Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Non – Cancer Diseases: Policy No. 454

Last Approval: 06/12/2024
Next Review Due By: June 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

This policy covers hematopoietic stem cell transplantation for the following diseases:

Inborn Errors of Immunity	Inborn Errors of Metabolism: Mucopolysaccharidoses Lysosomal Disorders

Hematopoietic Stem Cell Transplantation (HSCT) refers to transplantation of hematopoietic stem cells from a donor into a patient. Hematopoietic stem cells are immature cells that can develop into any of the three types of blood cells (red cells, white cells, or platelets). Hematopoietic stem cells are created in the bone marrow and are found there, in peripheral blood, and in high concentrations in umbilical-cord blood. HSCT can be autologous (using the patient's own stem cells) or allogeneic (using stem cells from a donor). In allogeneic HSCT, it is preferable for donors to have a human leukocyte antigen (HLA) type that is identical to the recipient. As HLA variability increases, transplant-related morbidity and mortality (including graft rejection and graft-versus-host disease) also increases. HSCT can be utilized in the treatment of a variety of diseases from blood cancers to solid tumors (Chao 2024; Deeg & Sandmaier 2022; [1-2]Negrin 2022).

Haploidentical Allogeneic HSCT is becoming a viable alternative for patients in need of a bone marrow transplant but lack a fully matched donor of stem cells. In general, allogeneic hematopoietic cell transplantation may cure a broad variety of malignant and non-malignant disorders. The hematopoietic stem cells required are obtained from a related or unrelated donor's bone marrow or peripheral blood. For best outcomes, the stem cell donor is a human leukocyte antigen (HLA)-matched sibling; however, there is only a 25 percent chance a sibling will be a full match for a patient in need of a stem cell transplant. When there is not an HLA-matched sibling, alternative sources of donor grafts may be used including suitably HLA-matched adult unrelated donors, umbilical cord blood stem cells, and partially HLA-mismatched, or HLA-haploidentical donors are options. Haploidentical related donors have a 50% match for important HLA markers. There are advantages and disadvantages of HLA-haploidentical HSCT. Advantages include the rapid availability of donor stem cell source from family and graft versus leukemic effect which may improve overall survival. Haploidentical family members are available much faster than the many months it takes to conduct a nationwide search for unrelated donors, which means this alternative donor source may be especially relevant for minority ethnic groups for which well-matched unrelated donors are less common. The disadvantages of haploidentical allogeneic HSCT is alloreactivity leading to graft rejection and graft versus host disease (Fuchs & Luznik 2021; NCCN 2024).

Inborn Errors of Immunity (IEIs), historically called primary immunodeficiency disorders, are inherited defects of the immune system that result in the impaired ability to fight pathogens and manifests inpatients as failure to thrive, autoimmune disease, and recurrent or chronic infections. IEIs are a vast and growing cohort of hundreds of genetic mutations that can produce disease states that range from severe and life-threatening beginning in the neonatal period to mild disorders diagnosed in adulthood. IEIs may be the primary diagnosis, i.e., Severe Combined Immunodeficiency Disorder (SCID), or a part of an overarching genetic syndrome, i.e., Omenn Syndrome; and is treated based on the specific phenotype and severity of disease (Keller 2023). Treatment can include immunoglobulin therapy, antimicrobial

therapies, enzyme replacement therapy, gene therapy, HSCT, and more. HSCT is a critical therapy in the treatment of SCID, as allogeneic HSCT allows immune reconstitution (Dvorak 2023). HSCT use in non-SCID disease processes is infrequent, however, it remains an important therapy in many cases (Puck 2022).

Mucopolysaccharidoses (MPS) are a type of inborn errors of metabolism (IEM) caused by enzyme deficiencies required for the breakdown of glycosaminoglycans (GAGs), also known as mucopolysaccharides. Ineffective degradation of GAGs results in their accumulation in lysosomes causing cellular dysfunction. Hunter syndrome is an example of an MPS disorder (MPS type II) and is inherited in an X-linked pattern, however, most MPS disorders are autosomal recessive. MPS disorders are classified into 7 different types (MPS I, MPS II, MPS III, MPS IV, MPS V, MPS VI, MPS VII) depending on the age of presentation, clinical presentation, and biochemical profile. The dominant clinical features can range from mild to severe and tend to be grouped as soft tissue storage and skeletal disease with or without brain disease, skeletal disease without brain disease, and central nervous system disorders. MPS disorders' age of clinical presentation can range from infancy to adulthood, with the more severe forms presenting earlier in life. The severity of the disease guides treatment, which is some combination of diet modification, enzyme replacement therapy, gene therapy, and HSCT, which is a standard of care for MPS I (Hurler Syndrome) (Hahn 2022; Hahn 2024).

