Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Aplastic Anemia and Other Bone Marrow Failure Disorders: Policy No. 143

Last Approval: 2/14/2024
Next Review Due By: February 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Aplastic anemia (AA), also called hypoplastic anemia, is a potentially fatal bone marrow failure disorder that is characterized by pancytopenia and a hypocellular bone marrow and can be acquired or congenital. The most common causes of acquired aplastic anemia include idiopathic (no known cause), hepatitis, drugs, chemical toxins, pregnancy, pure red cell anemia, paroxysmal nocturnal hemoglobinuria and parovirus B19. Congenital aplastic anemia usually is caused by genetic mutations in the hTR gene or a rare autosomal recessive inherited disease (Fanconi anemia). Affected patients present with recurrent infections due to neutropenia, bleeding episodes due to thrombocytopenia, and fatigue due to anemia. The diagnosis of AA is established following bone marrow aspiration and biopsy. Aplastic anemia is classified as non-severe (NSAA), severe (SAA) and very severe based on the degree of the peripheral blood cytopenias (Olson 2022; Olson & Dunbar 2023; Rogers & Myers 2022; DynaMed 2022)

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, 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 (GVHD), also increase (Deeg & Sandmaier 2022; Fuchs & Luznik 2021; Kahn & Myers 2021; Negrin 2021).

Allogeneic HSCT from a human leukocyte antigen (HLA)-matched sibling donor (MSD) can provide curative therapy for individuals with SAA. It is considered a standard of care for individuals younger than 50 years of age, despite treatment-related morbidity and mortality. Older individuals and those without HLA-identical related donors generally receive first-line therapy with immunosuppressive drugs. Alternative donor transplantation may be an option in children who do not have a matched donor. For patients who lack an HLA-matched sibling, alternative sources of donor grafts include suitably HLA-matched unrelated donors (URDs), or HLA-haploidentical, related donors (Deeg & Sandmaier 2022; Fuchs & Luznik 2021; Kahn & Myers 2021; Negrin 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.

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
2. Psychosocial evaluation and clearance:
   a. Absence of any history of medical treatment non-compliance
   b. Member understands surgical risk and post procedure follow-up required
   c. Adequate family and social support
   d. No behavioral health 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
3. EKG
4. Chest x-ray
5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers**;**
   b. Members > 50 years age;
   c. Those with a clinical or family history of heart disease or diabetes.
6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease;
7. Neurological exam and clearance for transplant including **ONE** of the following:
   a. Normal neurologic exam
   b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy)
   c. Abnormal neurological exam with positive findings including **ONE** of the following:
      i. Lumbar puncture normal cytology;
      ii. Lumbar puncture with cytological exam abnormal with central nervous system disease treated prior to clearance
8. A Performance Status that includes **ONE** of the following:
   a. Karnofsky score 70-100%;
   b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.
9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: Human immunodeficiency virus (HIV); Epstein Barr virus; Hepatitis B virus; Hepatitis C virus; cytomegalovirus; rapid plasma reagin (RPR) and/or fluorescent treponemal antibody:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months;
        ii. Human immunodeficiency virus 1 (HIV-1) ribonucleic acid RNA undetectable RNA undetectable;
        iii. On stable anti-retroviral therapy >3 months;
        iv. No other complications from acquired immunodeficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
   c. Urine drug screen if Member has a history of and/or current drug abuse

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

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

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

13. One of the following tests:
    a. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;*
    b. 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 Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Aplastic Anemia

Allogeneic HSCT **is considered medically necessary** and may be authorized in adults and children who have a *fully matched-HLA sibling donor* **OR** a haploidentical related donor when there are no matched sibling or unrelated donors* for the treatment of bone marrow failure syndrome when **ALL** of the following criteria are met:

* Sharing a haplotype; having the same alleles at a set of closely linked genes on one chromosome.

1. All transplant evaluation criteria are met;

2. Must be < 60 years of age;^

3. Must have a diagnosis of aplastic anemia (includes congenital and acquired) defined as:

    a. Severe aplastic anemia with **ONE** of the following:
        - A marrow biopsy showing less than 25 percent of normal cellularity;
        - A marrow showing less than 50 percent normal cellularity in which fewer than 30 percent of the cells are hematopoietic and at least **TWO** of the following are present:
            i. Absolute reticulocyte count <40,000/microL;
            ii. Absolute neutrophil count (ANC) <500/microL;
            iii. Platelet count <20,000/microL.
    b. Very severe aplastic anemia defined as an ANC of <200/microL.

