Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Immunodeficiency Disorders: Policy No. 265

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

Primary and combined immunodeficiency syndromes are inherited defects in the immune system that inhibit the ability of the immune system to defend against infection “due to impaired or absent T cell response to infection with or without impaired B cell and/or natural killer cell responses (DynaMed 2023).” Severe combined immunodeficiency (SCID) refers to combined immunodeficiencies that lead to death, typically within the first year of life, due to overwhelming infection as a result of an absent immune system (Heimall 2019). According to Heimall (2019), “SCID can be categorized as typical SCID or, if less severe, leaky SCID based upon the severity of T cell qualitative and quantitative deficiency.” Clinical symptoms will present more rapidly in typical SCID than leaky SCID. As of 2022, all states within the United States screen for SCID as part of newborn screening for immune disorders (Dvorak 2022). Routine screening is performed as “infants with SCID are generally healthy at birth, protected by transplacentally acquired maternal immunoglobulin G antibodies in the first one to three months of life (Puck 2023).”

Once the antibody protection begins to wane, these infants will begin to develop persistent severe and/or fatal infections from pathogens within the environment and from routine vaccinations that contain live organisms (Puck 2023). Other clinical manifestations that may present include chronic diarrhea associated with failure to thrive, the absence of discernible peripheral lymphoid tissue (except in Omenn syndrome), and the absence of a thymic shadow on chest x-ray (DynaMed 2023; Heimall 2019). Laboratory studies used to definitively diagnose SCID include absolute lymphocyte count, CD3+ T cell count, and T cell mitogen responses (Heimall 2019). Other laboratory studies that may be performed include B and natural killer cell counts, T cell antigen responses, quantitative immunoglobulin levels, and specific antibody responses to antigens (Heimall 2019).

Early detection of SCID can improve outcomes as it allows for prompt isolation, consultation with a specialized care team, and can reduce the time to treatment. Allogeneic hematopoietic stem cell transplantation (HSCT) is generally the preferred treatment method for SCID as it typically improves reconstitution of B and T cells (Dvorak 2022). However, it is important to note that not all subtypes of SCID are corrected by allogeneic HSCT (Dvorak 2022). Those that do respond to allogeneic HSCT typically have higher survival rates if transplanted within the first three months of life, particularly if transplanted prior to acquiring their first infection (Dvorak 2022).

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) **is considered medically necessary** and may be authorized for the treatment of immunodeficiency disorders when **ALL** of the following criteria are met:

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

2. Diagnosis of **ONE** of the following immunodeficiency disorders (including, but not limited to):

a. Absent T-cell function as evidenced by a diagnosis of **ONE** of the following:
   - Hemophagocytic Lymphohistiocytosis; **OR**
   - SCID; **OR**
   - Wiskott-Aldrich Syndrome; **OR**
   - X-linked lymphoproliferative syndrome.

OR

b. Absent or defective natural killer function as evidenced by a diagnosis of Chediak-Higashi syndrome; **OR**

c. Absent or defective neutrophil function as evidenced by a diagnosis of **ONE** of the following:
   - Primary granulocyte dysfunction; **OR**
   - Chronic granulomatous disease; **OR**
   - Omenn Syndrome; **OR**
   - Leukocyte adhesion deficiency; **OR**
   - DiGeorge Syndrome; **OR**
   - Kostmann Syndrome.

AND

3. The requesting transplant recipient is free from **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 comorbidities 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:
      a. A reasonable expectation that the Member can adequately comply with a complex, post-transplant plan of care; **AND**
      b. The Member is free from addiction for at least 6 months.;
   i. Inadequate social/family support.

AND

4. 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. 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 Allogeneic HSCT

HSCT (ablative or non-myeloablative) **may be authorized after the first prior stem cell transplantation has occurred** only one time for Members with immunodeficiency disorders 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. A suitable allogeneic donor has been identified if applicable.

*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.

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 allogeneic (ablative or non-myeloablative) transplant due to persistent, progressive, or relapsed disease.
3. Autologous HSCT.
4. A planned tandem allogeneic HSCT.
5. HSC collection, storage, and freezing for a future unplanned transplant, including collection during the in utero .

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 HSCT for immunodeficiency disorders 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 stem cell transplantation based on demographic and clinical information ([1]NMDP date unknown). There is a large amount of published literature regarding transplant outcomes in immunodeficiency disorders. A summary of relevant studies is below.

