

**Policy terminated because no longer the standard of care.**

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## **1.0 Description of the Procedure, Product, or Service**

This policy addresses high-dose chemotherapy with hematopoietic stem-cell support as a treatment of breast cancer. Bone marrow transplants typically include high-dose chemotherapy (HDC).

"High-dose chemotherapy" (HDC) involves the administration of cytotoxic agents for the treatment of cancer. It uses doses several times greater than the standard therapeutic dose. In some cases, whole body or localized radiotherapy is also given and is included in the term HDC. The rationale for HDC is that many cytotoxic agents act according to a steep dose-response curve. Thus, small increments in dosage will result in relatively large increases in tumor cell kill. Increasing the dosage also increases the incidence and severity of adverse effects related primarily to bone marrow ablation (e.g., opportunistic infections, hemorrhage, organ failure).

Various techniques have been developed to counter the myelosuppressive effects, and secondary susceptibility to infections of HDC regimens. The main technique is the infusion into the recipient of hematopoietic stem cells to repopulate the bone marrow. Hematopoietic stem cells are primitive cells capable of replication and formation into mature blood cells. Stem cells can be harvested from three sources:

- a. Bone marrow cells: Bone marrow stem cells can be harvested from a related or unrelated donor.
- b. Peripheral stem cells: Stem cells may be harvested from the peripheral blood circulation. This may involve several pheresis procedures. Pheresis involves withdrawing blood from a donor in which a portion containing stem cells is separated and retained with the remainder re-transfused back to the donor.
- c. Umbilical cord: Blood harvested from the umbilical cord and placenta shortly after the delivery of neonates contains stem cells. Although cord blood is an allogeneic source, these stem cells are associated with a lower incidence of rejection or graft versus host disease.

When harvested from and infused back into the same recipient, stem cells are referred to as autologous. Stem cells harvested from a healthy, histocompatible donor and infused into a recipient are referred to as allogeneic.

Breast cancer is the most common malignancy among women and has a high fatality rate. In women, breast cancer is rare before the age of 30, and the incidence rises rapidly after menopause. Breast cancer is commonly categorized according to the stage of disease.

## **1.1 Medical Term Definitions**

- a. Ablation: the removal of tissue or an abnormal growth, usually by cutting; may also refer to a very high dose of treatment that is calculated to kill a tumor.
- b. Allogeneic: genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism
- c. Autologous: derived from the same organism, i.e., self donation.
- d. Cytotoxic agents: drugs which possess a specific destructive action on certain cells; often used to refer to drugs used to fight cancer, such as chemotherapy.
- e. Harvesting: to remove tissues or cells from a donor and preserve for transplantation.
- f. Hematopoietic: pertaining to or effecting the formation of blood cells.
- g. Histocompatible: tissue compatible; donor and recipient are well enough matched that a transplant will be easily accepted.
- h. Malignancy: a cancer.
- i. Metastatic: transfer of disease from one organ or part of the body to another not directly connected with it.
- j. Myelosuppressive: something that inhibits bone marrow activity, resulting in decreased production of blood cells and platelets.
- k. Opportunistic: a microorganism that does not usually cause disease but that, under certain circumstances such as impaired immune system due to other diseases or drug treatment becomes pathogenic.
- l. Placenta: Temporary organ formed from both fetal and maternal tissues that provides nutrients and oxygen to the developing fetus, carries away fetal metabolic wastes, and produces the hormones of pregnancy.
- m. Steep dose response curve: a theory in delivery of cytotoxic agents that small increments in dosage will result in relatively large increases in tumor cell kill.
- n. Stem cells: immature generic blood cells that will mature into the various types of blood cells in the body.
- o. Umbilical cord: a flexible structure through which the umbilical arteries and vein pass and which connects the fetus to the placenta..

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

### 3.0 When the Procedure, Product, or Service Is Covered

#### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

#### 3.2 Specific Criteria

HDC and autologous stem cell support for breast cancer may be covered for recipients participating in an approved clinical trial.

### 4.0 When the Procedure, Product, or Service Is Not Covered

#### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

#### 4.2 Specific Criteria

Bone marrow transplant for breast cancer is not covered for the following:

- a. HDC and stem cell support is considered investigational in the treatment of breast cancer.
- b. Tandem autologous transplantation (i.e., two courses of HDC) is considered investigational as a treatment of breast cancer.
- c. HDC with allogeneic stem cell support is considered investigational as a treatment of breast cancer.

#### 4.3 Other Information

A literature search found no new reports of clinical outcomes from trials directly comparing HDC with autologous stem cell support versus conventional dose therapy for patients with metastatic breast cancer. Several randomized trials reported outcomes in comparison of HDC with autologous stem cell support versus conventional doses for adjuvant therapy of high-risk non-metastatic breast cancer. The studies did not support conclusions that HDC with autologous stem cell support improved outcomes when

compared to conventional adjuvant therapy. Data related to outcomes of multiple cycles (tandem transplants) in comparison to single transplant or conventional-dose regimens were unavailable.

There is inadequate data available to evaluate outcomes of HDC with allogeneic stem cell support for the treatment of breast cancer.

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval is required for bone marrow transplant for breast cancer. Refer to Subsections 3.2 and 4.2.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
4/30/12	Throughout	Policy Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

CPT Codes				
38205	38206	38230	38240	38241
38242				

HCPCS Codes
S2150

**Note:** Claims will deny if prior approval has not been obtained. Refer to **Subsections 3.2 and 4.2.**

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Inpatient Hospital and Outpatient Hospital

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.