Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes (MDS): Policy No. 309

Last Approval: 4/10/2024
Next Review Due By: October 2024

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

Myelodysplastic syndromes (MDS) consist of a heterogeneous group of malignant hematopoietic stem cell disorders characterized by abnormal bone marrow and blood cell morphology. Patients with MDS have reductions in the production of red blood cells, platelets, and mature granulocytes that result in symptoms such as anemia, bleeding, fatigue, easy bruising, and increased risk of infection. The median age at diagnosis is approximately 70 years however, patients as young as 2 years have been reported. The diagnosis of MDS is made upon a complete blood count, an evaluation of the bone marrow, and a peripheral smear, with prognosis based on a variety of factors. The Revised International Prognostic Scoring System (IPSS-R) or the Molecular International Prognostic Score System (IPSS-M) should be used to incorporate information on bone marrow blast percentage, karyotype, and cytopenias for the purpose of stratifying the MDS into risk groups to guide management. Patients with lower scores are primarily treated with supportive care or low intensity therapies such as azacytidine, decitabine, or immunosuppressive therapy. Patients with a moderate to high scores are primarily treated with combination chemotherapy and/or allogeneic hematopoietic stem cell transplantation (HSCT) to alter the disease course. HSCT has shown to greatly improve overall survival rates in all risk groups.

Hematopoietic Stem Cell Transplantation (HSCT) 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 there, in peripheral blood, and in high concentrations in umbilical-cord blood. Hematopoietic stem cell transplantation (HSCT) can be autologous (using the patient'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 based on 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 increases.

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.

Transplant Evaluation

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

Components of the transplant evaluation include:

1. History and physical examination; **AND**

2. Psychosocial evaluation and clearance:
    a. Absence of any history of medical treatment non-compliance; **AND**
    b. Member understands surgical risk and post procedure follow-up required; **AND**
    c. Adequate family and social support; **AND**
    d. No behavioral health disorders 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, unless actively treated and controlled

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:
    a. Normal neurologic exam; **OR**
    b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy); OR
    c. Abnormal neurological exam with positive findings including **ONE** of the following:
        i. Lumbar puncture normal cytology; OR
        ii. Lumbar puncture with cytological exam abnormal with central nervous system 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: Human immunodeficiency virus (HIV); Epstein Barr virus; Hepatitis B virus; Hepatitis C virus; cytomegalovirus; rapid plasma reagin and/or fluorescent treponemal antibody:*
        i. If HIV positive **ALL** of the following must be met:
            1. CD4 count >200 cells/mm-3 for >6 months; **AND**
            2. Human immunodeficiency virus 1 (HIV-1) ribonucleaic acid RNA undetectable; ; **AND**
            3. On stable anti-retroviral therapy >3 months; **AND**
            4. 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.

AND

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).*; **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 or a total vaginal hysterectomy) within the last three years with complete workup and treatment of abnormal results as indicated*; **AND**

12. 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 within the last 12 months; **AND**

13. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated*;

OR

14. Prostate Specific Antigen, 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) for MDS

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) **may be authorized in adults and children** for the treatment of Myelodysplastic Syndromes (MDS) when **ALL** of the following criteria are met:

1. All transplant evaluation criteria are met; **AND**

2. Member has **ANY** of the following clinical indications:
   a. IPSS-R* score of >3-4.5 (intermediate) or >4.5 (high/very high); and/or an IPSS-M** score of 1 (moderate high) and above; **OR**
   b. MDS with poor prognostic features including ANY of the following:
      i. Treatment related MDS; **OR**
      ii. Refractory cytopenias; **OR**
      iii. Adverse cytogenetics and molecular features; **OR**
      iv. Transfusion dependence; **OR**
      v. Failure of hypomethylating agents or chemotherapy; **OR**
      vi. Moderate to severe marrow fibrosis

*NOTE: Risk stratification according to the Revised International Prognostic Scoring System (IPSS-R). For more information on the IPSS-R refer to (Della Porta et al. 2017)
**NOTE: Risk stratification according to the Molecular International Prognostic Scoring System. For more information on the IPSS-M refer to (Bernard et al. 2022), (Ma et al. 2023), and (Sauta et al. 2023)

AND

3. The requesting transplant recipient is free from **ALL** 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:

   i. Documented history of non-compliance
   ii. 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 significant and/or daily cannabis use) requires 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; **AND**
   ii. The member is free from addiction for at least 6 months
i. Inadequate social/family support.

