02-38241-01

Original Effective Date: 08/15/02

Reviewed: 04/25/24

Revised: 05/15/24

# Subject: Autologous Hematopoietic Cell Transplantation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	<u>Reimbursement</u>	Program Exceptions	Definitions	<u>Related</u> <u>Guidelines</u>
Other	<b>References</b>	<u>Updates</u>			

#### **DESCRIPTION:**

#### Hematopoietic Stem Cell Transplantation

Hematopoietic stem cell transplantation (HCT) refers to the infusion of hematopoietic stem cells to restore bone marrow function in individuals with cancer who receive bone-marrow-toxic doses of drugs with or without whole-body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or from a donor (allogeneic (allo-HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood. Although cord blood is an allogeneic source, the stem cells in it are antigenically "naive" and thus are associated with a lower incidence of rejection or graft-versus-host disease.

#### **Autologous HCT**

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. The success of autologous HCT is predicated on the ability of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the individual before undergoing bone marrow ablation. As a consequence, autologous HCT is typically performed as consolidation therapy when the individual's disease is in complete response. Those who undergo autologous HCT are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not graft-versus-host disease.

### **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 Bone Marrow/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)]:

 Upon the recommendation of the Bone Marrow Transplant Panel, each of the following procedures meets a minimum level of evidence based on high quality systematic reviews of case control or cohort studies, high quality case-control or cohort studies with a very low risk of confounding bias, or chance, and a high probability that the relationship is causal, and is considered accepted within the appropriate oncological specialty and not experimental for the purposes of Section 627.4236, F.S.

Autologous hematopoietic cell transplantation is covered when performed for one of the following indications:

- Acute myelogenous leukemia (stem cells collected in remission)
- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma
- Ewing's sarcoma, chemotherapy sensitive after first relapse
- Neuroblastoma
- Germ cell tumor, after failure of first therapy but not progressing on salvage therapy
- Multiple <u>myeloma</u> (including double bone marrow transplant), Waldenstrom macroglobulinemia and primary amyloidosis
- Primitive neuroectodermal tumor PNET (including medulloblastoma and pinealoblastoma), chemotherapy sensitive after first relapse
- Medulloblastoma and other PNET tumors, metastatic, at diagnosis
- Acquired or genetic severe aplastic anemia unresponsive to immunosuppression

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. Each of the following procedures is considered accepted within the appropriate oncological specialty and not experimental for the purposes of section 627.4236, F.S., provided that the bone marrow transplantation procedure is performed in the context of a well-designed clinical treatment trial as described in subsection (6).

Routine care costs associated with the bone marrow transplant will be covered for the following procedures:

- Chronic lymphocytic leukemia
- Breast carcinoma
- Ewing's sarcoma, localized, greater than 8 cm or metastatic at presentation
- Soft tissue sarcoma, pediatric, after failure of first therapy
- Wilm's tumor, at relapse
- Germ cell tumor, high risk, at diagnosis
- Multiple autologous bone marrow transplants for pediatric solid tumors
- Metastatic malignant melanoma
- Autoimmune 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 CTN) 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 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 (5)
  - 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 BMT CTN at 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.

Autologous 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):

- Systemic sclerosis (scleroderma), when ALL of the following are met:
  - o Adult less than age 60
  - o Maximum duration of condition of 5 years
  - Modified Rodnan Scale score ≥ 15
  - Internal organ involvement (e.g., abnormal electrocardiogram; diffusing capacity of carbon monoxide (DLCo) <80% of predicted value; decline of forced vital capacity (FVC) of ≥10% in last 12 months; pulmonary fibrosis; ground glass appearance on high resolution chest CT; scleroderma-related renal disease)
  - History of < 6 months treatment with cyclophosphamide
  - No active gastric antral vascular ectasia
  - None of the following exclusion criteria are present: left ventricular ejection fraction <50%; tricuspid annular plane systolic excursion <1.8 cm; pulmonary artery systolic pressure >40 mm Hg; mean pulmonary artery pressure >25 mm Hg; DLCo <40% of predicted value; FVC <45% of predicted value; or creatinine clearance <40 ml/minute</li>
  - Metastatic retinoblastoma
  - **POEMS Syndrome** (polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes) (also known as osteosclerotic myeloma, Crow-Fukase syndrome, or Takatsuki syndrome) (in addition to subsection (3) above):
    - To treat disseminated POEMS syndrome (e.g., diffuse sclerotic lesions, disseminated bone marrow involvement)
  - <u>Embryonal tumors of the central nervous system (CNS)</u> (in addition to subsection (1) above) [well-defined embryonal tumors of the CNS include medulloblastoma, atypical teratoid/rhabdoid tumor, embryonal tumor with multilayered rosettes, C19MC-altered and embryonal tumor with multilayered rosettes (not otherwise specified) pineoblastoma, pituitary blastoma, CNS neuroblastoma, and ganglioneuroblastoma]
    - As consolidation therapy for previously untreated embryonal tumors of the central nervous system (CNS) that show partial or complete response to induction chemotherapy, or stable disease after induction therapy; OR
    - To treat recurrent embryonal tumors of the CNS.
  - Ewing's sarcoma (in addition to subsections (1) and (2) above):
    - As initial treatment of high-risk Ewing's sarcoma [eg, the presence of metastatic disease; location of tumor in an area such as the pelvis; larger tumor size; older age of the individual] OR
    - For recurrent or refractory Ewing's sarcoma
  - Germ cell tumors (in addition to subsection (2) above):
    - In individuals with favorable prognostic factors [eg, those with a testis or retroperitoneal primary site, a complete response to initial chemotherapy, low levels of serum markers, and low-volume disease] that have failed a previous course of conventional-dose salvage chemotherapy, OR
    - In individuals with unfavorable prognostic factors [eg, an extratesticular primary site, an incomplete response to initial therapy, high levels of serum markers, high-volume disease, or