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.

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to hematopoietic stem cell transplantation (HSCT).

I. Inborn Errors of Immunity/ Immunodeficiency Disorders

Medically Necessary

1. *Allogenic HSCT,* ablative or non-myeloablative, may be **considered medically necessary** from a donor that is matched in at least six out of eight HLA markers **OR** from cord blood matched in at least four of six HLA markers when there are no matched siblings or unrelated donors, **ALL** MCP 459 Transplant Evaluation criteria are met, **AND** treatment is intended for ONE of the following:

    a. Absent, severely diminished, or dysregulated T-cell function, as seen in disorders such as SCID, non-SCID combined immunodeficiencies, hemophagocytic lymphohistiocytosis, Wiskott-Aldrich Syndrome, IPEX, and X-linked lymphoproliferative disease

    b. Absent, severely diminished, or dysregulated natural killer cell function, as seen in disorders such as Chediak-Higashi syndrome

    c. Absent, severely diminished, or dysregulated neutrophil function, as seen in disorders such as primary granulocyte dysfunction, chronic granulomatous disease, Omenn Syndrome, leukocyte adhesion deficiency, and Kostmann Syndrome

2. *Repeat Allogenic HSCT* may be considered medically necessary in the case of primary graft failure **OR** failure to engraft*

*NOTE: Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 0.5 x 109/L or ANC > 500/uL at any time after transplantation ([1]NMDP date unknown).

Investigational, Unproven, and/or Not Medically Necessary

1. A second or repeat allogeneic (ablative or non-myeloablative) transplant due to persistent, progressive, or relapsed disease
2. Autologous HSCT
3. A planned tandem allogeneic HSCT
4. Hematopoietic stem cell collection, storage, and freezing for a future unplanned transplant, including in utero collection

Continuation of Therapy criteria may be found in MCP 459 Pre-Transplant and Transplant Evaluation.

II. Inborn Errors of Metabolism: Mucopolysaccharidoses Lysosomal Storage Disorders

Medically Necessary

1. *Allogenic HSCT*, ablative or non-myeloablative, may be **considered medically necessary** for the treatment of MPS Lysosomal Disorders from a donor that is matched in at least a six out of eight HLA markers **OR** from cord blood matched in at least four out of six HLA markers when there are no matched siblings or well-matched unrelated donors when **ALL** the following are met:
    a. **ALL** MCP 459 Transplant Evaluation criteria are met
    b. Diagnosis of an MPS Lysosomal Disorder
        a. MPS I (Hurler, Hurler – Scheie, or Scheie Syndrome)
        b. MPS II (Hunter Syndrome)
        c. MPS III (SanFilippo Syndrome)
        d. MPS VI (Maroteaux – Lamy Syndrome)
        e. MPS VII (Sly Syndrome)
    c. Age < 2 years
    d. Neurologically intact or with moderate cognitive impairment, as evidence by a Developmental Quotient > 70
    e. Failed conventional therapy (e.g., diet modification and/or enzyme replacement therapy), if applicable, for Hurler – Scheie, Scheie, Hunter, SanFilippo, Maroteaux – Lamy, and Sly Syndrome
2. *Repeat Allogenic HSCT* may be considered medically necessary in the case of primary graft failure **OR** failure to engraft*

*NOTE: Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 0.5 x 109/L or ANC > 500/uL at any time after transplantation ([1]NMDP date unknown).