AND

4. 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; **OR**
   b. Active peptic ulcer disease; **OR**
   c. Active gastroesophageal reflux disease; **OR**
   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; **OR**
   e. Obesity with body mass index of >30 kg/m^2 ; **OR**
   f. Chronic liver disease, such as Hepatitis B/C/D or cirrhosis, requires consultation by a gastroenterologist or hepatologist; **OR**
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Criteria for Subsequent Hematopoietic Allogenic Stem Cell Transplantation (HSCT) for MDS

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 MDS 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*; **AND**
3. Late relapse (greater than 18 months after HCT) as salvage therapy.

*NOTE: Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 0.5 x 10^9/L or > ANC500 at any time after transplantation ([4-5] 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; **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. A second or repeat allogeneic (myeloablative or non-myeloablative) transplant due to persistent, progressive, or early relapsed disease.
2. Autologous HSCT.
3. Hematopoietic stem cell collection, storage, and freezing for a future unplanned transplant is not covered.

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

Shimomura et al. (2021) conducted an evaluation study to analyze epidemiological data and identify prognostic factors for adolescents and young adults undergoing allogenic HSCT, as HSCT is the only curative treatment for MDS in this population. Six hundred and forty-five patients were selected from patients enrolled in a multicenter prospective registry for HSCT from 2000 to 2015. Survival rates were estimated using the Kaplan–Meier method. Prognostic factors were identified using the multivariable Cox proportional hazards model. The 3-year overall survival rate was 71.2% (95% confidence interval [CI]: 67.4–74.6%). In multivariable analysis, active disease status (adjusted hazard ratio: 1.54, 95% CI: 1.09–2.18, p = 0.016), poor cytogenetic risk (1.62, 1.12–2.36, p = 0.011), poor performance status (2.01, 1.13–3.56, p = 0.016), human leukocyte antigen (HLA)-matched unrelated donors (2.23, 1.39–3.59, p < 0.001), HLA-mismatched unrelated donors (2.16, 1.09–4.28, p = 0.027), and cord blood transplantation (2.44, 1.43–4.17, p = 0.001) were significantly associated with poor 3-year overall survival.

Yoo et al. (2020) conducted a single center retrospective study analyzing the outcomes of allogenic HSCT for childhood MDS. Thirty-six patients (low-grade MDS, 24; advanced MDS, 12) were included in the study, having received HSCT at the Asan Medical Center over two different decades. Outcomes were analyzed according to disease status, conditioning regimen, various donor types, and period of HSCT. During a median follow-up of 5.6 (range, 1.4-21.1) years, the probability of overall survival (OS) and failure-free survival was 77% and 69%, respectively. The cumulative incidence of transplantation-related mortality (TRM) was 12%. Comparable outcomes were observed for HSCT from haploidentical family donors vs. HLA-identical donors (TRM, 10% vs. 14%, P= 0.837; OS, 86% vs. 79%, P = 0.625) making the feasible outcomes of haploidentical HSCT an attractive alternative in the future procedures.

Zhou et al. (2020) conducted an evaluation study to analyze the outcomes post – HSCT in patients with hypoplastic MDS (hMDS). Between September 2013 and October 2019, a total of 20 consecutive patients with hMDS and 1 patient with clonal cytopenia of undermined significance who underwent allo-HSCT were enrolled in this study. The donor sources included 9 matched sibling donors, 2 matched unrelated donors, 4 mismatched unrelated donors and 6 haploidentical donors. The median time for myeloid engraftment was 11 days (range 9-17 days), and for platelet engraftment was 10 days (range 7-17 days). The cumulative incidence of myeloid and platelet recovery was 95.2 ± 6.0% and 90.5 ± 7.3%, respectively, 40.0 ± 11.3% for grades II-III acute graft-versus-host disease (GVHD), 36.8 ± 11.5% for chronic GVHD and 23.8 ± 9.6% for non-relapse mortality. No patients experienced relapse. Sixteen surviving patients were followed up for a median of 1113 days (range 110-2305 days), and the overall survival and relapse-free survival rates were both 72.7 ± 10.6%. The conclusion of this limited retrospective analysis suggests that patients with hMDS have a favorable survival after allogenic HSCT.