relapsing mediastinal nonseminomatous germ cell tumors] as initial treatment of first relapse (ie, without a course of conventional-dose salvage chemotherapy), **OR** 

- o In individuals with platinum-refractory disease, OR
- Tandem autologous HCT or transplant with sequential high-dose chemotherapy for treatment of testicular tumors either as salvage therapy or with platinum-refractory disease
- Acute lymphoblastic leukemia (ALL):
  - To treat adult acute ALL in first complete remission but at high risk of relapse, defined as one of the following:
    - Age older than 35 years
    - Leukocytosis at presentation of >30,000/µL (B-cell lineage) or >100,000/µL (T-cell lineage)
    - "Poor prognosis" genetic abnormalities such as the Philadelphia chromosome [t(9;22)]
    - Extramedullary disease
    - Time to attain complete remission longer than 4 weeks
  - To treat pediatric acute ALL in first complete remission but at high risk of relapse, defined as one of the following:
    - Poor response to initial therapy, including prior response to prednisone prophase (defined as an absolute blast count of 1000/µL or greater)
    - Poor treatment response to induction therapy at 6 weeks, with ≥1% minimal residual disease measured by flow cytometry
    - All children with T- cell phenotype
    - Children with either the t(9;22) or t(4;11), regardless of early response measures
  - To treat pediatric ALL in second or greater remission
  - To treat pediatric refractory ALL

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.

Autologous bone marrow transplantation administered with high dose chemotherapy for all other indications is considered **experimental or investigational**, as there is insufficient scientific evidence to establish definite conclusions regarding the efficacy of autologous stem cell transplantation and specifically for the following indications:

- Chronic lymphocytic leukemia (except as noted in subsection (2) above)
- Small lymphocytic lymphoma
- Ependymoma
- Chronic myeloid leukemia (except as noted in subsection (3) above for CMML)

- Germ cell tumors as a component of first-line treatment (except as noted in subsection (2) above)
- Solid tumors in adults (e.g., lung, colon, rectal, pancreas, stomach, bile duct, esophageal, gallbladder, renal cell, cervical, uterine, fallopian tube, prostate, nasopharyngeal, paranasal sinus, neuroendocrine tumors, soft tissue sarcomas, thyroid, thymus, tumors of unknown primary origin, malignant melanoma (except as noted in subsection (2) above))
- Autoimmune diseases (except as mandated in subsection (2) above) (e.g., multiple sclerosis, systemic lupus erythematosus, juvenile idiopathic or rheumatoid arthritis, chronic inflammatory demyelinating polyneuropathy (CIDP), or type I diabetes mellitus)
- Advanced stage epithelial ovarian cancer
- Acute adult lymphoblastic leukemia (ALL) in second or greater remission or those with refractory disease

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

Harvesting (bone marrow and peripheral stem cells) and cryopreservation (storage) services are eligible for coverage when a bone marrow transplant has been identified by the physician as a course of treatment and is planned or anticipated in the future.

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 autologous stem-cell transplant in the original donor.

#### **BILLING/CODING INFORMATION:**

Management of recipient hematopoietic progenitor cell donor search and cell
acquisition
Blood-derived hematopoietic progenitor cell harvesting for transplantation, per
collection; autologous
Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen
harvest, without washing, per donor
Transplant preparation of hematopoietic progenitor cells, thawing of previously frozen
harvest, with washing, per donor
Transplant preparation of hematopoietic progenitor cells; specific cell depletion within
harvest, T-cell depletion
Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
Transplant preparation of hematopoietic progenitor cells; red blood cell removal
Transplant preparation of hematopoietic progenitor cells; platelet depletion
Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma,
mononuclear, buffy coat layer
Bone marrow, aspiration only, autologous
Hematopoietic progenitor cell (HPC); autologous transplantation

CPT Coding:

# **HCPCS Coding:**

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)

# 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	LOINC Time Frame Modifier Codes Narrative
		Modifier Code	
Physician history and	28626-0	18805-2	Include all data of the selected type
physical			that represents observations made six months or fewer before starting date of
			service for the claim
Attending physician visit	18733-6	18805-2	Include all data of the selected type
note			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	34483-8	18805-2	Include all data of the selected type
administered medications			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
	24002.4	40005.0	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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>

#### **DEFINITIONS:**

Acquired: not genetic, but produced by influences originating outside the organism.

**Allogeneic:** having a different genetic constitution, but belonging to the same species. Allogeneic <u>stem</u> <u>cell support</u> provides two theoretical advantages – (1) the lack of tumor contamination associated with the use of autologous stem cells and (2) the possibility of a beneficial graft vs. tumor effect.

