Molina Clinical Policy
Hematopoietic Stem Cell Transplantation for Sickle Cell Disease or Thalassemia Major: Policy No. 209

Last Approval: 10/12/2023
Next Review Due By: October 2024

DISCLAIMER

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

OVERVIEW

Sickle cell disease (SCD) is an inherited hemoglobinopathy characterized by chronic hemolytic anemia and intermittent painful obstruction of blood vessels (vaso-occlusive crisis). The trademark feature of SCD is the presence of sickle-shaped red blood cells on peripheral blood smear. The disease can occur in individuals of any ethnicity, but is most common in individuals of African, Caribbean, Mediterranean, Middle Eastern, and Indian ancestry. Approximately 1 in 500 African American infants born in the United States are diagnosed with SCD which has led to screening panels in newborns. Approximately 60-70% of SCD cases in the United States are caused by a homozygous (e.g., present on both copies of the gene) variant known as hemoglobin S (HbS). Other forms of SCD have the variant known as hemoglobin C (HbC). Various types of thalassemia are also classified as an inherited hemoglobinopathy characterized by anemia that affects males and females. The disorders occur most often among people of Italian, Greek, Middle Eastern, Southern Asian, and African descent. It is estimated that 1000 individuals in the U.S. have beta thalassemia major (TM), the most severe form of thalassemia and the only form for which transplant is indicated. (Chao, 2022; Deeg & Sandmaier, 2022; Field & Vichinsky, 2022; Negrin, 2022; NHLBI, 2022; Rodgers et al., 2022; Khan & Rodgers, 2021; Hayes, 2020; [1-2] DynaMed, n.d.; SCDAA, 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 or HCT) 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 or 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, also increase. (Chao, 2022; Deeg & Sandmaier, 2022; Field & Vichinsky, 2022; Negrin, 2022; Rodgers et al., 2022; Khan & Rodgers, 2021; Hayes, 2020).

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.

Hematopoietic Stem Cell Transplantation for Sickle Cell Disease or Thalassemia Major may be considered medically necessary when the following criteria are met:

Transplant Evaluation

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

Components of the transplant evaluation include:

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

2. Psychosocial evaluation and clearance:
   a. Absence of any history of medical treatment non-compliance; **AND**
   b. Member understands surgical risk and post-procedure follow-up required; **AND**
   c. Adequate family and social support; **AND**
   d. No behavioral health disorder by history or psychosocial issues:
      i. If history of behavioral health disorder, no severe psychosis or personality disorder may be present; **AND**
      ii. Mood/anxiety disorder must be excluded or treated.

AND

3. EKG; **AND**

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

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

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
   a. Normal neurologic exam; **OR**
   b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy); **OR**
   c. Abnormal neurological exam with positive findings including **ONE** of the following:
      - Lumbar puncture with normal cytology; **OR**
      - Lumbar puncture with cytological exam abnormal, however central nervous system disease treated prior to clearance.

AND

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

AND

9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: Human immunodeficiency virus; Epstein Barr virus (; Hepatitis virus B ; Hepatitis C virus; cytomegalovirus ; rapid plasma reagin and/or fluorescent treponemal antibody:*
      - If HIV positive **ALL** of the following must be met:

i. CD4 count >200 cells/mm-3 for >6 months; **AND**
ii. Human immunodeficiency virus 1 ribonucleic acid undetectable; **AND**
iii. On stable anti-retroviral therapy >3 months; **AND**
iv. No other complications from acquired immunodeficiency syndrome (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

c. Urine drug screen if Member has a history of and /or current drug abuse.

AND

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

AND

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

AND

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

AND

13. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;*

OR

14. Prostate specific antigen if history of prostate cancer or previously elevated prostate specific antigen with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Criteria for Hematopoietic Allogenic Stem Cell Transplantation (HSCT)

Hematopoietic Allogeneic Stem Cell Transplantation (HSCT) ablative or non-myeloablative from a human leukocyte antigen (HLA)-matched donor (e.g., at least six out of eight match of the HLA-A, HLA-B, HLA-C and HLA-DRB1 markers for the treatment of a child or adolescent at increased risk of complications of SCD or TM) can be approved when **ALL** of the following criteria are met: (Locatelli et al., 2013)

1. All pre-transplant criteria are met; **AND**

2. In children and adolescents **with SCD** who are ≤ 16 years of age who have **ONE or more** of the following:
   a. Stroke or central nervous system (CNS) event lasting longer than 24 hours; **OR**
   b. Progressive neurologic deterioration (e.g., abnormal cerebral MRI and arteriogram) and impaired neuropsychiatric testing; **OR**
   c. Recurrent acute chest syndrome or Stage I or II sickle lung disease; **OR**
   d. Recurrent vaso-occlusive painful episodes; **OR**
   e. Sickle nephropathy [glomerular filtration rate (GFR) 30-50 percent of predicted normal; **OR**
   f. Osteonecrosis of multiple joints.