Yu et al. (2017) conducted a clinical control study to compare the outcomes of supportive care and chemotherapeutics in low risk MDS patients versus allogenic HSCT treatment in high risk MDS patients. One hundred and eighty two patients were enrolled, 91 in the control group who did not receive allogenic HSCT and 91 in the group who did receive allogenic HSCT. The complete remission (CR) rate in the HSCT group was significantly higher than that in the control

group (53.8% vs. 33.0%; P < 0.05). The quality of life of patients in the HSCT group was much higher than that in the control group (53.8% vs. 37.4%; P < 0.05). The overall survival (OS) rates were 79.0% and 56.0% (P < 0.05) in the HSCT group and the control group, respectively.

National and Specialty Organizations

The **American Society for Transplantation and Cellular Therapy (ASTCT)** (formerly the American Society for Blood and Marrow Transplantation) published a 2015 clinical guideline on *Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation.* The guideline focused on the role of cytotoxic therapy with hematopoietic stem cell transplantation in the therapy of MDS stated that HLA-matched allogeneic donor (sibling, other family member, unrelated individual, or cord blood) HSCT is recommended if an appropriate donor is available and that there are sufficient data demonstrating a long-term curative outcome for related and unrelated allogeneic HSCT. (Majhail et al. 2015).

In 2020, the ASTCT published an update to align with state of the art and emerging indications as the therapeutic scope of HSCT has widened. The updated also addressed the new treatment strategy using modified immune effector cells (including chimeric antigen receptor T cells and engineered T-cell receptors) as a therapeutic agent. Additional highlights of the 2020 guideline update include recommendations for indications for HSCT to include new data and to incorporate indications for immune effector cell therapy (IECT), where appropriate. Indications for HSCT/IECT were categorized in the following categories (Kanate et al. 2020).

1. Standard of care, where indication is well defined and supported by evidence.
2. Standard of care, clinical evidence available, where large clinical trials and observational studies are not available but have been shown to be effective therapy.
3. Standard of care, rare indication, for rare diseases where demonstrated effectiveness exists but large clinical trials and observational studies are not feasible.
4. Developmental, for diseases where preclinical and/or early-phase clinical studies show HSCT/IECT to be a promising treatment option.
5. Not generally recommended, where available evidence does not support the routine use of HSCT/IECT; the ASTCT will continue to periodically review and update guidelines as new evidence is available.

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.).

The **National Comprehensive Cancer Network (NCCN)** Guidelines (2022) for Myelodysplastic Syndromes recommend that allogeneic HSCT from an HLA-matched sibling donor or matched unrelated donor is a preferred approach for treating a selected group of patients with MDS, particularly those with intermediate to high-risk disease. This includes both standard and reduced intensity conditioning strategies. In patients who relapse after a prolonged remission following the first transplant, a second transplant or donor lymphocyte infusion immune based therapy may be considered. Whether transplants should be performed before or after patients achieve remission following induction chemotherapy has not been established. Comparative clinical trials are needed to address these issues.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
	Collection Codes
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38230	Bone marrow harvesting for transplantation; allogeneic
	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
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

04/10/2024 Correction to ANC value in coverage section. Annual review scheduled for October 2024.
10/12/2023 Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and IPSS-M score, removal of abnormal serology criteria and cannabis use section, and addition of substance abuse to absolute contraindications. Overview, Summary of Medical Evidence, and References sections updated. IRO peer reviewed by a practicing physician board certified in hematology and oncology September 2023.
10/12/2022 Policy reviewed, no changes to criteria, included section on marijuana use.
10/13/2021 Policy reviewed, no changes to criteria, added items under National & Specialty Organizations, updated references.
09/16/2020 Policy reviewed, no changes to criteria, updated references.
09/18/2019 Policy reviewed, no changes to criteria, updated references.
03/08/2018 New policy.

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