4. Any of the following rare bone marrow failure disorders:
    a. Diamond-Blackfan anemia (DBA)
    b. Fanconi's anemia (FA)
    c. Schwachman-Diamond syndrome (SDS)
    d. Pure red cell aplasia
    e. Paroxysmal nocturnal hemoglobinuria
    f. Congenital amegakaryocytic thrombocytopenia (CAMT)
    g. Dyskeratosis congenital

Additional Age Criteria for Aplastic Anemia Diagnosis

1. For Members age < 50 years, stem cells are obtained from bone marrow.

2. For Members age > 50 years, the following criteria must be met:
   a. Failed at least one course of immunosuppressive therapy (IST) with antithymocyte globulin (ATG) and cyclosporin;
   b. Stem cells are obtained from bone marrow.

Additional HSCT Criteria

Allogeneic HSCT **is considered medically necessary** and may be authorized in adults and children who have a *matched unrelated donor* for the treatment of bone marrow failure syndrome when **ALL** of the following criteria are met:

1. All transplant evaluation criteria are met;

2. Must be < 60 years of age;

3. Failed at least one course of immunosuppressive therapy with antithymocyte globulin and cyclosporin;

4. Stem cells are obtained from bone marrow;

5. Must have aplastic anemia (includes congenital and acquired) defined as:
   a. Severe aplastic anemia including ONE of the following:
      - A marrow biopsy showing less than 25 percent of normal cellularity;
      - A marrow showing less than 50 percent normal cellularity in which fewer than 30 percent of the cells are hematopoietic and at least TWO of the following are present:
        i. Absolute reticulocyte count <40,000/microL;
        ii. Absolute neutrophil count (ANC) <500/microL;
        iii. Platelet count <20,000/microL.

   b. Very severe aplastic anemia defined as an ANC of < 200/microL.

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

7. 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;
   b. Active peptic ulcer disease;
   c. Active gastroesophageal reflux disease;

d. Cerebrovascular Accident (CVA) with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months;
e. Obesity with body mass index of >30 kg/m^2;
f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis requires consultation by a gastroenterologist or hepatologist;
g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Continuation of Therapy

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

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

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

Limitations and Exclusions

1. A second or repeat allogeneic (myeloablative or non-myeloablative) HSCT 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

ElGohary et al. (2020) completed a meta-analysis and systematic review with the goal of assessing "the feasibility and safety of haploidentical HSCT in patients with severe and very severe [aplastic anemia]." The primary outcomes measured included the incidence of grades II-IV acute GVHD and chronic GVHD, transplant-related mortality (incidence of death without disease progression), and the rate of successful engraftment. Secondary outcomes measured included regimen-related toxicity, post-transplant lymphoproliferative disease, hemorrhagic cystitis, and the occurrence of cytomegalovirus and Epstein-Barr virus viremia ≤ 100 days post-transplant. A total of 15 studies with a total of 577 patients were included in the meta-analysis. Pooled results showed an overall engraftment rate of 97.3% with reduced intensity conditioning regimens having a greater proportion of engraftment success compared to non-myeloablative conditioning regimens (97.7% vs 91.7%, p = 0.03). GVHD prophylaxis regimens did not appear to have

a significant effect on engraftment success. The overall rate of acute GVHD (grade II-IV) was 26.6% with a lower rate noted in non-myeloablative conditioning regimens (18.7% vs 29.5%, p = 0.008). Conditioning regimens containing post-transplant cyclophosphamide were also associated with a lower rate of acute GVHD when compared to methotrexate and other regimens (18.7%, 28.6%, and 27.8% respectively, p = 0.02). The overall rate of chronic GVHD was 25% with no significant differences noted between conditioning regimens. The pooled rate of transplant-related mortality was 6.7% with no significant differences between reduced intensity conditioning and non-myeloablative conditioning regimens (5.3% vs 11.8%, p = 0.15). The use of post-transplant cyclophosphamide for GVHD prophylaxis led to "a relative, but nonsignificant, increase in the incidence of mortality per year (27.9%) as compared with [methotrexate] (6.5%) and other regimens (5.6%, p = 0.06)." The pooled rate of regimen-related toxicity was 6.2% and the pooled rate of hemorrhagic cystitis was 21.6% with no differences noted for conditioning or GVHD prophylaxis regimens in either outcome. The rate of cytomegalovirus infection was 44.3% with non-myeloablative conditioning regimens favoring lower rates of infection compared to reduced intensity conditioning (21.61% vs 53.3%, p = 0.04). Post-transplant cyclophosphamide was associated with a significantly lower incidence of cytomegalovirus infection compared to methotrexate and other regimens (10.4% vs 55.7% vs 38.6% respectively, p < 0.001). Researchers noted that conditioning regimens containing post-transplant cyclophosphamide or methotrexate "had a reduced incidence of [cytomegalovirus] infections in susceptible patients in comparison to other GVHD prophylactic regimens (0% and 2.1% vs 33.0% respectively, p < 0.001)." Epstein-Barr viral infections occurred in 23.8% of patients and post-transplant lymphoproliferative disease was reported in 1.5% of patients with no significant differences noted for conditioning or GVHD prophylaxis. Researchers noted that the engraftment outcomes for haploidentical HSCT appear favorable if a matched sibling or unrelated donor is not available for transplant. However, more research is needed to determine if there is a preferred conditioning regimen, GVHD prophylaxis regimen, or graft source to improve outcomes.