Lankester et al. (2022) reported study outcomes for the Stem Cell Transplant in Primary Immune Deficiency in Europe (SCETIDE) registry that enrolled patients from 43 treatment centers. The goal of the study was to determine genotype specific HSCT outcomes, immune reconstitution, and the predictive value for clinical outcomes. Researchers opted to exclude patients with Omenn syndrome from the study. A total of 338 patients were included in data analysis. None of the included patients were diagnosed with SCID using newborn screening programs. However, all patients were diagnosed before 1 year of age and received a transplant before the age of 15 months. Patients were grouped into two cohorts: typical SCID and other SCID. Patients in the typical SCID cohort had "genetically confirmed IL-2 receptor gamma chain (IL2Rg), Janus kinase 3 (JAK3), or IL-7 receptor deficiency, recombinase activating gene (RAG) 1, RAG2, or DCLRE1C deficiency, or adenosine deaminase (ADA) deficiency." Those in the other SCID cohort had "PNP, RMRP, ZAP70, LIG1, LIG4, XLF, AK2, and CD3 deficiency diagnosed before the age of 1 year with CD31 T lymphocytes of <300 cells/mL." Pretransplant data reported included active infections (mycobacterial infection, symptomatic bacillus Calmette-Guerin-itis, and respiratory viral and systemic viral infections) and conditioning regimens used. Overall survival (OS) for the combined cohorts was 83.6% at 1-year post-transplant and 81.1% at 2 years post-transplant. OS for the combined cohorts at last follow-up (median 4.5 years, range 0.16-11.8 years) was 75.8%. Two-year OS was also reported for each major genotype specific group and was 85.7% for ADA, 87.1% for IL2Rg, 84.0% for JAK3, 64.6% for IL-7 receptor deficiency, 79.7% for RAG1/2 deficiency, and 79.4% for DCLRE1C deficiency. Event-free survival (EFS) for the combined cohorts was 77.6% at 1-year posttransplant, 74.0% at 2-years posttransplant, and 67.9% at last follow-up. A total of 37 patients required a second transplant and 14 patients required a stem cell boost. Researchers found that 2-year OS was similar when comparing matched donor types with HLA matching (91.9% for matched sibling donor, 91.7% matched related donor, and 87.9% matched unrelated donor). Overall, 2-year OS for matched donor types with HLA matching was 90.2%. Matched donor types and HLA matching proved to be superior to mismatched related and unrelated donor types. Two-year OS for mismatched related donors was 76.7% and 70.3% for mismatched unrelated donors compared to 90.2% for matched donor types with HLA matching. Researchers also found that the presence of a pre-transplantation infection had a strong negative impact on OS and EFS. The 2-year OS for noninfected patients was 86.6% compared to 73% for infected patients. Two-year EFS for noninfected patients was 79.9% compared to 65.5% for infected patients. Age at transplantation (before or after 3.5 months of age) did not appear to significantly affect OS (87.8% before 3.5 months compared to 82.0% after 3.5 months) or EFS (78.8% before 3.5 months compared to 72.2% after 3.5 months). Acute graft versus host disease (GVHD) was reported in 318 out of 338 patients with the incidence of grades 0 or 1 being 72.6%, grade 2 being 16%, and grades 3 or 4 being 11.3%. The 2-year OS for GVHD was 93.4% for grades 0 or 1, 89.5% for grade 2, and 75.5% for grades 3 or 4. Researchers noted that the presence of a pretransplant infection and a mismatched related donor were strongly associated with an unfavorable OS and EFS in multivariate analysis. Long-term clinical outcomes (median 6.2 years, range 2.0-11.8 years) were available for 152 patients, with 61.2% (n=93) of patients being reported as "alive and well" and 48% (n=73) "alive and well without immunoglobulin therapy dependency." A total of 8 deaths were reported post-transplantation in the long-term outcomes cohort with 4 occurring during years 2-3, 2 occurring in year 4, and 2 occurring after year 4. Approximately 87 patients died < 1-year post-transplantation and 8 died > 1-year but < 2-years post-transplantation. Post-transplantation complications were reported in 47 patients and sequelae were reported in 40 patients in the long-term outcomes' cohort.

