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

Last Approval: 12/8/2021
Next Review Due By: December 2022

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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

The National Marrow Donor Program (NMDP) (2021) describes acute leukemias comprise 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, ultimately 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 (CNS), 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 (ANLL). 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 (FAB) Cooperative Group classification is based on morphological-histochemical cell characteristics and identifies eight subtypes of AML and categorized as M0 - M7.

The World Health Organization (WHO) 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 (NCI) (2021) 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/gycoproteins. 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 ultimately die from leukemia. Among those who achieve first CR (CR1), 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. (NMDP, 2021; NCI, 2021).

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.

Members must meet United Network for Organ Sharing (UNOS) / Organ Procurement and Transplantation Network (OPTN) policies and guidelines for pre-transplantation evaluation and listing criteria and the diagnosis must be made by a specialist in the disease and/or a Transplant Surgeon.

Pre-Transplant Evaluation

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

Criteria for transplant evaluation include:

1. History and physical examination; **AND**
2. Psychosocial evaluation and clearance:
   a. No behavioral health disorder by history or psychosocial issues:
      - If history of behavioral health disorder, no severe psychosis or personality disorder;
      - Mood/anxiety disorder must be excluded or treated;
      - Member has understanding of surgical risk and post procedure compliance and follow-up required.

   AND
   b. Adequate family and social support.

AND

3. EKG; **AND**
4. Chest x-ray; **AND**
5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers; **OR**
   b. Members > 50 years age; **OR**
   c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**

7. Neurological exam and clearance for transplant including **ONE** of the following:
   - Normal exam by H&P; **OR**
   - Abnormal neurological exam with positive findings including **ONE** of the following:
     - Lumbar puncture normal cytology; **OR**
     - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

AND

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

AND

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: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months; **AND**
        ii. HIV-1 RNA undetectable; **AND**
        iii. On stable anti-retroviral therapy >3 months; **AND**
        iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
      - If abnormal serology, need physician plan to address and/or treatment as indicated.
        i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
        ii. Ceruloplasmin, α1-antitrypsin phenotype
        iii. Alpha-fetoprotein
   c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age ≥ 50) 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).*

AND

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 [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. PSA if history of prostate cancer or previously elevated PSA 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)

Hematopoietic Allogeneic Stem Cell Transplantation (HSCT) **is considered medically necessary** and may be authorized in adults and children for the treatment of AML (*ablative or non-myeloablative*) from a human leukocyte antigen (HLA)-matched donor* **OR** haploidentical related donor (sharing a haplotype; having the same alleles at a set of closely linked genes on one chromosome) (NCCN, 2021; Brissot et al., 2019) **OR** cord blood when there are no matched sibling or unrelated donors^ when ANY of the following criteria are met:

* At least six out of eight match of the HLA-A, HLA-B, HLA-C and HLA-DRB1 markers).
^ At least four out of six match of the HLA-A, HLA-B and HLA-DRB-1 markers)

1. All pre-transplant criteria are met; **AND**

2. In **adults** who are > age 18 with **ANY** of the following:
   a. History of myelodysplastic syndrome (MDS); **OR**
   b. Failed induction therapy: presence of leukemia blasts in the blood, bone marrow or any extramedullary site after 4-6 weeks of chemotherapy; **OR**
   c. High white blood cell count (WBC) > 100,000 at diagnosis; **OR**
   d. AML after first relapse; **OR**
   e. Extramedullary disease outside the bone marrow especially affecting central nervous system; **OR**
   f. Requiring > one cycle to achieve remission; **OR**
   g. Complete first remission (CR-1);** **OR**
   h. Poor to intermediate risk stratification^^

OR

3. In **children** who are < age 18 with any of the following:
   a. in children who are < 2 years at diagnosis; **OR**
   b. failed induction therapy: presence of leukemia blasts in the blood, bone marrow or any extramedullary site after 4-6 weeks of chemotherapy; **OR**
   c. high white blood cell count (WBC) > 100,000 at diagnosis; **OR**
   d. AML after first relapse; **OR**
   e. extramedullary disease outside the bone marrow especially affecting central nervous system; **OR**
   f. requiring > one cycle to achieve remission; **OR**
   g. Abnormality of chromosome 5 or 7; **OR**
   h. Complete first remission (CR-1);** **OR**
   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, 2021; NCCN, 2021).