OR

3. In children and adolescents **with TM** who are ≤ 16 years of age and have deterioration with conventional treatments including transfusions, splenectomy, and deferoxamine;

AND

4. The requesting transplant recipient is free of **ALL** of the following absolute contraindications:
   a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery.
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer).
   c. Systemic and/or uncontrolled infection.
   d. AIDS (CD4 count < 200cells/mm3).
   e. Unwilling or unable to follow post-transplant regimen as documented by history of non-compliance and/or inability to follow through with medication adherence or office follow-up.
   f. Chronic illness, aside from transplant indication, with one year or less life expectancy.
   g. Limited, irreversible rehabilitation potential.
   h. Active untreated substance abuse or misuse (including daily significant cannabis use) requires documentation of a formal substance use disorder evaluation with clear and unambiguous documentation of:
      a. A reasonable expectation that the Member can adequately comply with a complex, post-transplant plan of care; **AND**
      b. The member is free from addiction for at least 6 months.
   i. Inadequate social/family support.

AND

5. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
   a. Smoking, documentation supporting free from smoking for 6 months; **OR**
   b. Active peptic ulcer disease; **OR**
   c. Active gastroesophageal reflux disease; **OR**
   d. Cerebrovascular accident (CVA) with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
   e. Obesity with body mass index of >30 kg/m^2 may increase surgical risk; **OR**
   f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Criteria for Subsequent Hematopoietic Stem Cell Transplantation

A second or repeat Hematopoietic Allogeneic Stem Cell Transplantation (ablative or non-myeloablative) **may be authorized** only one time when **ALL** of the above criteria for transplant have been met and **ANY** of the following:

1. Primary graft failure indicated by no signs of engraftment* by 42 days after the transplant; **OR**
2. Failure to engraft.*

*NOTE: Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 5 x 10^9/L or > ANC500 at any time after transplantation.

Criteria for Donor Lymphocyte Infusion (DLI)

Donor Lymphocyte Infusion (DLI) including collection and cryopreservation **may be authorized** following a medically necessary allogeneic hematopoietic stem cell transplant when **ONE** of the following criteria are met:

1. For incomplete chimerism and disease relapse in the setting of incomplete chimerism (defined as incomplete donor stem cell grafting in the recipient's bone marrow); **OR**
2. Donor lymphocytes must be collected from the original hematopoietic stem cell donor.

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 allogeneic (ablative or non-myeloablative) transplant due to persistent, progressive, or relapsed disease.
3. Autologous stem cell transplantation.
4. Hematopoietic stem cell collection, storage and freezing for a future unplanned transplant.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The published, peer-reviewed scientific literature supports the safety and effectiveness of allogeneic HSCT for the treatment of SCD and TM in selected individuals and consists of systematic reviews, retrospective and prospective multi-center clinical studies and case series. Several studies evaluated up to 485 SCD and TM symptomatic patients, the majority of whom received donor allografts from siblings who were human leukocyte antigen (HLA) identical. The results from these series were similar, with overall survival rates ranging from 92–94% and event-free survival from 82–86% with a median follow-up ranging from 0.9–17.9 years. (Arnold et al. 2017; Jagannath et al. 2016; Dedeken et al. 2014; Locatelli et al. 2013; Oringanje et al. 2013; Kavanagh et al. 2011).

Improved outcomes have not been demonstrated for autologous HSCT compared with allogeneic HSCT and conventional chemotherapy in individuals with SCD and TM therefore the role of autologous HSCT for this indication

has not been established. Clinical trials are evaluating the role of unrelated donor HCT in treating severe SCD and TM and enrolling children with a history of severe symptoms manifesting as strokes, frequent pain crises, or acute chest syndrome. Experience with myeloablative HCT in older teenagers and adults with SCD and TM is insufficient and the role for this age group has not been established. A summary of the most relevant medical evidence is outlined below.

The largest case series analyzed the outcomes of 485 patients with TM or SCD receiving HLA-identical sibling cord blood transplantation (CBT, n = 96) or bone marrow transplantation (BMT, n = 389). Compared with patients given BMT, CBT recipients were significantly younger (median age 6 vs 8 years, P = .02), and were treated more recently (median year 2001 vs 1999, P < .01). A higher proportion of patients with TM belonging to classes II-III of the Pesaro classification received BMT (44%) compared with CBT (39%, P < .01). In comparison with patients receiving BMT (n = 259, TM; n = 130, SCD), those given CBT (n = 66, TM; n = 30, SCD) had slower neutrophil recovery, less acute graft-versus-host disease (GVHD) and none had extensive chronic GVHD. With a median follow-up of 70 months, the 6- year overall survival was 95% and 97% after BMT and CBT, respectively (P = .92). The 6-year disease-free survival (DFS) was 86% and 80% in TM patients after BMT and CBT, respectively, whereas DFS in SCD patients was 92% and 90%, respectively. The cell dose infused did not influence outcome of patients given CBT. In multivariate analysis, DFS did not differ between CBT and BMT recipients. Patients with TM or SCD have excellent outcomes after both HLA identical sibling CBT and BMT (Locatelli et al. 2013).

