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Introduction

Specialized services for blood and marrow transplantation include both autologous and allogeneic stem cell transplants. The principle underlying stem cell transplantation is the transfer of hematopoietic stem cells after the administration of high-dose chemotherapy, with or without radiotherapy. The source of hematopoietic stem cells can be either bone marrow (bone marrow transplants, BMTs) or the peripheral blood (peripheral blood stem cell transplants, PBSCTs). The fetal blood harvested from the placenta and umbilical cord (cord blood transplants) is also a stem cell source.

Autologous stem cell support/transplantation (previously referred to as an autologous bone marrow transplant) involves re-infusing intravenously a portion of the patient's own stem cells to rescue the patient and re-establish his/her bone marrow which has been eradicated by high-dose chemotherapy/radiotherapy used to destroy malignant cells. Autologous stem cells can be harvested from bone marrow or from circulating blood through the process of pheresis. Tandem transplantation is defined as two or more planned courses of high-dose chemotherapy with stem cell support.

Allogeneic stem cell transplantation involves the administration of blood or marrow stem cells from either a family member (usually an HLA-matched sibling but on occasion a haploidentical relative) or a matched unrelated donor following administration of chemo/radiotherapy. The genetic disparity between donor and recipient means that allogeneic transplantation is associated with a number of life-threatening complications, including graft-versus-host disease, graft rejection, and delayed immune reconstitution. Immunologic compatibility between donor and patient is a critical factor for achieving a good outcome. Cord blood donors do not have to be matched as closely as bone marrow or peripheral blood progenitor cell donors.

The following policy contains the minimal criteria for stem cell transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Prior Approval staff.

1.0 Definition of the Procedure

High-dose chemotherapy, bone marrow or peripheral stem cell transplants involves the administration of cytotoxic agents using doses several times greater than the standard therapeutic dose along with the reinfusion of stem cell for either bone marrow or peripheral blood donors.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/medbillcaguide.htm>

EPSDT provider page: <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>

3.0 When the Procedure Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers high-dose chemotherapy, and autologous bone marrow or peripheral stem cell transplants for ovarian cancer and germ cell tumors arising in the ovaries for recipients who meet indications for transplantation related to the following disease processes:

- a. for treatment of germ cell tumors of the ovary that do not achieve a complete remission (refractory, or those exhibiting partial response to standard chemotherapy)
- b. for germ cell tumors of the ovary in a second complete remission or in a second relapse.

4.0 When the Procedure Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

The N.C. Medicaid program does not cover high-dose chemotherapy, autologous or allogeneic bone marrow or peripheral stem cell transplant for ovarian cancer and germ cell tumors arising in the ovaries when one of the following conditions exists:

- a. **Autologous or allogeneic therapy** for epithelial ovarian cancer.
- b. **Autologous therapy** as initial treatment of poor risk ovarian germ cell tumors or as treatment following the first relapse.
- c. Tandem high-dose chemotherapy and **autologous** bone marrow or peripheral stem cell support of germ cell tumors of the ovary.
- d. **Allogeneic therapy** as a treatment of germ cell tumors of the ovary including but not limited to after failed high-dose chemotherapy with autologous stem cell support.

- e. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

- f. Psychosocial history that would limit the ability to comply with medical care pre and post transplant.
- g. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

If prior approval has been given for stem cell transplants, donor expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA-approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

Division of Medical Assistance
High-dose chemotherapy, Bone Marrow
or Peripheral Stem Cell Transplant for
Ovarian Cancer and Germ Cell Tumors
Arising in the Ovaries

Clinical Coverage Policy No. 11A-13
Original Effective Date: January 1, 1994
Revised Date:
Date of Termination: March 1, 2012

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
3/1/12	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Providers bill professional services on the CMS-1500 claim form.

Donor expenses are billed on the recipient claim.

Hospitals bill for services on the UB-92 or UB-04 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered under the high-dose chemotherapy, bone marrow or peripheral stem cell transplant for ovarian cancer and germ cell tumors arising in the ovaries include

38204	38205	38206	38207	38208	38209	38230	38240
38241	38242	86812	86813	86816	86817	86821	86822
96400	96405	96406	96408	96410	96412	96414	96420
96422	96423	96425	96440	96445	96450	96545	
S2150	J9000 through J9999						

D. Reimbursement

Providers must bill their usual and customary charges.