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## Subject: Allogeneic Bone Marrow and Stem Cell Transplantation

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### **DESCRIPTION:**

#### **Hematopoietic Stem Cell Transplantation**

Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in those with cancer who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HSCT) or from a donor (allogeneic HSCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HSCT. However, immunologic compatibility between donor and recipient is a critical factor for achieving a good outcome of allogeneic HSCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the Class I and Class II loci on chromosome 6. Depending on the disease being treated, an acceptable donor will match the recipient at all or most of the HLA loci.

#### **Conventional Preparative Conditioning for HSCT**

The conventional (“classical”) practice of allogeneic HSCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect mediated by non-self immunologic effector cells that develop after engraftment of allogeneic stem cells within the individual’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease without the use of pretransplant

conditioning. However, intense conditioning regimens are limited to candidates who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allogeneic HSCT, immunosuppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the individual to opportunistic infections.

### **Reduced-Intensity Conditioning for Allogeneic HSCT**

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in traditional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden but also to minimize as much as possible associated treatment-related morbidity and non-relapse mortality (NRM) in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of NRM and relapse due to residual disease. RIC regimens can be viewed as a continuum in effects, from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and recipient condition. Those who undergo RIC with allogeneic HSCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For the purposes of this Medical Coverage Guideline, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

## **POSITION STATEMENT:**

### **Certificate of Medical Necessity**

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Stem Cell Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

In accordance with **Chapter 59-B of the Florida Administrative Code [(1) – (6)]**:

- (1) Allogeneic hematopoietic stem cell transplantation, myeloablative conditioning and reduced-intensity conditioning, is covered when performed for one of the following indications:
  - Acute myelogenous [leukemia](#)
  - Myeloid sarcoma
  - Chronic myelogenous leukemia
  - Acute lymphoblastic leukemia

- Chronic [lymphocytic leukemia](#)
- Non-Hodgkin's [lymphoma](#)
- [Myelodysplastic syndrome](#)
- Hodgkin's lymphoma relapsed after autologous transplant, but not progressing on salvage therapy
- Severe or very severe aplastic anemia, from HLA-compatible siblings
- Severe aplastic anemia unresponsive to immunosuppression
- Sickle cell anemia, thalassemia, and other severe red cell disorders
- Severe combined immune deficiency disorder, and other severe immune deficiency disorders

In cases where treatment for any of the above conditions includes a clinical trial that conforms to subsection (6) (below), routine care costs associated with the bone marrow transplant will be covered.

(2) Allogeneic hematopoietic stem cell transplantation, myeloablative conditioning and reduced-intensity conditioning, is covered for the following indications when the bone marrow transplantation procedure is performed in the context of a well-designed clinical treatment trial as described in subsection (6):

- Multiple myeloma and other plasma cell dyscrasias (e.g., Waldenstrom's, amyloid)
- Renal cell carcinoma
- Hodgkin's lymphoma
- Sickle cell anemia, thalassemia and other severe red cell disorders

(3) The following rare diseases, where there are no existing clinical trials available, are covered for bone marrow transplant at the Blood and Marrow Transplant Clinical Trials Network (BMT CNT) core or non-core facilities when deemed medically necessary:

- Myelofibrosis
- Chronic myelomonocytic leukemia (CMML)
- Paroxysmal nocturnal hemoglobinuria (PNH)
- POEMS syndrome

(4) Transplants from living related donors, incompatible for one HLA-A, -B, and -DRB1 loci, are covered for bone marrow transplant at BMT CTN core or non-core medical facilities.

(5) Any bone marrow transplant performed outside of a clinical trial will be covered when all the following criteria are met:

- The plan of care follows a clinical trial protocol that meets the requirements of subsection (6);
- Patient cannot be enrolled in the proposed clinical trial;
- Bone marrow transplant treatment is medically necessary;
- Patient is an appropriate candidate for bone marrow transplant; and
- Treatment center is part of the Blood and Marrow Transplant Clinical Trials Network (BMT CNT) as a core or non-core center.

- (6) A well-designed and conducted clinical treatment trial is one which includes an IRB-approved written protocol. At a minimum, such protocol shall have specific criteria for evaluating the effect of treatment with defined endpoints that are precise, meaningful, and reliable and which allow valid conclusions to be drawn about therapeutic efficacy and safety. Protocols should include an adequate statistical section describing the method of randomization and stratification, if any, expected outcome parameters relating to response rates, time to progression, survival times and other relevant information. Such clinical treatment trials shall be consistent with protocols reviewed and approved by the National Cancer Institute for scientific merit.