A retrospective analysis by Rousso et al. (2015) was conducted of HSCT in children with primary immunodeficiency (PID) in a tertiary medical center over the period of 1983 to 2012. Participants included 93 children with PID with a median follow-up of 3.6 years (range, 29 d to 21.2 y) after HSCT. The 2-year survival rates after HSCT for children with severe combined immune deficiency, hemophagocytic lymphohistiocytosis/lymphoproliferative disease, Wiskott-Aldrich syndrome, granulocyte defect, and undefined PID were 65.7%±6.8%, 80%±10.3%, 83.3%±15.2%, 75%±12.5%, and 25%±21.7%, respectively. Survival was associated with year of HSCT and matching. The hazard ratio (HR) (95% CI) for HSCT done in 1983 to 1999 compared with 2000 to 2012 and for matched (related and unrelated) compared with mismatched donor were 2.14 (0.99 to 4.653) and 3.07 (1.46 to 6.4), respectively. Survival was not associated with age, sex of the recipient, underlying PID, conditioning regimen, and presence of acute graft-versus-host disease. After adjustment to the underlying PID, donor and use of fludarabine-based conditioning, the HR (95% CI) for HSCT from the year 2000 was 4.69 (range, 1.4 to 15.45). Advances in HSCT over time have improved the survival of children with PID.

Gungor et al. (2014) performed a prospective study in 16 centers in 10 countries worldwide enrolled patients aged 0 to 40 years with CGD treated with RIC HSCT consisting of high-dose Flu, serotherapy or low-dose alemtuzumab, and low-dose (50% to 72% of myeloablative dose) or targeted busulfan administration. Unmanipulated bone marrow or peripheral blood stem cells from HLA-matched related-donors or HLA-9/10 or HLA-10/10 matched unrelated-donors were infused. The primary end points were OS and EFS, probabilities of OS and EFS at 2 years, incidence of acute and chronic GVHD, achievement of at least 90% myeloid donor chimerism, and incidence of graft failure after at least 6 months of follow-up. A total 56 patients (median age 12.7 years) with chronic granulomatous disease were enrolled; 42 patients (75%) had high-risk features (i.e., intractable infections and autoinflammation), 25 (45%) were adolescents and young adults (age 14-39 years). Median time to engraftment was 19 days for neutrophils and 21 days for platelets. At median follow-up of 21 months, OS was 93% (52/56) and EFS was 89% (50/56). The 2-year probability of OS was 96% (95% confidence interval [CI], 86.46 to 99.09) and of EFS was 91% (79.78 to 96.17). Graft-failure occurred in 5% (3/56) of patients. The cumulative incidence of acute GVHD of grade III to IV was 4% (2/56) and of chronic GVHD was 7% (4/56). Stable (>/=90%) myeloid donor chimerism was documented in 52 (93%) surviving patients.

National and Specialty Organizations

The **American Society for Transplantation and Cellular Therapy (ASTCT)** published updated guidelines in 2020 with recommendations for allogeneic HSCT for SCID, SCID-variants of T cell immunodeficiency, and Wiskott-Aldrich syndrome as “standard of care, rare indication,” indicating that “demonstrated effectiveness exists [for rare diseases] but large clinical trials and observational trials are not feasible (Kanate et al. 2020).” The ASTCT recommends allogeneic HSCT as “standard of care” for hemophagocytic disorders. The guidelines do not recommend autologous HSCT for SCID, SCID-variants of T cell immunodeficiency, Wiskott-Aldrich syndrome, or hemophagocytic disorders.

The **National Marrow Donor Program (NMDP)** recommends HCT at time of diagnosis or if detected on newborn screening for immunodeficiency disorders. The NMDP has published guidance on: *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 **American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology** published the *Practice Parameter on Diagnosis and Management of Primary Immunodeficiency* (Bonilla et al. 2015). The purpose of the practice parameter is to provide consultant allergists/immunologists or other practitioners with a practical guide for the clinical recognition and diagnosis of immunodeficiency, along with the general principles that guide management of these disorders. In addition, the practice parameter organizes current knowledge and practice in the diagnosis and management of PID diseases.

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 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 August 30, 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 update to criteria, updated references.
09/16/2020	Policy reviewed, no updates to criteria, updated references.
09/18/2019	Policy reviewed, no update to clinical criteria, updated references, and professional guidelines. In the Diagnosis section, added definitions for: absent T-cell function, absent or defective natural killer function, and absent or defective neutrophil function. IRO Peer Review on April 17, 2019, by a practicing, board-certified physician with specialties in Oncology and Hematology.
03/08/2018	Policy reviewed, no updates.
06/22/2017	Policy reviewed, no updates.
02/10/2016	New policy.

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