Investigational, Unproven, and/or Not Medically Necessary

1. A second or repeat allogeneic (ablative or non-myeloablative) transplant due to persistent, progressive, or relapsed disease
2. Autologous HSCT
3. A planned tandem allogeneic HSCT
4. Hematopoietic stem cell collection, storage, and freezing for a future unplanned transplant, including in utero collection

III. Haploidentical Allogenic HSCT

Medically Necessary

1. *Haploidentical Allogenic HSCT* may be **considered medically necessary** when there are no matched sibling or well matched unrelated donors, and **ALL** the following criteria are met:

    a. Member receiving transplant has met all disease specific criteria for HSCT transplantation

    b. Donor must be medically, socially, and psychologically fit to donate

    c. Donor age <40 years preferred over donor age ≥40 years

    d. No major ABO incompatibility between donor and recipient; major ABO incompatibilities include:
        i. Recipient blood type O: Donor type A, B, or AB
        ii. Recipient blood type A: Donor blood type B or AB
        iii. Recipient blood type B: Donor blood type A or AB
        iv. Recipient blood type AB: No major ABO incompatibilities

    e. Matched CMV IgG serologic status between donor and recipient include:
        i. For a recipient who is CMV IgG negative, use a CMV IgG negative donor
        ii. For a recipient who is CMV IgG positive, use a CMV IgG positive donor

    f. Use an ABO compatible donor over a minor ABO incompatible donor (ABO compatible transplants are O→O, A→A, B→B, or AB→AB).

Investigational, Unproven, and/or Not Medically Necessary

1. Haploidentical HSCT is considered **investigational** when the following contraindications are present:

    a. Donor is medically or psychologically unfit

    b. Recipient has anti-donor HLA antibodies of sufficient strength to result in a positive crossmatch result by flow cytometry or by complement-dependent cytotoxicity assay

Continuation of Therapy criteria may be found in MCP 459 Pre-Transplant and Transplant Evaluation.

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

Inborn Errors of Immunity (IEIs)

Marsh et al. (2018) conducted an analysis of the indications, practice changes, and survival of patients with inborn errors of immunity treated with allogeneic HSCT between 1974–2016 using data from the Center for International Blood and Marrow Transplant Research (CIBMTR). Due to the passage of the Stem Cell Therapeutic and Research Act of 2005 all allogeneic transplants in the United States are reported to the CIBMTR, thus the authors categorized transplantations by broad disease category (SCID vs non-SCID) and transplant periods: 1974–1989, 1990–1999, 2000–2009, and 2010–2016. A total of 981 SCID and 1902 non-SCID patients underwent allogeneic HCT between 1974–2016. The number of transplantations increased over time, culminating in 352 SCID and 816 non-SCID transplants performed between 2010-2016. The median age for transplantation was 0.5 years for SCID and 2 years for non-SCID patients, with both indications and pre-transplant regimens evolving over the decades. Overall survival rates increased across all diagnoses and ages resulting with 3 – year overall survival (OS) rates prior to 2000 being

64% for SCID (95% confidence interval [CI] 58–69%) and 62% for non-SCID (CI 57–67%), versus from 2000–2009 being 73% for SCID (CI 68–78%) and 70% for non-SCID , and from being 2010–2016 80% for SCID (CI 76–85%) and 75% for non-SCID (CI 72–79%) (p<0.001). SCID was added to newborn screening in 2010, and likely accounts for the superior increase in SCID survival after 2010, as those diagnosed by newborn screening experienced a 94% 3-year survival probability (CI 89–98%).

Miyamoto et al. (2022) conducted a retrospective analysis on HSCT for non-SCID inborn errors of immunity between the years 1985 – 2016 utilizing data from the Japanese national database, Transplant Registry Unified Management Program. A total of 566 underwent allogeneic HSCT during the 31-year analysis period. The 10-year OS and event-free survival (EFS) were 74% and 64%, respectively. Donor source of all HSCTs were 39% unrelated bone marrow donor, 33% sibling matched bone marrow donor, and 28% unrelated cord blood donor, with 10-year OS rates being 79%, 81%, and 69% respectively. The analysis revealed that the intensity of conditioning was not associated with OS or neutrophil recovery; however, myeloablative conditioning was more frequently associated with infection-related death. The authors did note that OS has increased in the most recent decade.