^^ Risk Status of AML Based on Cytogenetic and Molecular Factors (NCI, 2021)		
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

OR

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; **AND**
   b. No signs or symptoms of the disease.

AND

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; **OR**
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
   c. Systemic and/or uncontrolled infection; **OR**
   d. AIDS (CD4 count < 200cells/mm3); **OR**
   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

   OR
   f. Chronic illness with one year or less life expectancy; **OR**
   g. Limited, irreversible rehabilitation potential; **OR**
   h. Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present; **OR**
   i. No adequate social/family support.

AND

6. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (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; **OR**
   b. Active peptic ulcer disease; **OR**
   c. Active gastroesophageal reflux disease; **OR**
   d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
   e. Obesity with body mass index of >30 kg/m^2 may increase surgical risk; **OR**
   f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Additional Criteria for Hematopoietic Autologous Stem Cell Transplantation (HSCT)

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

1. Member has AML in complete first remission (CR-1); **AND**
2. All pre-transplant criteria are met; **AND**
3. Member does not have an allogeneic donor or has medical contraindications to an allogeneic transplantation procedure; **AND**
4. Member is in complete morphologic and cytogenetic complete remission (CR) at the time of stem cell harvest; **AND**
5. Member does not have myelodysplastic syndrome (MDS); **AND**
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) after the first autologous stem cell transplantation has occurred **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. 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); **OR**

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

*** Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 5 x 10^9/L or > ANC500 at any time after transplantation (NMDP).

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; **AND**
   b. History and physical within the last 12 months; **AND**
   c. Kidney profile within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
   e. Psychosocial evaluation or update within the last 12 months; **AND**
   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; **AND**
   b. Presence of no absolute contraindication as listed above; **AND**
   c. History and physical within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
   e. Psychosocial evaluation or update within the last 12 months; **AND**
   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 (ablative or non-myeloablative) transplant due to persistent, progressive or 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

The published medical evidence and outcomes for hematopoietic stem cell transplantation for AML in children and adults in the United States consists of registry data obtained from transplant centers that perform adult and pediatric transplantation and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes for transplantation based on demographic and clinical information.

Professional Society Guidelines

The **National Marrow Donor Program (NMDP)** in partnership with the **American Society for Blood Marrow Transplantation (ASBMT)** published two documents – *Recommended Timing for Transplant Consultation* and *Patient Eligibility for HSCT.* These indicate SAA and other bone marrow failure (including Fanconi anemia, Diamond-Blackfan anemia and others) as indications for HSCT.

Several professional society organizations have recommended that Allogeneic SCT is the preferred method of treatment for individuals in first complete remission (CR1) with HLA matched sibling donor, AML after relapse, and second complete remission (CR2). (Brissot et al., 2019; NCI; NMDP). The NCCN (2020) has outlined risk stratification to guide individual treatment recommendations and prognosis based upon risk status. Transplant indications include intermediate or poor risk stratification.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing
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	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic
38241	Bone marrow or blood-derived peripheral stem cell transplantation; autologous
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions

HCPCS Codes

HCPCS	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

APPROVAL HISTORY

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.

REFERENCES

Government Agency

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Peer Reviewed Publications

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3. Brissot E, Labopin M, Ehninger G, Stelljes M, Brecht A, Ganser A, Tischer J, et al. Haploidentical versus unrelated allogeneic stem cell transplantation for relapsed/refractory acute myeloid leukemia: A report on 1578 patients from the Acute Leukemia Working Party of the EBMT. Haematologica. 2019 Mar;104(3):524-532. doi: 10.3324/haematol.2017.187450. Accessed November 19, 2021.
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Other Evidence Based Reviews and Publications

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*