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

Last Approval: 2/8/2023
Next Review Due By: February 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

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 generally 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, 2022; Rogers & Myers, 2022; DynaMed, n.d.)

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) from a donor into a patient. HSCs are immature cells that can develop into any of the three types of blood cells (red cells, white cells or platelets). HSCs are created in the bone marrow and are found in the bone marrow and peripheral blood. There is also a high concentration of HSCs in umbilical-cord blood. Hematopoietic stem-cell transplantation (HSCT) can be either autologous (using the person's own stem cells) or allogeneic (using stem cells from a donor). In allogeneic HSCT, it is preferable for donors to have a human leukocyte antigen (HLA) type that is identical to the recipient. Matching is performed on the basis of variability at three of more loci of the HLA gene (e.g., HLA-A, HLA-B, HLA-DRB1). As HLA variability increases, transplant-related morbidity and mortality, including graft rejection and graft-versus-host disease (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.

Pre-Transplant Evaluation

(AMR, 2019; CMS, 2016; ECOG, n.d.; [1-6] NMDP, n.d.)

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

Criteria for transplant evaluation include:

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

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

   AND
   b. Adequate family and social support.

AND

3. EKG; **AND**

4. Chest x-ray; **AND**

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

AND

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

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

AND

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

AND

9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months; **AND**
        ii. HIV-1 RNA undetectable; **AND**

iii. On stable anti-retroviral therapy >3 months; **AND**
iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

- If abnormal serology, need physician plan to address and/or treatment as indicated.
  i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
  ii. Ceruloplasmin, α1-antitrypsin phenotype
  iii. Alpha-fetoprotein

c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

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

Within the last 12 months:

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

* Participating Centers of Excellence may waive these criteria.

Criteria for Hematopoietic Allogenic Stem Cell Transplantation (HSCT)

Hematopoietic Allogeneic Stem Cell Transplantation (HSCT) **is considered medically necessary** and may be authorized in adults and children 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 pre-transplant criteria are met; **AND**

2. Must be < 60 years of age;^ **AND**

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

   a. Severe aplastic anemia (SAA) with **ONE** of the following:
   - A marrow biopsy showing less than 25 percent of normal cellularity; **OR**
   - 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; **AND/OR**
     ii. Absolute neutrophil count (ANC) <500/microL; **AND/OR**
     iii. Platelet count <20,000/microL.

   OR

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

OR

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.

OR

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; **AND**
   b. Stem cells are obtained from bone marrow.

Additional HSCT Criteria

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

1. All pre-transplant criteria are met; **AND**
2. Must be < 60 years of age; **AND**
3. Failed at least one course of IST with ATG and cyclosporin; **AND**
4. Stem cells are obtained from bone marrow; **AND**
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; **OR**
      - 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; **OR**
        ii. Absolute neutrophil count (ANC) <500/microL; **OR**
        iii. Platelet count <20,000/microL.

   OR

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

AND

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; **OR**
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
   c. Systemic and/or uncontrolled infection; **OR**

d. AIDS (CD4 count < 200cells/mm3); **OR**
e. Unwilling or unable to follow post-transplant regimen:
   - Documented history of non-compliance
   - Inability to follow through with medication adherence or office follow-up

OR

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

AND

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

For Members with Significant or Daily Cannabis Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
2. If the Member's cannabis use is in compliance with a formal, State-based program for managed medical cannabis, the request should include:
   - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
   - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

Continuation of Therapy

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

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

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

Limitations and Exclusions

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

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.

A meta-analysis was conducted by Peinmann et al. (2011) to compare outcomes of first-line matched related donor HSCT to IST in patients with acquired SAA. A total of 26 non-randomized controlled trials were reviewed; this included 7,955 patients enrolled between 1970 to 2001; no RCTs were identified. Risk of bias was high except in four studies. Improved survival was found among those in the HSCT group who were of younger age and with recent year of treatment. Among the IST group, improved survival was found among those of advanced age, having SAA without very SAA, and a combination of anti-lymphocyte globulin with cyclosporine A. In 19 studies (n=4855 patients), summary statistics were sufficient to be included in meta-analysis. A pooled estimate was not justified by considerable heterogeneity. Adverse events were reported inconsistently and varied significantly across studies. Young age and recent year of treatment were identified as factors for improved survival in the transplant group. Advanced age, SAA without very SAA, and combination of anti-lymphocyte globulin with cyclosporine A were also factors for improved survival in the immunosuppressive group. Considerable heterogeneity of non-randomized controlled studies did not justify a pooled estimate. Adverse events were inconsistently reported and varied significantly across studies.

Data from 195 children with acquired SAA who underwent URD transplantation between 1989 and 2003 were analyzed by Perez-Alburne et al. (2008). The goal was to determine if URDs provide a source of hematopoietic stem cells in children with SAA who fail IST and lack a human leucocyte antigen (HLA)-MSD. Neutrophil recovery (86% at day-28) was higher with total body irradiation-containing conditioning regimen and in younger recipients (age ≤16) receiving grafts from older donors (age >40). Recovery was lower after mismatched transplants and transplantations prior to 1997. Mortality rates were higher after mismatched transplants, in recipients with a poor performance score, and when the interval between diagnosis and transplantation was longer than four years. When restricted to donor-recipient pairs with allele-level HLA typing (8-loci; n = 118), mortality rates were also higher after mismatched transplants and older recipients receiving grafts from older donors; five-year probabilities of overall survival after HLA-A, -B, -C, -DRB1 matched and mismatched transplants adjusted for donor and recipient age were 57% and 39%, respectively. The authors concluded that URD transplantation is an acceptable alternative for children; early referral for transplantation and identification of an HLA-matched (allele-level) donor offers the best outcome.