The outcomes of 50 consecutive children with severe SCD that received HSCT between November 1988 and April 2013 were reported. The stem cell source was bone marrow (n = 39), cord blood (n = 3), bone marrow and cord blood (n = 7) and peripheral blood stem cells (n = 1). All patients had >1 severe manifestation: 37 presented with recurrent vaso-occlusive crises/acute chest syndrome, 27 cerebral vasculopathy and 1 nephropathy. The conditioning regimen consisted of busulfan +cyclophosphamide (BuCy) before November 1991 and BuCy + rabbit antithymocyte globulin after that date. Since 1995, all patients have been treated with hydroxycarbamide (HC) prior to transplantation for a median duration of 27 years. Median age at transplantation and median follow-up was 8.3 and 7.7 years, respectively. Acute graft-versus-host disease (GVHD) and chronic GVHD were observed in 11 and 10 patients, respectively. An excellent outcome was achieved, with 8-year overall survival and event-free survival (EFS) rates of 94.1% and 85.6%, respectively. Since HC introduction, no graft failure occurred and EFS reached 97.4%. Prior treatment with HC may have contributed to successful engraftment (Dedeken et al. 2014).

Arnold et al., (2017) performed a retrospective study of children transplanted for SCD in the USA during 2000-2013 using two large databases. Univariate and Cox models were used to estimate associations of demographics, SCD severity, and transplant-related variables with mortality and chronic graft-versus-host disease. Among 161 patients with a 2-year overall survival rate of 90% (95% confidence interval [CI] 85-95%) mortality was significantly higher in those who underwent late transplantation versus early (hazard ratio (HR) 21, 95% CI 2.8-160.8, P=0.003) and unrelated compared to matched sibling donor transplantation (HR 5.9, 95% CI 1.7-20.2, P=0.005). Chronic graft versus host disease was significantly more frequent among those transplanted late (HR 1.9, 95% CI 1.0-3.5, P=0.034) and those who received an unrelated graft (HR 2.5, 95% CI 1.2-5.4; P=0.017).

National and Specialty Organizations

The **National Heart, Lung and Blood Institute (NHLBI)** (2014) published a guideline on *The Management of Sickle Cell Disease (4th ed.).* A section on hematopoietic cell transplantation is included, noting that HCT is the only therapy for SCD that has curative potential. The NHLBI recommends that children with SCD who experience significant, noninfectious complications caused by vaso-occlusion should be considered for HCT; if full siblings are available, HLA typing should be performed as results are best when performed in children with a sibling donor who is HLA-identical. HCT is recommended for patients who have experienced significant complications caused by SCD (e.g., stroke, recurrent episodes of acute chest syndrome or pain). Further research is needed on the identification of clinical or genetic markers that reliably predict an adverse outcome thereby allowing the application of HCT before significant clinical complications occur. The NHLBI also published the *Evidence-Based Management of Sickle Cell Disease: Expert Panel Report* in 2002. The need for additional research is reiterated for transplantation for those with SCD.

The **American Society for Blood and Marrow Transplantation (ASBMT)** published *Practice Guidelines: Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation*. Multiple stakeholders were included in the development of the guidelines, including transplant experts and advocates to provide guidance on routine indications for HCT. Recommendations for indications of HCT were categorized by various levels of standard of care as well as those that lack necessary evidence for efficacy.

The **American Society of Hematology** published *Guidelines for Sickle Cell Disease: Prevention, Diagnosis, and Treatment of Cerebrovascular Disease in Children and Adults* (2020). Data suggest that HSCT is a reasonable option for children with SCD when performed in a clinical trial setting however, more research is needed. The long-term benefit versus the risk of using HSCT for primary stroke prevention has not been systematically studied; this includes late effects of myeloablative and nonmyeloablative therapy in children and adults with SCD. Future clinical trials are needed to determine the optimal HSCT strategy for primary stroke prevention.

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
38230	Bone marrow harvesting for transplantation; allogeneic
	Cell Processing Services
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
	Cell infusion codes
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38242	Allogeneic lymphocyte infusions
38243	Hematopoietic progenitor cell (HPC); HPC boost
	Histocompatibility codes
86812	HLA typing; A, B, or C (e.g., A10, B7, B27), single antigen
86813	HLA typing; A, B, or C, multiple antigens
86816	HLA typing; DR/DQ, single antigen
86817	HLA typing; DR/DQ, multiple antigens

HCPCS (Healthcare Common Procedure Coding System) Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which

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

APPROVAL HISTORY

10/12/2023	Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and substance use to absolute contraindications, and removal of abnormal serology criteria and cannabis use sections. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on September 20, 2023, by a practicing, board-certified physician with specialties in Pediatrics and Pediatric Hematology/Oncology.
10/12/2022	Policy reviewed, no changes to criteria, included section on marijuana use.
10/13/2021	Policy reviewed, no changes to criteria; included updates from ASBMT, ASH, NHLBI; updated references.
9/16/2020	Policy reviewed, no changes, updated references.
9/18/2019	Policy reviewed, no changes.
9/13/2018	Policy reviewed, no changes.
12/13/2017	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence (professional guidelines) and references.
9/15/2016	Policy reviewed, no changes.
6/2/2015	Policy reviewed, updated pre-transplant criteria, continuation of therapy, absolute and relative contraindications and coding.
11/11/2014	New policy.

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