Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Primary Myelofibrosis / Myeloproliferative Neoplasms: Policy No. 324

Last Approval: 10/12/2023
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

Chronic myelogenous leukemia, polycythemia vera, essential thrombocythemia, and primary myelofibrosis (PMF) are myeloproliferative disorders characterized by clonal expansion of abnormal hematopoietic stem/progenitor cells. Myeloproliferative neoplasms (MPNs) are characterized by the dysregulated proliferation of myeloid cells including megakaryocytes and myeloid and erythroid progenitors in the bone marrow resulting in ineffective erythropoiesis, the production of cytokines within the marrow microenvironment, and the reactive deposition of fibrous connective tissue (reticulin or collagen) in the bone marrow, often with osteosclerosis. In later fibrotic stages, the peripheral blood demonstrates teardrop-shaped red cells (e.g., dacrocytes), nucleated red blood cells, and early myeloid forms (e.g., a triad termed leukoerythroblastosis), and extramedullary hematopoiesis results in hepatomegaly and splenomegaly. Most patients with PMF present with anemia, marked splenomegaly, early satiety, and hypercatabolic symptoms including severe fatigue, low-grade fever, night sweats, bone pain, and weight loss (Chao 2022; Holmberg et al. 2022; Deeg et al. 2022; Negrin 2022; Tefferi 2022; DynaMed 2023).

During the clinical course, massive splenomegaly, some hepatomegaly, along with progressive anemia requiring frequent red blood cell transfusions is frequently seen. Portal hypertension might accompany marked splenomegaly and could contribute to variceal bleeding or ascites. The median age for diagnosis is 64-67 years of age and approximately 50-65% of patients are positive for the Janus2 kinase (JAK2 V617F) mutation and 26-35% with mutations in calreticulin (CALR). At the current time, allogeneic hematopoietic stem cell transplantation (HSCT) constitutes the only treatment modality with a curative potential in PMF. Other treatment modalities are only palliative and include ruxolitinib as first-line therapy for management of disease-related symptoms. Hydroxyurea is considered a first-line therapy for control of hyperproliferation manifestations of myelofibrosis (constitutional symptoms, hepatosplenomegaly, and reduction of leukocytosis and thrombocytosis) (Chao 2022; Holmberg et al. 2022; Deeg et al. 2022; Negrin 2022; Tefferi 2022; DynaMed 2023).

Management of patients with PMF is determined by the risk of disease progression and estimated overall survival (OS) as calculated by prognostic scores. The International Prognostic Scoring System (IPSS), the Dynamic International Prognostic Scoring System (DIPSS) and the Dynamic International Prognostic Scoring System Plus (DIPPS-Plus) score are the three most common scores used for risk stratification. IPSS should be used at time of diagnosis and DIPSS-Plus incorporates karyotyping and is used during the course of treatment. DIPSS can be used if karyotyping is not available. The DIPSS and DIPSS-Plus scoring systems are outlined below (DynaMed 2023; Tefferi 2023; Tefferi 2022).

The score assigns points for the following five variables:

- Age >65 years: 1 point
- Leukocyte count >25,000/microL (>25 x 109/L): 1 point
- Hemoglobin <10 g/dL (<100 g/L): 2 points
- Circulating blast cells ≥1%: 1 point
- Constitutional symptoms*: 1 point

The resulting score is interpreted as follows:

- 0 points – low risk
- 1 to 2 points – intermediate-1 risk
- 3 to 4 points – intermediate-2 risk
- 5 to 6 points – high risk

The DIPSS-Plus score assigns points for the following variables:

- DIPSS low risk: 0 points
- DIPSS intermediate-1 risk: 1 point
- DIPSS intermediate-2 risk: 2 points
- DIPSS high risk: 3 points
- Unfavorable karyotype**: 1 point
- Platelet count <100,000/microL (<100 x 109/L): 1 point
- Anemia requiring transfusion: 1 point

The resulting score is interpreted as follows:

- 0 points – low risk
- 1 point – intermediate-1 risk
- 2 to 3 points – intermediate-2 risk
- 4 to 6 points – high risk

* Constitutional symptoms include weight loss >10% of the baseline value in the year preceding PMF diagnosis, and/or unexplained fever or excessive sweats persisting for more than one month.

