/1/2015	Policy reviewed; minor revision to the criteria; updated guideline and reference sections.
10/31/2012	New policy.

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