Medica

UTILIZATION MANAGEMENT POLICY

TITLE: BONE MARROW OR STEM CELL (PERIPHERAL OR UMBILICAL CORD BLOOD) TRANSPLANTATION

EFFECTIVE DATE: April 15, 2024

This policy was developed with input from specialists in nephrology, transplants, and oncology, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

I. Definitions
   A. **Allogeneic** graft is one in which the donor and recipient are of different genetic origins.
   B. **Autologous** bone marrow transplant (ABMT) refers to the removal and storage of some of the patient's own stem cells for restoring bone marrow function after high dose chemotherapy or radiotherapy.
   C. **Bone marrow transplant** (BMT) is the reconstitution of the full hematopoietic system by transfer of the pluripotent cells present in the bone marrow (stem cells). A BMT involves a transplant not only of the donor myeloid, erythroid, and megakaryocytic systems, but also of lymphoid and macrophage-monocyte systems. There are four types of disease for which BMT has been widely utilized:
      1. **Genetic disease**
         For immunologic deficiency diseases, the objective is to replace the recipient's genetically defective lymphoid system with the normal lymphoid tissue of the donor. For genetic diseases such as thalassemia major or various inborn errors of metabolism (inherited metabolic disorders), the abnormal marrow must be destroyed and replaced by normal stem cells.
      2. **Aplastic anemia**
         Aplastic anemia, which may result from several causes, is a condition that occurs when the body stops producing enough new blood cells and results in loss of the marrow. A stem cell transplant to rebuild the bone marrow with stem cells from a donor may offer the only successful treatment.
      3. **Hematologic malignancy**
         For leukemia and other hematologic malignancies, the objective is the complete destruction of the malignant cell population and unavoidably, normal stem cells, by intensive chemo-radiotherapy followed by restoration of normal marrow function by the transplanted stem cells.
      4. **Non-hematologic malignancy** (Chemotherapy or high-dose chemotherapy with autologous peripheral stem cell/bone marrow rescue [HDC/ABMT]). For patients with poor-prognosis cancer

necessitating treatment with high dose therapy, autologous stem cell transplantation rescue may be used in selected conditions to reconstitute the devastated marrow population.

D. **Chemosensitive** disease is malignant disease that demonstrates at least a partial response to a course of chemotherapy.
E. **Donor Lymphocyte Infusion (DLI),** also known as a donor leukocyte infusion or buffy coat infusion, may be performed following allogeneic transplant. Individuals may be infused with lymphocytes obtained via leukapheresis from the original donor. The DLI attempts to induce a beneficial graft-versus-tumor response or improve the level of engraftment with or without the need for additional stem cell harvest from the donor. This is not a second stem cell transplant.
F. **Stem cell boost** is a Hematopoietic Stem Cell Infusion (HSCI) provided to a transplant recipient to assist with hematopoietic recovery or declining donor chimerism. It is generally not preceded by a preparative regimen and is not considered a new transplant event. In this procedure, the patient receives a boost of hematopoietic stem cells from the original donor's blood or sometimes, the bone marrow. The stem cell boost term is used interchangeably with other terms such as reinfusion, support and rescue.
G. **Stem cells** are blood cells at the earliest stage of development in the bone marrow. They can be taken from the bone marrow, peripheral bloodstream, or from umbilical cord blood.
H. **Stem Cell Transplant**
    1. **Allogeneic stem cell transplant** employs chemotherapy, immunosuppressive agents and/or radiation to provide adequate immunosuppression to permit engraftment of stem cells from a human donor other than the patient him/herself. The intensity of the agents used for immunosuppression may be either myeloablative or non-myeloablative depending on the disease being treated and specific patient and donor characteristics. Stem cells may be obtained from the bone marrow, peripheral blood, or umbilical cord blood. The stem cell donor may be related or unrelated to the potential recipient.
    2. **Autologous stem cell transplant** utilizes the patient's own stem cells to re-establish hematopoietic cell function following intensive doses of chemotherapy, with or without radiation. Stem cells may be obtained from repeated aspirations of bone marrow, peripheral blood or umbilical cord blood. Modifications of the autologous graft may at times be performed to enhance the graft function or change gene expression (in hemoglobin or other disorders).
    3. **Non-myeloablative stem cell transplant (NST)/Reduced–intensity conditioning stem cell transplant (RICST)** is a stem cell transplant in which full marrow ablation does not occur. This transplant provides sufficient immunosuppression to achieve donor engraftment, with less toxicity. It is also called a "mini" transplant.
    4. **Tandem transplant** involves two sequential courses of high dose chemotherapy, each followed by stem cell transplant, within a six-month period. This is generally an autologous procedure but at times can be an autologous graft, followed later by an allogeneic graft.
    5. **Umbilical cord blood stem cell transplant** employs the infusion of stem cells obtained from the umbilical cord or placenta of a newborn child. A two antigen (Ag) mismatch is acceptable. Cord blood transplantation in patients weighing more than 40kg sometimes utilizes cord blood from at least two donors ("double cord").
I. **Syngeneic** graft describes a graft in which the donor and recipient are genetically identical twins.
J. **Transplant or graft** is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual.
K. Transplant **evaluation** is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual's diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; and psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.
L. **Treatment response**, in medicine, is an improvement related to treatment. A number of disease specific systems exist for measuring response.
    1. A **complete response**, in general, is the disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured. Also called complete remission.
    2. A **partial response**, in general, is defined as a decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment. Also called partial remission.