** Unfavorable karyotype includes complex karyotype or one or two abnormalities that include +8, –7/7q–, i(17q), –5/5q–, 12p–, inv(3), 11q23.

Stem Cell Transplantation

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. 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 (GVHD), also increase (Chao 2022; Deeg et al. 2022; Holmberg et al. 2022; Negrin 2022).

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 disorder by history or psychosocial issues:
      i. If history of behavioral health disorder, no severe psychosis or personality disorder may be present; **AND**
      ii. Mood/anxiety disorder must be excluded or treated, 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 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, however 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 virus B; Hepatitis C; cytomegalovirus; rapid plasma reagin; 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; **AND**
        ii. Human immunodeficiency virus 1 (HIV-1) ribonucleic acid undetectable; **AND**
        iii. On stable anti-retroviral therapy >3 months; **AND**
        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.

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 prostate specific antigen with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Criteria for Allogeneic HSCT

Allogeneic 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 PMF (Myeloproliferative Neoplasms MPS) when **ALL** of the following criteria are met:

1. All transplant evaluation criteria are met; **AND**
2. For age < 45 years, conventional intensity conditioning (CIC) allogeneic HSCT is recommended; **OR**
3. For age > 45 years, reduced intensity conditioning (RIC) allogeneic HSCT is recommended; **AND**
4. Any of the following clinical indications (see table above for additional scoring information):
   a. High risk disease defined as the following:
      - DIPSS-Plus score of 4-6 points; **OR**
      - DIPSS score of 5-6 points.

   OR

   b. Intermediate risk disease defined as the following:
      - DIPSS-Plus score of 1 point for intermediate-1 risk (INT-1); **OR**
      - DIPSS-Plus score of 2-3 points for intermediate-2-risk (INT-2); **OR**
      - DIPSS score of 1-2 points for intermediate-1 risk (INT-1), **OR**
      - DIPSS score of 3-4 points for intermediate-2 risk (INT-2).

OR

c. Any PMF-MPS disease with poor prognostic features including any of the following:
   - Dependent on transfusions of red blood cells; **OR**
   - Dependent on transfusions of platelets or has frequent infarctions; **OR**
   - Has an absolute neutrophil count less than 1000/mm3; **OR**
   - Resistant to conservative therapy with poor initial response or at progression of disease.

AND

5. The requesting transplant recipient is free of **ALL** 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 as documented by history of non-compliance and/or inability to follow through with medication adherence or office follow-up.
   f. Chronic illness, aside from transplant indication, 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; **AND**
      ii. The Member is free from addiction for at least 6 months.
   i. Inadequate social/family support.

AND

6. The requesting transplant recipient should be evaluated carefully 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 requires 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 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.

Criteria for Subsequent Allogenic HSCT

Allogeneic 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 5 x 10^9/L or > ANC500 at any time after transplantation.

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) HSCT when the above criteria are not met.
2. A second or repeat autologous or allogeneic (ablative or non-myeloablative) HSCT due to persistent, progressive, or early relapsed disease.
3. Autologous HSCT.
4. HSC 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

Peer reviewed publications regarding the efficacy of allogeneic HSCT in PMF include retrospective analyses of highly selected populations and small single arm prospective trials. A summary of relevant studies is below.