**Autologous bone marrow cells:** stem cells are harvested from the individual's own bone marrow prior to the cytotoxic therapy, then reinfused into the individual after the therapy.

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

**HLA:** special identifying markers that are on all cells of the body. HLA markers must match fairly closely between donor and recipient, 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:** "liquid" tumors; 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).

**Lymphoma:** tumor of the white blood cells called lymphocytes. Different types include Hodgkin, (Follicular) Non-Hodgkin (NHL), and Small Lymphocytic Lymphoma (SLL).

Myeloma: tumor of one of the types of white blood cells.

**Stem cell support:** a machine can separate only the most important cells (stem cells) from a bone marrow sample or blood sample (peripheral blood stem cells, PBSC), to be transplanted back into the same individual later, after treatment. The machine can also be used to remove cancerous stem cells and keep the normal cells. Stem cells can be collected from the bone marrow or from the peripheral blood.

**Syngeneic:** genetically identical especially with respect to antigens or immunological reactions. Refers to stem cells harvested from an identical twin.

**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:**

#### Allogeneic Hematopoietic Cell Transplantation, 02-38240-01

#### **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.

# Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

**Florida Statute 627.64197 Coverage for organ transplants.**—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 627.65736 Coverage for organ transplants.**—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 641.31075 Coverage for organ transplants.**—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

# **REFERENCES:**

- 1. Agency for Health Care Administration; Rules of the Department of Health and Rehabilitative Services, Chapter 59-B, Florida Administrative Code, Section 59-B-12.001 (09/26/00; amended 07/07/13).
- 2. AHRQ Effective Healthcare Program. Comparative Effectiveness Review 48: Hematopoietic Stem-Cell Transplantation in the Pediatric Population. AHRQ Pub. No. 12-EHC018-1; February 2012).
- 3. AHRQ National Guideline Clearinghouse: Dose-intensive chemotherapy with growth factor or autologous bone marrow/stem cell transplant support in the first-line treatment of advanced or metastatic adult soft tissue sarcoma: a practice guideline. NGC-5006. Verma S, Younus J, Stys-Norman D, Haynes AE, Blackstein M, Sarcoma Disease Site Group. Dose-intensive chemotherapy with growth factor or autologous bone marrow/stem cell transplant support in the first-line treatment of advanced or metastatic adult soft tissue sarcoma: a practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Apr 11. 24 p. (Evidence-based series; no. 11-5).
- 4. AHRQ National Guideline Clearinghouse: Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion. NGC-6193. British Committee for Standards in Haematology, Transfusion Task Force, Boulton FE, James V. Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion. Transfus Med 2007 Oct;17 (5):354-65.
- AHRQ National Guideline Clearinghouse: Guidelines on the management of acute myeloid leukaemia in adults. NGC-6225 British Committee for Standards in Haematology, Milligan DW, Grimwade D, Cullis JO, Bond L, Swirsky D, Craddock C, Kell J, Homewood J, Campbell K, McGinley S, Wheatley K, Jackson G. Guidelines on the management of acute myeloid leukaemia in adults. Br J Haematol. 2006 Nov;135 (4):450-74.
- 6. AHRQ National Guideline Clearinghouse. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the treatment of diffuse large B cell lymphoma: update of the 2001 evidence-

based review. NGC-8491. American Society for Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2011 Jan;17(1): 18-9.