Allogeneic hematopoietic stem-cell transplantation also **meets the definition of medical necessity** when performed for one of the following indications (in addition to any mandated coverage in subsections (1) – (6) above):

**Hodgkin's lymphoma:**

- Allogeneic transplant, using either myeloablative or reduced-intensity conditioning regimens, for primary refractory or relapsed Hodgkin lymphoma
- **Multiple myeloma:**
  - Tandem transplantation with an initial autologous transplant, followed by a non-marrow-ablative conditioning regimen and allogeneic transplant to treat newly diagnosed multiple myeloma
- **Myeloproliferative neoplasms (polycythemia vera (PCV), essential thrombocytopenia (ET), primary myelofibrosis (PMF), neutrophilic leukemia (CNL), chronic eosinophilic leukemia/hypereosinophilic syndrome (CEL/HES), mast cell disease (MCD):**
  - Myeloablative allogeneic transplant, **OR**
  - Reduced intensity allogeneic transplant in those who would be unable to tolerate a myeloablative conditioning regimen
- **Neuroblastoma (high-risk only):**
  - Not a candidate for autologous transplant

It should be noted that there are non-malignant diseases that are genetic disorders or that result in bone marrow failure or lead to immunodeficiency syndromes for which bone marrow transplantation may be appropriate. While these non-malignant diseases are not described in the preceding lists, there are generally accepted and appropriate indications for bone marrow transplantation in these cases. In addition, there are malignant diseases that are uncommon in their occurrence that also are not included in the above lists for which the appropriateness of bone marrow transplantation may be determined on a case by case basis. Examples of other indications for which allogeneic bone marrow transplantation may be indicated include, but are not limited to the following:

- Absent or defective T cell function (e.g., severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked lymphoproliferative syndrome)
- Absent or defective natural killer function (e.g., Chediak-Higashi syndrome)
- Absent or defective neutrophil function (e.g., Kostmann syndrome, chronic granulomatous disease, leukocyte adhesion defect)

- Aplastic anemia (including hereditary forms, such as Fanconi anemia, dyskeratosis congenita, Shwachman-Diamond, Diamond Blackfan) and acquired anemia (e.g., secondary to drug or toxin exposure) (in addition to coverage mandated in subsection (1) above)
- Sickle cell anemia in children and young adults with either a history of prior stroke or at increased risk of stroke or end-organ damage
- Homozygous beta-thalassemia (e.g., thalassemia major) (in addition to coverage mandated in subsections (1) and (2) above)
- Infantile malignant osteopetrosis (Albers-Schonberg disease or marble bone disease)
- Inherited metabolic disease (e.g., lysosomal and peroxisomal storage disorders)

Allogeneic hematopoietic stem cell transplantation administered with high dose chemotherapy is considered **experimental or investigational** for the following indications:

- Epithelial ovarian cancer
- Autoimmune diseases such as multiple sclerosis, juvenile idiopathic and rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis/scleroderma, Crohn's disease, chronic inflammatory demyelinating polyneuropathy/polyradiculopathy, immune cytopenias, polymyositis, relapsing polychondritis, type I diabetes mellitus, dermatomyositis, neuromyelitis optica, systemic vasculitis, ulcerative colitis), autoimmune hepatitis, cryptogenic cirrhosis, thrombotic thrombocytopenic purpura
- Gliomas and astrocytomas (includes glioblastoma multiforme and oligodendroglioma)
- Solid tumors in adults (e.g., lung, colon, rectal, pancreas, stomach, esophageal, gallbladder, bile duct, cervical, uterine, fallopian tube, prostate, nasopharyngeal, paranasal sinus, neuroendocrine, soft tissue sarcomas, thyroid, thymus, tumors of unknown primary origin, malignant melanoma)
- Ewing sarcoma family of tumors
- Rhabdomyosarcoma
- Wilms tumor
- Osteosarcoma
- Retinoblastoma
- Breast cancer, any stage
- Medulloblastoma, PNETs or ependymoma
- Germ cell tumors, including but not limited to use as therapy after prior failed autologous hematopoietic stem-cell transplantation
- Embryonal tumors of the CNS

Processing, cryopreservation, storage and thawing of peripheral stem cells is eligible for coverage if the harvesting and transplantation is covered.