Cheminant et al. (2023) conducted a retrospective analysis of outcomes in adults with IEIs who received allogeneic HSCT versus those who were not transplanted and received conservative management. A total of 281 patients were included (79 transplanted, 202 non-transplanted) with a median age of 21 years at the time of transplantation and median follow up of 4.8 years (interquartile range, 2.5-7.2). The 79 transplanted patients underwent allogeneic HSCT between 2008 and 2018 for IEIs such as chronic granulomatous disease (n = 20) and various combined immune deficiencies (n = 59). To control for variables as much as possible the non-transplanted patients were selected from the French Centre de Référence Déficits Immunitaires Héréditaires registry and matched for birth decade, age at last review greater than index patient age at allogeneic HSCT, chronic granulomatous disease or combined immune deficiencies, and autoimmune/lymphoproliferative complications. One-year transplant-related mortality rate was 13%, and the estimated 5 – year disease free survival rate of 58% and 33% in transplanted vs non-transplanted patients, respectively. Non-transplanted patients had increased recurrent events compared to transplanted patients, leading the authors to conclude that allogeneic HSCT prevents progressive morbidity associated with IEIs in adults, which may outweigh the negative impact of transplant-related mortality.

Mucopolysaccharidoses Lysosomal Storage Disorders

Qu et al. (2022) completed a single-center study of 42 children with MPS who received HSCT and a follow-up of ≥ 1 year following transplant. Children included in the study had MPS type I (n=9), type II (n=14), type IV (n=15), or type VI (n=4) and received either peripheral blood stem cells (n=24) or umbilical cord stem cells (n=18). Those that received umbilical cord stem cells received the blood from a matched family fresh cord blood donor (n=1), a mismatched unrelated cord blood donor (7/10 to 9/10 HLA-matched [n=15]), or from a double-mismatched unrelated cord blood donor (1 from a 6/10 to 8/10 HLA-matched donor and 1 from a 6/10 to 7/10 HLA-matched donor). Those that received peripheral blood stem cells received the blood from a matched family donor (n=4), a matched unrelated donor (n=10), a mismatched unrelated donor (7/10 to 9/10 HLA-matched [n=4]), or from a haploid donor (n=6). Children receiving peripheral blood stem cell transplants were condition with intravenous busulfan every 6 hours for 16 doses, intravenous cyclophosphamide, and antihuman thymocyte globulin. Specific lysosomal enzyme levels returned to normal in all recipients and 95.2% achieved full chimerism. The estimated OS at 1-year was 92.9% with no significant difference between peripheral or umbilical cord blood transplants. There was also no significant difference in acute or chronic GVHD between either group. High rates of pneumonia were noted in both groups (45.8% for peripheral blood and 33.3% for umbilical blood). A total of 3 deaths were reported following peripheral blood HSCT, 1 each due to grade III and IV GVHD, thrombotic microangiopathy, and combined grade III and IV GVHD and thrombotic microangiopathy. No patients with MPS type IV or VI died following transplantation. Researchers noted improvement in respiratory and CNS functions following HSCT. Valvular heart disease improved in some patients but progressed in others.

Gentner et al. (2021) reported interim results on an ongoing phase 1-2, non-randomized, single-center study involving 8 children diagnosed with MPS type I who lacked a suitable allogeneic donor for HSCT. The participants received autologous HSCT, and progenitor cells transduced ex vivo with an alpha-L-iduronidase (IDUA) encoding lentiviral vector after myeloablative conditioning. Median age at time of autologous HSCT was 1.9±0.5 years. Primary safety end points of the study include overall survival, hematologic engraftment by day 45, short- and long-term safety of drug-product infusion, and adverse event monitoring. The primary efficacy end point is blood IDUA activity at 1-year post-treatment. Secondary efficacy end points include anti-IDUA antibody immune response and engraftment of transduced cells at

levels of 30% or more, normalization of GAGs, and growth velocity at 1- and 3-years post-treatment. The study has an expected 5-year duration and is currently at a median follow-up period of 2.1 years. Patients will continue to be followed for at least 15 years. Interim results reported showed hematologic engraftment that was rapid and consistent in all patients. Neutrophil recovery occurred at a median of 20 days and early spontaneous platelet recovery occurred at a median of 14 days. There were no reports of graft-versus-host disease due to the autologous nature of transplantation. A total of 19 serious adverse events were reported with only 1 of those (an acute allergic reaction) potentially related to the treatment. Previously undetectable levels of IDUA in the cerebrospinal fluid at baseline were detectable starting at 3-months post-treatment and persisting through each subsequent follow-up. GAG levels in the cerebrospinal fluid were also noted to decline. The IDUA and GAG results suggest a rapid and profound metabolic correction of the central nervous system. All patients also progressively acquired motor skills with 6 patients having a total motor performance within normal range or in the low average of normal. Other typical clinical manifestations, such as coarse facial features, upper airway obstruction, hearing loss, and corneal opacity, which were evident at the time of treatment showed improvement or stabilization at 1- and 2-year follow-ups.