- AHRQ National Guideline Clearinghouse: Stem cell transplantation in adults: recommendations. NGC-7225 Imrie K, Rumble RB, Crump M, Advisory Panel on Bone Marrow and Stem Cell Transplantation, Hematology Disease Site Group. Stem cell transplantation in adults: recommendations. Toronto (ON): Cancer Care Ontario Program in Evidence-based Care; 01/30/09.
- AHRQ National Guideline Clearinghouse: Guidelines for policies on alternatives to allogeneic blood transfusion. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the therapy of myelodysplastic syndromes. Guideline Summary NGC-7415. Biol Blood Marrow Transplant 2009 Feb;15 (2):135-6.
- AHRQ National Guideline Clearinghouse: The role of cytotoxic therapy with hematopoietic stem cell transplantation in the therapy of acute myeloid leukemia in adults. Guideline Summary NGC-7416. Biol Blood Marrow Transplant 2008 Feb;14(2):135-6.
- AHRQ National Guideline Clearinghouse. Clinical management of myelodysplastic syndromes: update of SIE, SIES, GITMO practice guidelines. NGC-9596. Santini V, Alessandrino PE, Angelucci E, Barosi G, Billio A, Di Maio M, Finelli C, Locatelli F, Marchetti M, Morra E, Musto P, Visani G, Tura S, Italian Society of Hematology. Clinical management of myelodysplastic syndromes: update of SIE, SIES, GITMO practice guidelines. Leuk Res. 2010 Dec;34(12):1576-88.
- 11. AHRQ National Guideline Clearinghouse. Stem cell transplantation in lymphoma. NGC-9685. Kouroukis CT, Rumble RB, Kuruvilla J, Crump M, Herst J, Hamm C. Stem cell transplantation in lymphoma. Toronto (ON): Cancer Care Ontario; 2012 Dec 13.
- 12. Ayala E, Tomblyn M. Hematopoietic Cell Transplantation for Lymphoma. Cancer Control, October 2011, Vol. 18, No. 4.
- Bae SJ, Kang C et al. Iron Overload during Follow-up after Tandem High-Dose Chemotherapy and Autologous Stem Cell Transplantation in Patients with High-Risk Neuroblastoma. J Korean Med Sci 2012; 27: 363-369.
- 14. Bassan R, et al. Improved risk classification for risk-specific therapy based on the molecular study of minimal residual disease (MRD) in adult acute lymphoblastic leukemia (ALL). BLOOD, 30 APRIL 2009, VOLUME 113, NUMBER 18.
- 15. Beitinjaneh A, Saliba R, Okoroji G, Alousi AM, Popat UR, Korbling M, Anderlini P, Qazilbash M, Kebriaei P, Hosing C, Champlin RE, Khouri IF; University of Texas M. D. Anderson Cancer Center, Houston, TX. Autologous stem cell transplantation (ASCT) as upfront or salvage therapy for noncutaneous T-cell lymphoma (TCL): The University of Texas M. D. Anderson Cancer Center (MDACC) experience. 2011 ASCO Annual Meeting. General Poster Session, Leukemia, Myelodysplasia, and Transplantation. J Clin Oncol 29: 2011.
- Blessing MM, Alexandrescu S. Embryonal Tumors of the Central Nervous System: An Update. Surg Pathol Clin. 2020 Jun;13(2):235-247. doi: 10.1016/j.path.2020.01.003. Epub 2020 Apr 7. PMID: 32389264.
- 17. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.50 Placental and Umbilical Cord Blood as a Source of Stem Cells, 03/21 (Archived).
- 18. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.15 Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, 02/24.
- Blue Cross Blue Shield Association Evidence Positioning System<sup>®</sup>. 8.01.17 Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome, 02/24.
- 20. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.20 Hematopoietic Stem Cell Transplantation for Non-Hodgkin Lymphomas, 02/24.

- 21. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.21 Allogeneic Stem Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms, 02/24.
- 22. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.22 Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias, 03/21 (Archived).
- 23. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.23 Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer, 02/24.
- 24. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.24 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults, 02/24.
- 25. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.25 Hematopoietic Cell Transplantation for Autoimmune Diseases, 02/24.
- 26. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.26 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia, 02/24.
- 27. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.28 Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma, 02/24.
- 28. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.29 Hematopoietic Cell Transplantation for Hodgkin Lymphoma, 02/24.
- 29. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.30 Hematopoietic Cell Transplantation for Chronic Myelogenous Leukemia, 02/24.
- 30. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.32 Hematopoietic Cell Transplantation as a Treatment of Acute Lymphoblastic Leukemia, 02/24.
- 31. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.34 Hematopoietic Stem Cell Transplantation for Solid Tumors of Childhood, 02/24.
- 32. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.35 Hematopoietic Cell Transplantation in the Treatment of Germ Cell Tumors, 02/24.
- 33. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.42 Hematopoietic Stem Cell Transplantation for Primary Amyloidosis, 02/24.
- 34. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.54 Hematopoietic Stem Cell Transplantation for Waldenstrom Macroglobulinemia, 03/21 (Archived).
- 35. Borowitz MJ, et al. Prognostic significance of minimal residual disease in high risk B-ALL: a report from Children's Oncology Group study AALL0232. Blood 126.8 (2015): 964-971.
- 36. Brittain G, Petrie J, Duffy KEM, Glover R, Hullock K, Papaioannou D, Roldan E, Beecher C, Bursnall M, Ciccarelli O, Coles AJ, Cooper C, Giovannoni G, Gabriel I, Kazmi M, Kyriakou C, Nicholas R, Paling D, Peniket A, Scolding N, Silber E, de Silva T, Venneri A, Walters SJ, Young C, Muraro PA, Sharrack B, Snowden JA; StarMS trial team. Efficacy and safety of autologous haematopoietic stem cell transplantation versus alemtuzumab, ocrelizumab, ofatumumab or cladribine in relapsing remitting multiple sclerosis (StarMS): protocol for a randomised controlled trial. BMJ Open. 2024 Feb 5;14(2):e083582. doi: 10.1136/bmjopen-2023-083582.
- 37. Burman J, et al. Autologous haematopoietic stem cell transplantation for neurological diseases. J Neurol Neurosurg Psychiatry. 2018 Feb;89(2):147-155.
- 38. Campbell K, McGinley S, Wheatley K, Jackson G. Guidelines on the management of acute myeloid leukaemia in adults. Br J Haematol. 2006 Nov;135 (4):450-74.
- 39. Centers for Medicaid and Medicare Services (CMS). National Coverage Determination (NCD) STEM CELL TRANSPLANTATION (Formerly 110.8.1) 110.23 (01/27/16).
- 40. ClinicalTrials.gov. NCT00085202: Treatment of Patients With Newly Diagnosed Medulloblastoma, Supratentorial Primitive Neuroectodermal Tumor, or Atypical Teratoid Rhabdoid Tumor. Accessed at http://www.clinicaltrials.gov.