II. Comments
   A. Refer to Appendices for additional terms, definitions and classification tables.
   B. Stem cell source and preparative regimens are at the discretion of the treating physician.
   C. Donor lymphocyte infusion following allogeneic stem cell transplant is appropriate for incomplete chimerism or sometimes disease relapse. This is not a second stem cell transplant.
   D. Chimeric Antigen Receptor Therapy and/or the use of T-cells/natural killer cell protocols provide cellular immune treatment of the underlying disease and are not considered to be a transplant procedure.

BENEFIT CONSIDERATIONS
1. Prior authorization **is required** for:
   - Bone Marrow and Stem Cell Transplant **Evaluation**
   - Bone Marrow and Stem Cell **Transplantation**
   - Please see the prior authorization list for product specific prior authorization requirements.
2. Coverage may vary according to the terms of the member's plan document.
3. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member's plan document.
4. Complex cases require medical director or external review, and as necessary, discussion with the patient's physician.
5. Underlying co-morbidity that significantly alters the risk/benefit of transplant may preclude transplant eligibility.
6. Coverage of costs related to chemotherapy, drugs, other related supplies and services is limited to individuals who have one of the indications listed and are transplant candidates.
7. Coverage of costs related to collection and storage of umbilical cord blood stem cells is addressed in the member's plan document.
8. Medical director or external review is required for any of the following procedures if not performed in a clinical trial:
   - Any tandem stem cell transplant, except for the indications noted in the Medical Necessity Criteria
9. Use of progenitor/stem cells from bone marrow, peripheral blood or umbilical cord blood for non-conventional indications (such as direct injection into the heart muscle, bone or other body tissue) requires medical director or external review. Please refer to the following related Coverage Policies: Stem Cell and Cellular Bone Matrix Products for Orthopedic Applications*; Stem Cell Therapy for Peripheral Artery Disease; and Cell Therapy for the Treatment of Cardiac Disease.*
10. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
11. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA
I. Indications for Bone Marrow or Stem Cell Transplant **Evaluation**
   Documentation from the medical record indicates that **one of the following** criteria are met:
   A. For **allogeneic** transplant, documentation from the medical record indicates that the individual has **one of the following** diagnoses**:**
      1. Leukemia
         a. Acute Lymphocytic/Lymphoblastic Leukemia (ALL)
         b. Acute Myeloid Leukemia (AML)
         c. Chronic Lymphocytic Leukemia (CLL)
         d. Chronic Myeloid Leukemia (CML)
         e. Prolymphocytic Leukemia
      2. Lymphoma (*See Appendix 1)*
         a. Hodgkin's Lymphoma
         b. Small B-Cell Lymphocytic Lymphoma
         c. Follicle Center Lymphoma
         d. Lymphoplasmacytoid Lymphoma/Immunocytoma
         e. Marginal Zone Lymphoma
         f. Burkitt Lymphoma

g. Diffuse Large Cell Lymphoma
h. Mantle Cell Lymphoma
i. Precursor B-Cell Leukemia/Lymphoma
j. T-Cell Lymphoma