Gluckman et al. (2008) concluded that allogeneic HSCT may be an option for certain cases of DBA, FA, and paroxysmal nocturnal hemoglobinuria. A report from the DBA registry found that 20 of 354 registrants underwent HSCT. The five-year survival rate was 87.5% for recipients of HLA-identical sibling grafts.

Dufour et al. (2008) reported in a summary of allogeneic HSCT from matched related donors over six years in FA, totaling 103 individuals, that overall survival ranged from 83–88%, with transplant-related mortality ranging from 8%–18.5% and average chronic GVHD of 12%.

Santarone et al. (2010) performed a retrospective study of 26 individuals with paroxysmal nocturnal hemoglobinuria. The study analyzed the long-term clinical and hematologic results in patients who received HSCT between 1988 and 2006. Ages ranged from 22 to 60 years (median age 32). Of the donors, 23 were HLA-identical (22 siblings, 1 unrelated) and 3 were categorized as HLA-mismatched (2 related, 1 unrelated). A total of 15 patients received a myeloablative conditioning consisting of busulfan and cyclophosphamide (all were from an identical donor) – 11 received a reduced intensity conditioning (8 from an identical donor, 3 from a mismatched donor). Cumulative incidence of graft failure was 8% (4% primary, 4% secondary graft failure). Mortality related to transplant was 42% (26% and 63% for patients transplanted following myeloablative or reduced intensity conditioning, respectively). At the time of article publication, 15 patients were alive with complete hematologic recovery and no evidence of paroxysmal nocturnal hemoglobinuria. Median follow-up was 131 months (range 30-240); 11 were in the myeloablative conditioning group and 4 were in the reduced intensity conditioning group. Disease-free survival was based on the 10-year Kaplan-Meier probability which was 57% for all patients (65% for 23 patients transplanted from identical donor, 73% for 15 patients transplanted with myeloablative conditioning). Thromboembolic events and disease recurrence were not reported after transplant. In conclusion, there is a curative benefit for patients with paroxysmal nocturnal hemoglobinuria with HSCT.

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, n.d.). These indicate SAA and other bone marrow failure (including Fanconi anemia, Diamond-Blackfan anemia and others) as indications for HSCT.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
	Collection Codes
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
	Cell Processing Services
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, 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
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38242	Allogeneic lymphocyte infusions
38243	Hematopoietic progenitor cell (HPC); HPC boost

HCPCS Codes

HCPCS	Description
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including pheresis and cell preparation/storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days or 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

2/8/2023	Policy reviewed, no changes to criteria.
12/14/2022	Policy reviewed, no changes to criteria, included section on cannabis use.
12/8/2021	Policy reviewed, no changes to criteria, updated references.
12/9/2020	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.
7/10/2018	Policy reviewed, no changes to criteria.
9/19/2017	Policy reviewed, no changes to criteria.
9/21/2016	Policy updated, criteria was reviewed and updated to include: Diamond-Blackfan anemia (DBA) Fanconi's anemia (FA) and Schwachman-Diamond syndrome (SDS). Updated professional guidelines and references.
6/2/2015	Policy updated with new pretransplant criteria.
6/26/2013	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National coverage determination (NCD) – Stem cell transplantation 110.23. Available from CMS. Effective Date January 27, 2016. Accessed December 6, 2022.

Peer Reviewed Publications

1. Buchbinder D, Nugent DJ, Brazauskas R, Wang Z et al. Late effects in hematopoietic cell transplant recipients with acquired severe aplastic anemia: A report from the late effects working committee of the center for international blood and marrow transplant research. Biol Blood Marrow Transplant. 2012 Dec;18(12):1776-84. doi: 10.1016/j.bbmt.2012.06.018. PMID: 22863842. PMCID: PMC3496823.
2. Dufour C, Svahn J. Fanconi anaemia: New strategies. Bone Marrow Transplant. 2008 Jun;41 Suppl 2:S90-5. doi: 10.1038/bmt.2008.63. PMID: 18545254.
3. Gluckman E, Wagner JE. Hematopoietic stem cell transplantation in childhood inherited bone marrow failure syndrome. Bone Marrow Transplant. 2008 Jan;41(2):127-32. doi: 10.1038/sj.bmt.1705960. PMID: 18084332.
4. Kim H, Lee KH, Yoon SS, Sohn SK, et al. Allogeneic hematopoietic stem cell transplant for adults over 40 years old with acquired aplastic anemia. Biol Blood Marrow Transplant. 2012 Oct;18(10):1500-8. doi: 10.1016/j.bbmt.2012.03.015. PMID: 22472480.
5. Peinemann F, Labeit AM. Stem cell transplantation of matched sibling donors compared with immunosuppressive therapy for acquired severe aplastic anaemia: A Cochrane systematic review. BMJ Open. 2014 Jul 15;4(7):e005039. doi: 10.1136/bmjopen-2014-005039. PMID: 25031191. PMCID: PMC4120307.
6. Peinemann F, Bartel C, Grouven U. First-line allogeneic hematopoietic stem cell transplantation of HLA-matched sibling donors compared with first-line ciclosporin and/or antithymocyte or antilymphocyte globulin for acquired severe aplastic anemia. Cochrane Database Syst Rev. 2013 Jul 23;2013(7):CD006407. doi: 10.1002/14651858.CD006407.pub2. PMID: 23881658. PMCID: PMC6718216.
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