- 41. ClinicalTrials.gov. NCT00392886: Combination Chemotherapy With or Without Etoposide Followed By an Autologous Stem Cell Transplant in Treating Young Patients With Previously Untreated Malignant Brain Tumors. Accessed at http://www.clinicaltrials.gov.
- 42. Cornelissen JJ, et al. Myeloablative allogeneic versus autologous stem cell transplantation in adult patients with acute lymphoblastic leukemia in first remission: a prospective sibling donor versus nodonor comparison. BLOOD, 5 FEBRUARY 2009 VOLUME 113, NUMBER 6.
- 43. Dispenzieri A. How I treat POEMS syndrome. BLOOD, 14 JUNE 2012 VOLUME 119, NUMBER 24.
- 44. D'Souza A, et al. Long-term outcomes after autologous stem cell transplantation for patients with POEMS syndrome (osteosclerotic myeloma): a single-center experience. BLOOD, 5 JULY 2012 VOLUME 120, NUMBER 1.
- 45. ECRI Institute Evidence Report. Immunoablative Therapy with Bone Marrow or Peripheral Stem Cell Transplantation for Systemic Lupus Erythematosus. May 2009.
- 46. ECRI Institute Health Technology Forecast. Lymphoma (10/12/10).
- 47. ECRI Institute Health Technology Forecast. High-dose chemotherapy and stem cell transplant for scleroderma: high-stakes treatment. 06/15/12.
- 48. Florida Administrative Code & Florida Administrative Register. Rule: 59B-12.001: Bone Marrow Transplantation. Rulemaking Authority 627.4236 FS. Law Implemented 627.4236 FS. History–New 11-9-95, Formerly 10D-127.001, Amended 9-26-00, 8-10-05, 7-7-13, 7-12-15, 2-4-19. Accessed at https://www.flrules.org/gateway/ruleNo.asp?id=59B-12.001.
- 49. Florida State Statute 627.4236 Coverage for bone marrow transplant procedures. 627.4236(3). Accessed at http://www.flsenate.gov/.
- Florida State Statutes 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited; Florida Statute 627.64197 – Coverage for organ transplants; 627.65736 – Coverage for organ transplants; and 641.31075 – Coverage for organ transplants. Accessed at http://www.flsenate.gov/.
- 51. Gajjar A, et al. Risk-adapted craniospinal radiotherapy followed by high-dose chemotherapy and stem-cell rescue in children with newly diagnosed medulloblastoma (St Jude Medulloblastoma-96): long-term results from a prospective, multicentre trial. Lancet Oncol 2006; 7: 813–20.
- 52. Gökbuget N, et al. Adult patients with acute lymphoblastic leukemia and molecular failure display a poor prognosis and are candidates for stem cell transplantation and targeted therapies. BLOOD, 30 AUGUST 2012, VOLUME 120, NUMBER 9.
- 53. Goldstone AH, et al. In adults with standard-risk acute lymphoblastic leukemia, the greatest benefit is achieved from a matched sibling allogeneic transplantation in first complete remission, and an autologous transplantation is less effective than conventional consolidation/maintenance chemotherapy in all patients: final results of the International ALL Trial (MRC UKALLXII/ECOG E2993). Blood. 2008 Feb 15;111(4):1827-33.
- 54. Gotlib J. Hodgkin Lymphoma. The American Society of Hematology. 01/17/11.
- 55. Gunnellini M, Emili R, Coaccioli S, Liberati A. The Role of Autologous StemCell Transplantation in the Treatment of Diffuse Large B-Cell Lymphoma. Advances in Hematology Volume 2012, Article ID 195484.
- 56. Helbig G, et al. Autologous Hematopoietic Stem Cell Transplantation for High-risk Acute Lymphoblastic Leukemia: non-Randomized Study with a maximum Follow-up of more than 22 Years. Mediterr J Hematol Infect Dis 2014, 6(1): e2014047.
- 57. Ho VT, et al. Use of Matched Unrelated Donors Compared with Matched Related Donors is Associated with Lower Relapse and Superior Progression Free Survival after Reduced Intensity Conditioning Hematopoietic Stem Cell Transplantation. Biol Blood Marrow Transplant. 2011 August ; 17(8): 1196–1204.