3. Myelodysplastic and Mixed Myelodysplastic/Myeloproliferative Neoplasms
   a. Myelodysplastic syndrome (MDS)
   b. Primary Myelofibrosis and related conditions (e.g., Polycythemia Rubra Vera)
   c. Secondary Myelofibrosis
   d. Chronic Myelomonocytic Leukemia (CMML), including Juvenile Myelomonocytic Leukemia (JMML)
4. Multiple Myeloma/Plasma Cell Disorders
   a. Waldenstrom's Macroglobulinemia
5. Hematological Disorders
   a. Aplastic Anemia
   b. Blackfan-Diamond Syndrome
   c. Chronic Granulomatous Disease
   d. Congenital Agranulocytosis (Kostmann Syndrome)
   e. Congenital Amegakaryocytic Thrombocytopenia
   f. Dyskeratosis Congenita
   g. Fanconi Anemia (FA)
   h. Paroxysmal Nocturnal Hemoglobinuria (PNH)
   i. Schwachman-Diamond Syndrome (SDS)
   j. Sickle Cell Disease
   k. Thalassemia Major
6. Immunodeficiency Syndromes
   a. CD40 Ligand Deficiency
   b. Chediak-Higashi Syndrome
   c. Gaucher disease type I
   d. Hemophagocytic Lymphohistiocytosis (HLH) (same as familial erythrophagocytic lymphohistiocytosis [FEL])
   e. Immune dysregulation, polyendocrinopathy, enteropathy, X-linked (IPEX) syndrome
   f. Leukocyte Adhesion Deficiency
   g. Lysosomal storage disease
   h. Niemann-Pick type B
   i. Omenn Syndrome
   j. Severe combined immunodeficiency disease (SCID)
   k. Wiskott-Aldrich Syndrome
   l. X-linked Lymphoproliferative Syndrome
   m. Fucosidosis
7. Inherited Metabolic Disorders
   a. Adrenoleukodystrophy
   b. Epidermolysis Bullosa
   c. Globoid Cell Leukodystrophy (Krabbe Disease)
   d. Hurler Syndrome (MPS-1)
   e. Hunter Syndrome (MPS II)
   f. Mannosidosis and other liposomal storage diseases
   g. Maroteaux-Lamy Syndrome (MPS-VI)
   h. Metachromatic Leukodystrophy
   i. Mitochondrial Neurogastrointestinal Encephalopathy (MNGIE)
   j. Osteopetrosis (also called marble-bone disease, malignant osteopetrosis, or autosomal recessive osteopetrosis)
   k. Rett Syndrome
8. Other Malignancies
   a. Blastic Plasmacytoid Dendritic Cell Neoplasm

B. For **autologous** transplant, documentation from the medical record indicates that the individual has **one of the following** diagnoses**:**
   1. Leukemia
      a. Acute Lymphoblastic Leukemia (ALL)

b. Acute Myelogenous Leukemia (AML) (also known as Acute Non-Lymphocytic Leukemia [ANLL])
c. Prolymphocytic Leukemia