Choudhary et al. (2023) completed an observational, retrospective study at a single tertiary care center in India. The study included a total of 15 patients with a median age of 52 years (range 5-64 years) undergoing allogeneic HSCT for myelofibrosis. Primary outcomes measured included OS and disease-free survival (DFS). Secondary outcomes measured included acute and chronic GVHD, graft failure, and cytomegalovirus reactivation. Scores from both the DIPSS and the hematopoietic cell transplantation-specific co-morbidity index (HCT-CI) were used to assess risk prior to transplantation. Stem cells were HLA-matched with related, haploidentical, and unrelated donors. Participants received antimicrobial prophylaxis in the form of fluconazole, acyclovir, and co-trimoxazole. For this study, “engraftment was defined as an ANC > 500 /µL for three consecutive days and a platelet count > 20,000/µL for 7 days after the last platelet transfusion.” All patients receiving matched sibling donor transplants received a RIC regime. All patients received cyclosporine A and methotrexate for GVHD prophylaxis. Patients receiving haploidentical HSCT received intravenous cyclophosphamide and oral tacrolimus and mycophenolate post-transplant for GVHD prophylaxis. Prior to

transplant, "eight patients were in the high-risk DIPSS category, and seven were in the intermediate-risk category." Twelve patients received a matched sibling donor transplant, 2 received haploidentical transplant, and 1 received a matched unrelated donor transplant. Median follow-up was 364 days with a range from 7-2,815 days. There were 10 patients ≤ 55 years of age and 5 patients > 55 years of age. Overall OS was 60% (n=9). OS for the intermediate-2 risk was 100% (n=7) and high-risk was 25% (n=2). OS based on age was similar with ≤ 55 years (n=6) and > 55 years (n=3) both being 60%. Univariate analysis results of risk factors showed a higher OS for the intermediate-risk group compared to the high-risk group. Overall DFS was 60% (n=9). Approximately 27% (n=4) of all patients developed acute GVHD and 27% (n=4) developed chronic GVHD. No patients experienced graft failure. Only one patient developed cytomegalovirus reactivation. Approximately 40% (n=6) of patients included in the study died, with 5 of those deaths related to sepsis and 1 related to GVHD. The 5 deaths related to sepsis occurred before engraftment.

Bewersdorf et al. (2021) completed a systematic review and meta-analysis to determine the safety and efficacy of allogeneic HSCT for PMF. A total of 43 studies with 8739 patients were included in the meta-analysis. The primary outcomes assessed were OS, non-relapse mortality (NRM), relapse-free survival (RFS), progression-free survival (PFS), incidence of acute and chronic GVHD, and incidence of graft failure. The outcomes for OS, NRM, RFS, and PFS were reported at 1-year, 2-year, and 5-year intervals based on the data available for each interval. The OS was 66.7% at 1-year, 64.4% at 2-years, and 55.0% at 5-years and was reported by 15, 21, and 22 studies respectively. The NRM was 25.9% at 1-year, 29.7% at 2-years, and 30.5% at 5-years and was reported by 19, 12, and 10 studies respectively. The RFS was 65.3% at 1-year, 56.2% at 2-years, and 53.6% at 5-years and was reported by 7 studies for all intervals. The PFS was 56.9% at 1-year, 50.6% at 2-years, and 43.5% at 5-years and was reported by 10 studies. It is important to note that not all studies reported RFS and PFS at all timepoints and researchers had to rely on each study's definition of RFS and PFS. The incidence of acute and chronic GVHD was reported in 36 and 32 studies respectively with 26 studies only reporting grade II-IV GVHD. Acute GVHD was reported in 44.0% of patients overall with 15.2% of patients developing grade III or IV GVHD. Chronic GVHD was reported in 46.5% of patients overall with 26.1% of patients developing extensive, moderate, or severe chronic GVHD. The overall incidence of graft failure was 10.6%. The rate of primary graft failure was 7.3% and secondary graft failure was 5.9%. Researchers were unable to quantitatively assess adverse events other than acute or chronic GVHD. Researchers were also unable to stratify outcomes based on DIPSS. However, they noted that the survival outcomes reported in their analysis were in-line with other studies, indicating that allogeneic HSCT "should be considered for eligible patients with higher-risk myelofibrosis."