- 58. Hoelzer D, Bassan R, Dombret H, Fielding A, Ribera JM, Buske C. Acute lymphoblastic leukaemia in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology. 2016 Apr 7:mdw025.
- 59. Jessop H, Farge D, Saccardi R, et al. General information for patients and carers considering haematopoietic stem cell transplantation (HSCT) for severe autoimmune diseases (ADs): A position statement from the EBMT Autoimmune Diseases Working Party (ADWP), the EBMT Nurses Group, the EBMT Patient, Family and Donor Committee and the Joint Accreditation Committee of ISCT and EBMT (JACIE). Bone Marrow Transplant. 2019;54(7):933–942. doi:10.1038/s41409-019-0430-7.
- 60. Kalincik T, Sharmin S, Roos I, Freedman MS, Atkins H, Burman J, Massey J, Sutton I, Withers B, Macdonell R, Grigg A, Torkildsen Ø, Bo L, Lehmann AK, Havrdova EK, Krasulova E, Trnený M, Kozak T, van der Walt A, Butzkueven H, McCombe P, Skibina O, Lechner-Scott J, Willekens B, Cartechini E, Ozakbas S, Alroughani R, Kuhle J, Patti F, Duquette P, Lugaresi A, Khoury SJ, Slee M, Turkoglu R, Hodgkinson S, John N, Maimone D, Sa MJ, van Pesch V, Gerlach O, Laureys G, Van Hijfte L, Karabudak R, Spitaleri D, Csepany T, Gouider R, Castillo-Triviño T, Taylor B, Sharrack B, Snowden JA; MSBase Study Group Collaborators; MSBase Study Group Authors; Mrabet S, Garber J, Sanchez-Menoyo JL, Aguera-Morales E, Blanco Y, Al-Asmi A, Weinstock-Guttman B, Fragoso Y, de Gans K, Kermode A; MSBase Study Group. Comparative Effectiveness of Autologous Hematopoietic Stem Cell Transplant vs Fingolimod, Natalizumab, and Ocrelizumab in Highly Active Relapsing-Remitting Multiple Sclerosis. JAMA Neurol. 2023 Jul 1;80(7):702-713. doi: 10.1001/jamaneurol.2023.1184.
- 61. Kato H, Kawase T, Kako S, et al. Analysis of outcomes following autologous stem cell transplantation in adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia during first complete remission. Haematologica. 2014 Nov;99(11):e228-30.
- Khalafallah A, McDonnell K, Dawar HU, Robertson I, Woods D. Quality of Life Assessment in Multiple Myeloma Patients Undergoing Dose-Reduced Tandem Autologous Stem Cell Transplantation. Mediterr J Hematol Infect Dis 2011, 3(1).
- 63. Kosmas C, Athanasopoulos A, Politis P, Papachrysanthou T, Daladimos T, Papadaki A, Panagiotidi E, Moschovis D, Ziras N, Karabelis A, Mylonakis N; "Metaxa" Cancer Hospital, Pireaus, Greece. Successful autologous hematopoietic stem cell (AHSC) mobilization with salvage etoposide (VP16)-ifosfamide-platinum (VIP) followed by high-dose chemotherapy (HDC) and AHSC transplantation (AHSCT) in relapsed malignancies: preliminary single center experience. 2011 ASCO Annual Meeting. General Poster Session, Leukemia, Myelodysplasia, and Transplantation. J Clin Oncol 29: 2011.
- 64. Laubach J, Richardson P, Munshi N, Anderson K. The Evolving Role of Autologous Stem Cell Transplantation in the Treatment of Multiple Myeloma. American Society of Hematology. 04/27/10.
- 65. Lazarus HM, Advani AS. When, how, and what cell source for hematopoietic cell transplantation in first complete remission adult acute lymphoblastic leukemia? Hematology 2012.
- 66. Lehners N, et al. Analysis of long-term survival in multiple myeloma after first-line autologous stem cell transplantation: impact of clinical risk factors and sustained response. Cancer Med. 2018 Feb;7(2):307-316.
- Liu YC, Chien SH, Fan NW, Hu MH, Gau JP, Liu CJ, Yu YB, Hsiao LT, Chiou TJ, Tzeng CH, Chen PM. Prognostic Factors on the Graft-versus-Host Disease-Free and Relapse-Free Survival after Adult Allogeneic Hematopoietic Stem Cell Transplantation. Stem Cells International. 2016 Mar 30;2016.
- 68. Mariottini A, Muraro PA, Saccardi R. Should autologous hematopoietic stem cell transplantation be offered as a first-line disease modifying therapy to patients with multiple sclerosis? Mult Scler Relat Disord. 2023 Oct;78:104932. doi: 10.1016/j.msard.2023.104932. Epub 2023 Aug 6.

- 69. Michallet M, Dreger P et al. Autologous hematopoietic stem cell transplantation in chronic lymphocytic leukemia: results of European intergroup randomized trial comparing autografting versus observation. Blood 2011 117: 1516-1521.
- Miller AE, Chitnis T, Cohen BA, Costello K, Sicotte NL, Stacom R; National Medical Advisory Committee of the National Multiple Sclerosis Society. Autologous Hematopoietic Stem Cell Transplant in Multiple Sclerosis: Recommendations of the National Multiple Sclerosis Society. JAMA Neurol. 2021 Feb 1;78(2):241-246. doi: 10.1001/jamaneurol.2020.4025.
- 71. Moreb JS, Salmasinia D, Hsu J, Hou W, Cline C, Rosenau E. Long-TermOutcome after Autologous StemCell Transplantation with Adequate Peripheral Blood Stem Cell Mobilization Using Plerixafor and G-CSF in Poor Mobilizer Lymphoma and Myeloma Patients. Advances in Hematology Volume 2011, Article ID 517561.
- 72. Nabizadeh F, Pirahesh K, Rafiei N, Afrashteh F, Ahmadabad MA, Zabeti A, Mirmosayyeb O. Autologous Hematopoietic Stem-Cell Transplantation in Multiple Sclerosis: A Systematic Review and Meta-Analysis. Neurol Ther. 2022 Dec;11(4):1553-1569. doi: 10.1007/s40120-022-00389-x. Epub 2022 Jul 28.
- 73. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Accessed at NCCN.org.
- 74. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Accessed at NCCN.org.
- 75. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Anal Carcinoma. Accessed at NCCN.org.
- 76. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Accessed at NCCN.org.
- 77. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Basal Cell and Squamous Cell Skin Cancers. Accessed at NCCN.org.
- 78. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Bladder Cancer. Accessed at NCCN.org.
- 79. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Bone Cancer. Accessed at NCCN.org.
- 80. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. Accessed at NCCN.org.
- 81. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Accessed at NCCN.org.
- 82. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Cervical Cancer. Accessed at NCCN.org.
- 83. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia. Accessed at NCCN.org.
- 84. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Colon Cancer. Accessed at NCCN.org.
- 85. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Dermatofibrosarcoma Protuberans. Accessed at NCCN.org.
- 86. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Esophageal and Esophagogastric Junction Cancers. Accessed at NCCN.org.
- 87. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Gastric Cancer. Accessed at NCCN.org.