2. Lymphoma *(See Appendix 1)*
   a. Hodgkin's Lymphoma
   b. Non-Hodgkin's Lymphoma
      i. Follicle center lymphoma
      ii. Lymphoplasmacytoid lymphoma/Immunocytoma
      iii. Marginal zone lymphoma (mucosa-associated lymphoid tissue, splenic, nodal)
      iv. Burkitt lymphoma
      v. Diffuse large cell lymphoma (mediastinal large cell, primary effusion)
      vi. Mantle cell lymphoma
      vii. Precursor B-cell leukemia/lymphoma
      viii. T-cell lymphoma
3. Multiple Myeloma/Plasma Cell Disorders
   a. Multiple myeloma (*Single or Tandem auto is appropriate*)
   b. AL Amyloidosis
   c. Waldenstrom's Macroglobulinemia
   d. POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monocloncal Gammopathy Skin defects Syndrome)
4. Germ Cell Tumors (*Single or Tandem auto is appropriate for all of the germ cell tumors below*)
   a. Testicular Germ Cell Tumor
   b. Ovarian Germ Cell Tumor
   c. Extragonadal Germ Cell Tumor
   d. Seminoma
   e. Choriocarcinoma
   f. Embryonal carcinoma
   g. Mixed germ cell tumors
   h. Teratoma
   i. Yolk sac tumor
5. Brain Tumors
   a. Medulloblastoma
   b. Embryonal Tumors with Multi-layered Rosettes (ETMR). Formerly known as Primitive Peripheral Neuro-ectodermal Tumor (PNET)
   c. Oligodendroglioma
   d. Pineoblastoma
6. Other Malignancies
   a. Atypical teratoid rhabdoid tumors
   b. Neuroblastoma (*Single or Tandem auto is appropriate*)
   c. Retinoblastoma
   d. Ewing Sarcoma
   e. Supratentorial ependymoma
   f. Wilms Tumor.
7. Autoimmune Diseases
   a. Multiple Sclerosis
   b. Systemic Sclerosis (Scleroderma)

II. Indications For Bone Marrow Or Stem Cell **Transplantation**
Autologous/allogeneic bone marrow or stem cell transplantation is considered medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:
A. Individual meets the institution's eligibility criteria for transplant
B. Individual meets the criteria in Section I.

III. Indications For Bone Marrow/Stem Cell **Retransplantation**
Documentation in the medical records indicates that **all of the following** criteria are met:
A. The individual has **one of the following**:
   1. Relapse of original disease
   2. Failure to engraft.
B. All of the criteria in section II are met.

C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

MINNESOTA HEALTH CARE PROGRAMS (MHCP)

- For MHCP members, refer to https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_000094#

DOCUMENT HISTORY

Original Effective Date	January 1, 1990
MPC Endorsement Date(s)	12/1989, 11/1990, 11/1991, 09/1993, 12/1995, 02/1998, 02/1999, 01/2000, 01/2001, 03/2002, 02/2003, 12/2003, 11/2004, 11/2005, 11/2006, 11/2007, 11/2008, 11/2009, 02/2010, 02/2011, 02/2012, 02/2013, 02/2014, 04/2015, 06/2016, 02/2017, 02/2018, 02/2019, 02/2020, 02/2021, 09/2021, 02/2022, 02/2023, 02/2024
Administrative Update(s)	05/01/2017

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Pre-06/2016 MPC

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APPENDIX 1 – Classification of Lymphoid Neoplasms

2016 WHO classification of mature lymphoid, histiocytic, and dendritic neoplasms

Mature B-cell neoplasms

- Chronic lymphocytic leukemia/small lymphocytic lymphoma
- Monoclonal B-cell lymphocytosis*
- B-cell prolymphocytic leukemia
- Splenic marginal zone lymphoma
- Hairy cell leukemia
- *Splenic B-cell lymphoma/leukemia, unclassifiable*
  - *Splenic diffuse red pulp small B-cell lymphoma*
  - *Hairy cell leukemia-variant*
- Lymphoplasmacytic lymphoma
  - Waldenström macroglobulinemia
- Monoclonal gammopathy of undetermined significance (MGUS), IgM*
  - μ heavy-chain disease
  - γ heavy-chain disease
  - α heavy-chain disease
- Monoclonal gammopathy of undetermined significance (MGUS), IgG/A*
- Plasma cell myeloma
- Solitary plasmacytoma of bone
- Extraosseous plasmacytoma
- Monoclonal immunoglobulin deposition diseases*
- Extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma)
- Nodal marginal zone lymphoma
  - *Pediatric nodal marginal zone lymphoma*
- Follicular lymphoma
  - In situ follicular neoplasia*
  - Duodenal-type follicular lymphoma*
- Pediatric-type follicular lymphoma*
- *Large B-cell lymphoma with IRF4 rearrangement**
- Primary cutaneous follicle center lymphoma
- Mantle cell lymphoma
  - In situ mantle cell neoplasia*
- Diffuse large B-cell lymphoma (DLBCL), NOS
  - Germinal center B-cell type*
  - Activated B-cell type*
- T-cell/histiocyte-rich large B-cell lymphoma
- Primary DLBCL of the central nervous system (CNS)
- Primary cutaneous DLBCL, leg type
- EBV+ DLBCL, NOS*
- *EBV+ mucocutaneous ulcer**
- DLBCL associated with chronic inflammation
- Lymphomatoid granulomatosis
- Primary mediastinal (thymic) large B-cell lymphoma
- Intravascular large B-cell lymphoma
- ALK+ large B-cell lymphoma
- Plasmablastic lymphoma
- Primary effusion lymphoma
- *HHV8+ DLBCL, NOS**
- Burkitt lymphoma
- *Burkitt-like lymphoma with 11q aberration**
- High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements*
- High-grade B-cell lymphoma, NOS*
- B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma

Mature T and NK neoplasms

- T-cell prolymphocytic leukemia
- T-cell large granular lymphocytic leukemia
- *Chronic lymphoproliferative disorder of NK cells*

- Aggressive NK-cell leukemia
- Systemic EBV+ T-cell lymphoma of childhood*
- Hydroa vacciniforme–like lymphoproliferative disorder*
- Adult T-cell leukemia/lymphoma
- Extranodal NK-/T-cell lymphoma, nasal type
- Enteropathy-associated T-cell lymphoma
- Monomorphic epitheliotropic intestinal T-cell lymphoma*
- *Indolent T-cell lymphoproliferative disorder of the GI tract**
- Hepatosplenic T-cell lymphoma
- Subcutaneous panniculitis-like T-cell lymphoma
- Mycosis fungoides
- Sézary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
  - Lymphomatoid papulosis
  - Primary cutaneous anaplastic large cell lymphoma
- Primary cutaneous γδ T-cell lymphoma
- *Primary cutaneous CD8+ aggressive epidermotropic cytotoxic T-cell lymphoma*
- *Primary cutaneous acral CD8+ T-cell lymphoma**
- *Primary cutaneous CD4+ small/medium T-cell lymphoproliferative disorder**
- Peripheral T-cell lymphoma, NOS
- Angioimmunoblastic T-cell lymphoma
- *Follicular T-cell lymphoma**
- *Nodal peripheral T-cell lymphoma with TFH phenotype**
- Anaplastic large-cell lymphoma, ALK+
- Anaplastic large-cell lymphoma, ALK−*
- *Breast implant–associated anaplastic large-cell lymphoma**

Hodgkin lymphoma

- Nodular lymphocyte predominant Hodgkin lymphoma
- Classical Hodgkin lymphoma
  - Nodular sclerosis classical Hodgkin lymphoma
  - Lymphocyte-rich classical Hodgkin lymphoma
  - Mixed cellularity classical Hodgkin lymphoma
  - Lymphocyte-depleted classical Hodgkin lymphoma

Posttransplant lymphoproliferative disorders (PTLD)

- Plasmacytic hyperplasia PTLD
- Infectious mononucleosis PTLD
- Florid follicular hyperplasia PTLD*
- Polymorphic PTLD
- Monomorphic PTLD (B- and T-/NK-cell types)
- Classical Hodgkin lymphoma PTLD

Histiocytic and dendritic cell neoplasms

- Histiocytic sarcoma
- Langerhans cell histiocytosis
- Langerhans cell sarcoma
- Indeterminate dendritic cell tumor
- Interdigitating dendritic cell sarcoma
- Follicular dendritic cell sarcoma
- Fibroblastic reticular cell tumor
- Disseminated juvenile xanthogranuloma
- Erdheim-Chester disease*

Provisional entities are listed in italics.
*Changes from the 2008 classification.

Source: Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. *Blood*. May 2016;127(20):2375-2390. doi: 10.1182/blood-2016-01-643569. (Current as of January 02, 2024).