National and Specialty Organizations

The **National Comprehensive Cancer Network (NCCN)** (2023) guidelines for the treatment of MPN indicate that "allogeneic HSCT should be based on age, performance status, major comorbid conditions, psychosocial status, patient preference, and availability of caregiver." These guidelines include recommendations for allogeneic HSCT and classify the following by prognostic risk model (MIPSS, DIPSS, or DIPSS-Plus):

- *Lower-risk asymptomatic patients* should be observed and/or included in a clinical trial. Lower-risk symptomatic patients should receive ruxolitinib, peginterferon alfa-2a, or hydroxyurea (if cytoreduction would be symptomatically beneficial). Patients with thrombocytopenia or complex cytogenetics should be evaluated for allogeneic HSCT.
- *Higher risk patients* are treated based on platelet count. Those with a platelet count < $50x10^9$/L and not a transplant candidate should receive pacritinib and/or be considered for inclusion in a clinical trial. Those with a platelet count ≥ $50x10^9$/L and not a transplant candidate should receive ruxolitinib, fedratinib, or pacritinib and/or be considered for inclusion in a clinical trial. Those that are a transplant candidate should receive allogeneic HSCT regardless of platelet count.
- Patients with *accelerated or blast phase myelofibrosis* should have a bone marrow workup and evaluation completed. Those that are a transplant candidate should be included in a clinical trial and complete induction therapy (hypomethylating agents ± JAK inhibitors or intensive induction chemotherapy) followed by allogeneic HSCT (for patients in remission).

The **National Cancer Institute (NCI)** published a PDQ for chronic MPNs in 2020 (NCI 2020). The PDQ makes the following recommendations:

- Asymptomatic low-risk patients should be observed unless the patient develops "symptomatic anemia, marked leukocytosis, drenching night sweats, weight loss, fever, or symptomatic splenomegaly."
- Allogeneic HSCT or bone marrow transplant can be considered as an "aggressive approach" when a suitable donor is available. "Allogeneic HSCT is the only potentially curative treatment available, but the associated

mortality limits its use to younger, high-risk patients."

The **American Society for Transplantation and Cellular Therapy (ASTCT)** published guidelines for indications for HSCT and immune effector cell therapy (Kanate et al. 2020). The guidelines recommend allogeneic HSCT for primary (low-, intermediate-, and high-risk) and secondary myelofibrosis and myeloproliferative diseases as "standard of care, clinical evidence available." This recommendation indicates that HSCT "has shown to be an effective therapy [despite] large clinical trials and observational studies [not being available]." The guidelines do not recommend autologous HSCT for myelofibrosis or myeloproliferative diseases.

The **European Leukemia Net (ELN) and European Blood and Marrow Transplantation Group (EBMT)** have developed consensus recommendations for HCT in PMF [11]. They suggest HCT for patients <70 years of age with intermediate-2- or high-risk DIPSS Plus scores and patients <65 years of age with intermediate-1 DIPSS Plus score with refractory, transfusion-dependent anemia, or a percentage of blasts in the peripheral blood >2, or adverse cytogenetics (Kröger et al. 2015).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	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

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

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

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 substance use to absolute contraindications, and removal of abnormal serology criteria and cannabis use section. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on September 1, 2023, by a practicing, board-certified physician with specialties in Oncology, Hematology, and Internal Medicine.
10/12/2022	Policy reviewed, no changes to criteria, included section on marijuana use.
10/13/2021	Policy reviewed, no changes to criteria. Added information from the ASBMT, NMDP – updated references.
09/16/2020	Policy reviewed, no changes, updated references.
09/18/2019	Policy reviewed, no changes, updated references.
12/19/2018	New policy. IRO Peer Review on October 23, 2018, by a practicing, board-certified physician with specialties in Hematology and Oncology.

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