- 88. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Head and Neck Cancers. Accessed at NCCN.org.
- 89. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. Accessed at NCCN.org.
- 90. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Hodgkin Lymphoma. Accessed at NCCN.org.
- 91. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. Accessed at NCCN.org.
- 92. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Malignant Pleural Mesothelioma. Accessed at NCCN.org.
- 93. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Melanoma. Accessed at NCCN.org.
- 94. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Merkel Cell Carcinoma. Accessed at NCCN.org.
- 95. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma. Accessed at NCCN.org.
- 96. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Myelodysplastic Syndrome. Accessed at NCCN.org.
- 97. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Neuroendocrine Tumors. Accessed at NCCN.org.
- 98. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Accessed at NCCN.org.
- 99. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Accessed at NCCN.org.
- 100. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Occult Primary. Accessed at NCCN.org.
- 101. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Ovarian Cancer. Accessed at NCCN.org.
- 102. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Pancreatic Adenocarcinoma. Accessed at NCCN.org.
- 103. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Penile Cancer. Accessed at NCCN.org.
- 104. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. Accessed at NCCN.org.
- 105. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Rectal Cancer. Accessed at NCCN.org.
- 106. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer. Accessed at NCCN.org.
- 107. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Accessed at NCCN.org.
- 108. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic Light Chain Amyloidosis. Accessed at NCCN.org.
- 109. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. Accessed at NCCN.org.

- 110. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Testicular Cancer. Accessed at NCCN.org.
- 111. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyomas and Thymic Carcinomas. Accessed at NCCN.org.
- 112. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Accessed at NCCN.org.
- 113. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Accessed at NCCN.org.
- 114. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Waldenstrom's Macroglobulinemia / Lymphoplasmacytic Lymphoma. Accessed at NCCN.org.
- 115. Nishihori T, Alsina M. Advances in the Autologous and Allogeneic Transplantation. Strategies for Multiple Myeloma. Cancer Control October 2011, Vol. 18, No. 4.
- 116. Oliansky DM, Larson RA, Weisdorf D, Dillon H, Ratko TA, Wall D, McCarthy Jr. PL, Hahn T. The Role of Cytotoxic Therapy with Hematopoietic Stem Cell Transplantation in the Treatment of Adult Acute Lymphoblastic Leukemia: Update of the 2006 Evidence-Based Review. Biol Blood Marrow Transplant 18: 18-36 (2012).
- 117. Oyekunle A, Haferlach T, Kroger N, et al. Molecular Diagnostics, Targeted Therapy, and the Indication for Allogeneic Stem Cell Transplantation in Acute Lymphoblastic Leukemia. Adv Hematol. 2011;2011:154745.
- 118. Park ES, Sung KW et al. Tandem High-Dose Chemotherapy and Autologous Stem Cell Transplantation in Young Children with Atypical Teratoid/Rhabdoid Tumor of the Central Nervous System. J Korean Med Sci 2012; 27: 135-140.
- Pavlu J, Szydlo RM, Goldman JM, Apperley JF. Three decades of transplantation for chronic myeloid leukemia: what have we learned? BLOOD, 20 JANUARY 2011, VOLUME 117, NUMBER 3.
- 120. Peinemann F, Kroger N, Bartel C, Grouven U, Pittler M, et al. (2011). High-Dose Chemotherapy Followed by Autologous Stem Cell Transplantation for Metastatic Rhabdomyosarcoma—A Systematic Review. PLoS ONE 6(2): e17127.
- 121. Pession A, Masetti R, Di Leo C, Franzoni M, Prete A. HLA-mismatched hematopoietic stem cell transplantation for pediatric solid tumors. Pediatric Reports 2011; 3(s2):e12.
- 122. Ribera JM, et al. Comparison of intensive chemotherapy, allogeneic or autologous stem cell transplantation as post-remission treatment for adult patients with high-risk acute lymphoblastic leukemia. Results of the PETHEMA ALL-93 trial. Haematologica. 2005 Oct;90(10):1346-56.
- 123. Ribera JM, Ribera J, Genescà E. Treatment of Adolescent and Young Adults with Acute Lymphoblastic Leukemia. Mediterr J Hematol Infect Dis 2014, 6(1): e2014052.
- 124. Richardson SE, McNamara C. The Management of Classical Hodgkin's Lymphoma: Past, Present, and Future. Advances in Hematology Volume 2011, Article ID 865870.
- 125. Rimar D, Butbul Aviel Y, Gefen A, et al. Autologous Hematological Stem Cell Transplantation for Systemic Sclerosis in Israel. Isr Med Assoc J. 2020;22(2):104–110.
- Römer T, Temming P, Lohmann DR, et al. Ectopic intracranial retinoblastoma in a 3.5-month-old infant without eye involvement and without evidence of heritability. Pediatr Blood Cancer. 2019;66(5):e27599. doi:10.1002/pbc.27599. PMID: 30604586.
- 127. Rosiñol L, García-Sanz R et al on behalf of PETHEMA/Spanish Myeloma Group. Benefit from autologous stem cell transplantation in primary refractory myeloma? Different outcomes in progressive versus stable disease. Haematologica 2012; 97(4):616-621.

