

**Policy terminated because procedure/service is now included in each individual BMT policy.**

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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**

Non-myeloablative allogeneic stem cell transplant (minitransplant, mini allograft reduced intensity conditioning) for the treatment of malignancies: Non-myeloablative consists of administering lower doses of chemotherapy or radiotherapy followed by allogeneic bone marrow or peripheral blood stem cell administration to destroy malignant cells.

Non-myeloablative therapy is for patients not considered to be candidates for myeloablative transplant i.e., chronic myelogenous leukemia, acute myelogenous leukemia, acute lymphocytic leukemia, Hodgkins disease, non Hodgkins lymphoma (all ineligible for conventional allogeneic stem cell support). (Refer to individual policies.)

## 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 non-myeloablative allogeneic stem cell transplant (minitransplant, mini allograft reduced intensity conditioning) for the treatment of malignancies for patients who meet criteria\* for high-dose chemotherapy and allogeneic stem cell support but cannot tolerate the high doses.

**\*Note:** Refer to the individual clinical coverage policies, which address high-dose chemotherapies.

### 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 non-myeloablative allogeneic stem cell support for patients who do not meet criteria for high-dose chemotherapy and allogeneic stem cell support because of the following conditions (not all inclusive):

- a. Extremes of age
- b. Co-morbidities
- c. Multiple myeloma
- d. Renal cell carcinoma
- e. Solid tumors
- f. 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.

- g. Psychosocial history that would limit the ability to comply with medical care pre and post transplant
- h. 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 surgery.

A statement signed by the surgeon certifying that 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.

## **8.0 Policy Implementation/Revision Information**

**Original Effective Date:** January 1, 1994

### **Revision Information:**

<b>Date</b>	<b>Section Revised</b>	<b>Change</b>
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.
4/30/12	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

Refer to the individual medical coverage policies, which address high-dose chemotherapies for covered codes.

### D. Reimbursement

Providers must bill their usual and customary charges.