Aldenhoven et al. (2015) evaluated the survival and graft outcomes of MPS patients receiving HSCT. Two consecutive conditioning regimens were used, busulfan/cyclophosphamide or fludarabine/busulfan-based, both with exposure-targeted intravenous busulfan. A noncarrier matched sibling donor (MSD), matched unrelated cord blood (UCB), or matched unrelated donor (MUD) were preferred donors; however, if none were available, a mismatched UCB donor was used. A total of 62 MPS patients (56 MPS type I-Hurler, 2 MPS type II, 2 MPS type III, and 2 MPS type VI) received HSCT (41 UCB, 17 MSD, 4 MUD) at median age of 13.5 months. High overall survival (95.2%) and event-free survival (90.3%) were achieved with only low toxicity: 13.3% acute graft-versus-host disease aGVHD) grades II to IV and 14.8% chronic GVHD (1.9% extensive). A mismatched donor predicted a lower event-free survival (P = .04). A higher age at HSCT was a predictor for both aGVHD (P = .001) and chronic GVHD (P = .01). The use of a mismatched donor was a predictor for aGVHD (P = .01). Higher rates of full donor chimerism were achieved in successfully transplanted UCB recipients compared with MSD/MUD (P = .002). HSCT in MPS patients results in high safety and efficacy when international HSCT guidelines are followed, which allows extension of HSCT to more attenuated MPS types. Due to a reduction in HSCT related toxicity being associated with younger age at transplantation, newborn screening may further increase safety.

Two case reports support an increased quality of life following HSCT in patients with MPS VII Sly Syndrome. Yamada (1998) reported on a 12-year-old female who underwent successful HSCT and had almost normal levels of beta-glucuronidase activity in her lymphocytes and excretion of glycosaminoglycans in the urine was greatly diminished in the 31 months post HSCT. In addition to ultrastructural findings demonstrating no abnormal vacuoles and inclusion bodies in the cytoplasm of her rectal mucosal cells, the patient was able to walk alone for a long time without aid, ride a bicycle, and take a bath independently. The patient's recurrent upper respiratory and middle ear infections decreased in frequency and severity, as well as a decrease in the patient's dyspnea on exertion, severe snoring, and vertigo. Orii (2020) reported the 22 year follow up of the patient and revealed that her β-glucuronidase activity in leukocytes remained at normal levels, and urinary glycosaminoglycan excretion was reduced and kept within normal levels. Presently the patient remains able to walk independently and climb stairs, as well as sustain simple conversation. Due to the long-term stabilization of this patient's clinical picture, HSCT for MPS VII is a viable therapeutic option.

National and Specialty Organizations

The **American Academy of Allergy, Asthma & Immunology (AAAAI), the American College of Allergy, Asthma & Immunology (ACAAI), and the Joint Council of Allergy, Asthma & Immunology** published the *Practice Parameter on Diagnosis and Management of Primary Immunodeficiency* (Bonilla et al. 2015) 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.

The **American Society for Transplantation and Cellular Therapy (ASTCT**) published *Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy* (Kanate et al. 2020) which stipulates the various indications and uses for autologous and allogenic HSCT for different disease processes.

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).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) 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
	Histocompatibility codes
86812	HLA typing; A, B, or C (e.g., A10, B7, B27), single antigen
86813	HLA typing; A, B, or C, multiple antigens
86816	HLA typing; DR/DQ, single antigen
86817	HLA typing; DR/DQ, multiple antigens

HCPCS (Healthcare Common Procedure Coding System) Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

06/12/2024	New policy comprised of retired MCPs 265 (Immunodeficiency) and 256 (MPSs) into condensed HSCT for Non-Cancerous Diseases. Haploidentical transplant added to coverage criteria. IRO Peer Reviewed on May 24, 2024, by a practicing physician board certified in Pediatrics and Pediatric Hematology/Oncology.

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