- 128. Snowden JA, et al. Evolution, trends, outcomes, and economics of hematopoietic stem cell transplantation in severe autoimmune diseases. Blood Adv. 2017 Dec 20;1(27):2742-2755.
- 129. Stathopoulos P, Léger K, Foege M, et al (2021). Autologous hematopoietic stem cell transplantation in multiple sclerosis: a global approval and availability review. Bone Marrow Transplantation, 56(7):1754-1756.
- 130. Tyndall A. Successes and Failures of Stem Cell Transplantation in Autoimmune Diseases. American Society of Hematology. HEMATOPOIETIC STEMCELL TRANSPLANTATION I: TRANSPLANTATION IN BENIGN HEMATOLOGY. Hematology 2011.
- 131. Uppuluri R, Jayaraman D, Sivasankaran M, Patel S, Vellaichamy Swaminathan V, Raj R. Successful Treatment of Relapsed Isolated Extraocular Retinoblastoma in the Right Fibula With High-dose Chemotherapy and Autologous Stem Cell Transplantation. J Pediatr Hematol Oncol. 2019;41(5):402–403. PMID: 30933027.
- 132. UpToDate. Determining eligibility for autologous hematopoietic cell transplantation. 2024. Accessed at uptodate.com.
- 133. UpToDate. Early complications of hematopoietic cell transplantation. 2024. Accessed at uptodate.com.
- 134. UpToDate. Pulmonary complications after autologous hematopoietic cell transplantation. 2024. Accessed at uptodate.com.
- 135. UpToDate. Survival, quality-of-life, and late complications after hematopoietic cell transplantation in adults. 2024. Accessed at uptodate.com.
- 136. Voss MH, Feldman DR, Motzer RJ. High-dose chemotherapy and stem cell transplantation for advanced testicular cancer. Expert Rev Anticancer Ther. 2011 July; 11(7): 1091–1103.
- Wach M, Cioch M. Treatment of multiple myeloma patients with autologous stem cell transplantation: a fresh analysis. FOLIA HISTOCHEMICA ET CYTOBIOLOGICA Vol. 49, No. 2, 2011 pp. 248–254.

#### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/25/24.

#### **GUIDELINE UPDATE INFORMATION:**

08/15/02	Medical Coverage Guideline Reformatted – 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.
05/15/05	Revision consisting of addition of ICD-9 diagnosis code for primary amyloid light chain
	amyloidosis (277.3).
09/15/05	Scheduled review; expand list of covered indications to include metastatic malignant
	melanoma and multiple transplants for pediatric solid tumors.

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.
09/15/09	Scheduled review; update position statement and references.
10/15/10	Scheduled review; added ICD-10 codes added; revised to reflect criteria set forth in
	Chapter 59-B of the Florida Administrative Code, and; references updated; guideline
	reformatted.
09/15/11	Scheduled review; added Medicare program exception and updated references,
	formatting changes.
01/01/12	Annual HCPCS coding update. Added 38232. Revised 38208 and 38209 descriptors.
	Deleted 38230.
05/15/12	Revision; reformatted guideline.
06/15/12	Scheduled review. Revised description section and position statement. Added statement
	regarding cord blood collection and storage. Updated references and reformatted
	guideline.
01/01/13	Annual CPT coding update. Revised code descriptor for 38241.
09/15/13	Revision; updated Florida Administrative Rule 59B-12.001 language.
10/15/13	Scheduled review. Revised position statement and updated references.
11/15/14	Scheduled review. Revised position statement and updated references.
11/15/15	Scheduled review. Revised position statement and updated references.
05/15/16	Revision: updated coverage criteria for adult and pediatric acute lymphoblastic leukemia.
	Updated references.
01/01/18	Annual CPT/HCPCS coding update: deleted 38220.
04/15/18	Scheduled review. Revised criteria for germ cell tumor and list of conditions considered
	E/I. Revised Medicare Advantage program exception. Updated references.
01/15/19	Revision: updated language regarding prophylactic collection and storage of cord blood
	from a neonate.
05/15/20	Scheduled review. Revised MCG title, description, and position statement. Updated
	references.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical
	gifts and coverage of organ transplants. Updated references.
05/15/22	Scheduled review. Revised position statement and updated references.
05/25/23	Update to Program Exceptions section.
05/15/24	Scheduled review. Maintained position statement and updated references.