Zhang et al. (2019) completed a single-center, retrospective study to "explore the feasibility of upfront unrelated donor HSCT in the treatment of adult aplastic anemia." Inclusion criteria included: 1) a diagnosis of aplastic anemia based on the International AA Study Group criteria, 2) the patient received allogeneic HSCT as the first-line treatment, and 3) the patient did not receive horse antithymocyte globulin-based immunosuppressive therapy or cyclosporine A in the 6 months prior to enrollment. A total of 81 patients were enrolled in the study with 23 patients having an unrelated donor and 58 patients having a matched sibling donor. Seven of the 23 patients with an unrelated donor underwent mismatched unrelated donor HSCT, with 2 having a single mismatch at HLA-A, 2 having a single mismatch at HLA-C, and 3 having a single mismatch at HLA-DQB1. Both patient groups received conditioning therapy specific to the type of donor (unrelated vs. matched sibling). Engraftment was defined as "the first of an absolute neutrophil count ≥ $0.5x10^9$/L for 3 consecutive days and a platelet count ≥ $20x10^9$/L for the first day of 7 consecutive days without platelet transfusion." Patients were routinely monitored for acute and chronic GVHD, cytomegalovirus, and Epstein-Barr virus. Patients were treated preemptively in the event of cytomegaloviral or Epstein-Barr viral infections. The primary outcome measured was failure-free survival with death, primary or secondary graft failure, and relapse being considered as treatment failure. The secondary outcome measured was overall survival. Rates of engraftment, GVHD, and complications were also reported. Propensity score matching was used "to reduce the influence of potential confounders." Results showed no differences between either group for neutrophil and platelet engraftment, though the time to engraftment was significantly longer in the unrelated donor group (median 101 days [range 21-230 days] vs 50.5 days [range 23-295 days]). The 5-year failure-free survival rates were 82.0 ± 10.2% for the unrelated donor group and 89.3 ± 4.6% for the matched sibling donor group (p = 0.404). The 5-year overall survival rates were 87.0 ± 9.1% for the unrelated donor group compared to 94.2 ± 3.3% for the matched sibling donor group (p = 0.501). Univariate and multivariate analyses showed a significant impact on failure-free survival and overall survival in patients with an ECOG score of 3 prior to transplantation. The incidence of grade II acute GVHD was higher in the unrelated donor group (21.7% vs 3.4%, p = 0.007). There were no incidences of grades III-IV acute GVHD in either group. The rates of chronic GVHD and extensive chronic GVHD were noted to be higher in the unrelated donor group but there was no statistical significance noted (18.2% vs 8.8%, p = 0.285). The incidence of cytomegalovirus infection was similar between groups (82.6% vs 70.7%, p = 0.270). No significant differences were noted between either group in rates of Epstein-Barr viral infections and Epstein-Barr post-transplantation lymphoproliferative disorder. Researchers noted that the results of this study suggest that HSCT from an unrelated donor is a feasible option when a matched sibling donor is not available in patients ages 14-55 years. Researchers noted additional studies comparing "upfront unmatched related donor HSCT with those undergoing first-line matched sibling donor HSCT or immunosuppressive therapy" are needed.