Collection and storage of cord blood from a neonate **meets the definition of medical necessity** when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant.

Prophylactic collection and storage of cord blood from a neonate **does not meet the definition of medical necessity** when proposed for some unspecified future use as an allogeneic stem-cell transplant.

## BILLING/CODING INFORMATION:

### CPT Coding:

38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
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, buffy coat layer
38230	Bone marrow harvesting for transplantation, allogeneic
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38242	Allogeneic lymphocyte infusions
38243	Hematopoietic progenitor cell (HPC); HPC boost

### HCPCS Coding:

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 day of pre- and post-transplant care in the global definition (non-covered)
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### LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical including previous transplants, physician progress notes, treatment plan, radiology report(s), operative and/or pathology report(s), laboratory studies, medication history, type of transplant and reason for transplant, smoking/alcohol/drug abuse history, cardiac and pulmonary clearances, psychosocial assessment and all diagnostic testing.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology report	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physician operative report	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies	26436-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Current, discharge, or administered medications	34483-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

Transplant Rx	22043-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Transplant Rx at facility	21883-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Transplant risk factors	44758-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Reason for transplant	44756-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
History of tobacco use	11366-2	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Alcohol abuse	42830-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Drug abuse	42831-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Cardiac screen assessment	39257-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Pulmonary consultation note	34103-2	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Psychosocial well-being, addressed in care plan	58168-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of



			service for the claim.
Diagnostic studies (non-lab)	27899-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

### **REIMBURSEMENT INFORMATION:**

Refer to section entitled [POSITION STATEMENT](#).

### **PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage Products:** The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Stem Cell Transplantation (110.23) located at cms.gov.

### **DEFINITIONS:**

**Cryopreservation:** Preservation by subjection to extremely low temperatures.

**Germ cell tumors:** composed primarily of testicular neoplasms as well as ovarian and extragonadal germ cell tumors (no primary tumor in either testis or ovary). Germ cell tumors are classified by their histology, stage, prognosis, and response to chemotherapy. The most common testicular germ cell tumors are seminomas; all other histologic types are collectively referred to as nonseminomatous tumors. Nonseminomatous tumor types include embryonal cell tumor, yolk sac tumor, and teratomas. Malignant germ cell tumors of ovarian origin are classified as dysgerminomas or nondysgerminomas. Similarly, nondysgerminomas include immature teratomas, embryonal cell tumors, yolk sac tumor, polyembryoma, and mixed germ cell tumors.

**Hematopoiesis:** The formation of blood or of blood cells in the living body; also called hemopoiesis.

**High-risk neuroblastoma:** stage 4; aggressive tumors with a high likelihood of recurrence.

**HLA:** Special identifying markers that are on all cells of the body. HLA markers must match fairly closely between donor and patient, or rejection may occur. HLA identical means that two people have the same markers as each other (this can occur in twins or brothers and sisters).

**Leukemia:** A type of white blood cell that grows uncontrollably. Names are given depending on which type of white blood cell is abnormal. More sudden types include Acute Lymphoblastic Leukemia (ALL), Acute Non-lymphocytic Leukemia (ANLL), and Acute Myelocytic Leukemia (AML). More gradual types include Chronic Granulocytic Leukemia (CGL), Chronic Myelogenous Leukemia (CML) Chronic Myelomonocytic Leukemia (CMML), and Chronic Lymphocytic Leukemia (CLL).

**Leukopheresis:** A procedure by which the white blood cells are removed from a donor's blood which is then transfused back into the donor.

**Lymphocytic leukemia:** neoplasm of hematopoietic origin characterized by the accumulation of lymphocytes with a mature, generally well-differentiated morphology; these cells accumulate in blood, bone marrow, lymph nodes, and spleen.

**Lymphoma:** Tumor of the white blood cells called lymphocytes. Different types include Hodgkin's, (Follicular) Non-Hodgkins (HNL), and Small Lymphocytic Lymphoma (SLL).

**Myelodysplastic syndrome (MDS):** a heterogeneous group of clonal hematopoietic disorders with the potential to transform into acute myelocytic leukemia. MDS is classified into 5 subtypes: (1) refractory anemia; (2) refractory anemia with ringed sideroblasts; (3) refractory anemia with excess blasts; (4) refractory anemia with excess blasts in transformation; and (5) chronic myelomonocytic leukemia.