Peinemann et al. (2013, 2014) evaluated the efficacy and adverse events of first-line allogeneic HSCT of HLA-MSDs versus first-line IST in patients with acquired SAA. Three prospective trials (n=302) were included in the review; all

studies had a high risk of bias due to the study design. The pooled hazard ratio for overall mortality for the transplant group compared to the IST group was 0.95 (p = 0.90, low quality evidence). Overall mortality was not statistically significantly different between the groups. Treatment-related mortality ranged from 20-42% for the transplant group and was not reported for the IST group. Graft failure ranged from 3-16% for the transplant group; GVHD ranged from 26-51%. Neither endpoint was applicable for the IST group. There was no reported data by individual study authors with respect to response and relapse in the transplant group; the included studies did not address health-related quality of life. Karnofsky performance status scores ranged from 71-100%; this accounted for 92% in the transplant group and 46% in the IST group. As all studies were conducted over 10 years ago, results may not be applicable to today's standard of care. Conclusions regarding the comparative effectiveness of first-line allogeneic HSCT with an HLA-MSD compared with first-line IST were not made due to limited, low-quality data with a high risk of bias.

Buchbinder et al. (2012) conducted a descriptive analysis of 1718 patients post-HCT for acquired SAA. Data was reported between 1995 and 2006 to the Center for International Blood and Marrow Transplant Research (CIBMTR). This study analyzed the malignant and nonmalignant late effects in survivors with SAA after HCT; the prevalence and cumulative incidence estimates of late effects for 1-year HCT survivors with SAA were included. Of the HCT recipients, 1176 (68.5%) and 542 (31.5%) patients underwent MSD or URD HCT, respectively. Median age at the time of HCT was 20 years; the median interval from diagnosis to transplantation was 3 months for MSDs and 14 months for URD. The median follow-up was 70 months and 67 months for MSD and URD HCT survivors, respectively. Overall survival at 1 year, 2 years, and 5 years for the cohort was 76%, 73%, and 70%. Among one-year survivors of MSD HCT, 6% had one late effect and 1% had multiple late effects. For one-year survivors of URD HCT, 13% had one late effect and 2% had multiple late effects. Among survivors of MSD HCT, the cumulative incidence estimates of developing late effects were under 3% and did not increase over time. Among recipients of URD HCT, the cumulative incidence of developing several late effects exceeded 3% by 5 years: gonadal dysfunction 10.5%, growth disturbance 7%, avascular necrosis 6%, hypothyroidism 5.5%, and cataracts 5%. In conclusion, results indicated that all patients undergoing HCT for SAA remain at risk for late effects – counseling should be offered, and patients should be monitored for late effects for the duration of their life.

Kim et al. (2012) conducted a retrospective review on the impact of older age on transplantation outcomes and survival. A total of 225 adult patients with AA who underwent allo-HSCT were included – 57 patients were over age 40 years (older patient group [OPG]) and 168 patients were age 40 years or younger (younger patient group [YPG]). Favorable prognostic factors in all patients included those under age 40 at time of allo-HSCT, time from diagnosis to allo-HSCT being less than 6 months, and MRDs for all study patients. Risk analysis of survival in the OPG showed that patients under age 50 years was the only poor prognostic factor. There was not a significant difference among YPG and patients under age 50 in the OPG. In conclusion, undergoing allo-HSCT as early as possible to maximize survival was found most beneficial among patients ages 41 to 50 with severe AA and MRDs.

National and Specialty Organizations

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

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 or pre-and post-transplant care in the global definition

APPROVAL HISTORY

02/14/2024	Policy reviewed and updated to include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and additional disease processes to criteria, removal of abnormal serology criteria and daily cannabis use section, and addition of substance abuse statement. IRO Peer Review on February 2, 2024 by a practicing, board-certified physician with specialties in Pathology, Hematology, Internal Medicine, and Medical Oncology.
02/08/2023	Policy reviewed, no changes to criteria.
12/14/2022	Policy reviewed, no changes to criteria, included section on cannabis use.
12/08/2021	Policy reviewed, no changes to criteria, updated references.
12/09/2020	Policy reviewed, no changes to criteria.
12/10/2019	Policy reviewed and updated to include pure red cell aplasia, paroxysmal nocturnal hemoglobinuria, congenital amegakaryocytic thrombocytopenia (CAMT), dyskeratosis congenital. Updated guidelines, coding and references sections. Clarified that haploididentical transplants may be considered medically necessary when there are no matched sibling or URDs.
07/10/2018	Policy reviewed, no changes to criteria.
09/19/2017	Policy reviewed, no changes to criteria.
09/21/2016	Policy updated, criteria reviewed and updated to include: Diamond-Blackfan anemia (DBA) Fanconi's anemia (FA) and Schwachman-Diamond syndrome (SDS). Updated professional guidelines and references.
06/02/2015	Policy updated with new pretransplant criteria.
06/26/2013	New policy.

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