**Myeloproliferative neoplasm:** formerly known as chronic myeloproliferative disorder (CMPD); a subdivision of myeloid neoplasms that includes 4 classic disorders: chronic myeloid leukemia, polycythemia vera, essential thrombocytopenia, and primary myelofibrosis. The WHO classification also includes chronic neutrophilic leukemia, chronic eosinophilic leukemia/hypereosinophilic syndrome, mast cell disease, and MPN unclassifiable.

**Tandem transplant:** Two courses of high dose chemotherapy are given, opposed to the typical one course. Tandem transplants are typically administered at intervals of 2-6 months, depending on recovery from prior toxicity.

## **RELATED GUIDELINES:**

**[Autologous Bone Marrow and Stem Cell Transplantation, 02-38241-01](#)**

## **OTHER:**

### **Florida Statute 627.4236 Coverage for bone marrow transplant procedures (excerpt)**

(1) As used in this section, the term "bone marrow transplant" means human blood precursor cells administered to a patient to restore normal hematological and immunological functions following ablative or nonablative therapy with curative or life-prolonging intent. Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood. If chemotherapy is an integral part of the treatment involving bone marrow transplantation, the term "bone marrow transplant" includes both the transplantation and the chemotherapy.

(2) An insurer or a health maintenance organization may not exclude coverage for bone marrow transplant procedures recommended by the referring physician and the treating physician under a policy exclusion for experimental, clinical investigative, educational, or similar procedures contained in any individual or group health insurance policy or health maintenance organization contract issued, amended, delivered, or renewed in this state that covers treatment for cancer, if the particular use of the bone marrow transplant procedure is determined to be accepted within the appropriate oncological specialty and not experimental pursuant to subsection. (3) Covered bone marrow transplant procedures must include costs associated with the donor-patient to the same extent and limitations as costs associated with the insured, except the reasonable costs of searching for the donor may be limited to immediate family members and the National Bone Marrow Donor Program.

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### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 03/22/18.

### **GUIDELINE UPDATE INFORMATION:**

08/15/02	Medical Coverage Guideline Reformatted and Revised to reflect criteria set forth in Chapter 59-B of the Florida Administrative Code.
02/15/03	2003 HCPCS coding update.
08/15/03	Reviewed – no changes in coverage statement.
01/01/04	Annual HCPCS coding update.
04/01/04	2nd Quarter 2004 HCPCS coding update.
09/15/04	Scheduled review; no change in coverage statement.
01/01/05	HCPCS coding update: revised descriptor for S2150.

09/15/05	Scheduled review; add renal carcinoma as a covered indication.
09/15/06	Scheduled review; coverage statement revised to be consistent with Florida Administrative Code 59B-12.
07/15/07	Scheduled review; reformatted guideline; updated references.
01/01/08	Annual HCPCS coding update: removed G0265, G0266, and G0267
09/15/08	Scheduled review; revise position statement. Add excerpt from Florida Statute. Update references.
06/15/09	Remove reference to family related donor with 5/6 or 6/6 match.
09/15/09	Scheduled review; update position statement, definitions, and references.
10/15/10	Scheduled review; added ICD-10 codes; no change in position statement. Updated references and reformatted guideline.
09/15/11	Scheduled review; added Medicare exception, updated references, formatting changes.
10/01/11	Revision; added ICD9 code 282.44.
01/01/12	Annual HCPCS coding update. Revised 38208, 38209 and 38230 descriptors.
04/01/12	Revision; updated ICD10 coding with new and revised codes.
05/15/12	Revision; guideline reformatted.
06/15/12	Scheduled review. Revised description section and position statement. Updated references and reformatted guideline.
01/01/13	Annual CPT coding update. Added 38243. Revised code descriptors for 38240 and 38242.
09/15/13	Revision; updated Florida Administrative Rule 59B-12.001 language.
10/15/13	Scheduled review. Revised description and position statement. Updated references.
11/15/14	Scheduled review. Revised position statement and definitions section. Updated references.
11/15/15	Scheduled review. Revised position statement (added additional Florida Administrative Code mandated coverage). Updated references.
01/01/18	Annual CPT/HCPCS coding update: deleted 38220.
04/15/18	Scheduled review. Revised criteria for Hodgkin's lymphoma. Revised Medicare Advantage program exception and definitions section. Updated references.
1/15/2019	Revision: updated language regarding prophylactic collection and storage of cord blood from

	a neonate.
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