

**Policy terminated because Medicaid covers codes in the same manner as
Health Choice.**

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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 miscellaneous tumors in adults. 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 patient 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 retransfused 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 patient, 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. Miscellaneous solid tumors in adults includes small cell lung cancer, malignant melanoma, tumors of the gastrointestinal tract (colon, rectum, pancreas, gastric, esophagus, gallbladder, and bile duct), genitourinary system (renal cell carcinoma, cervical carcinoma, cancer of the uterus, fallopian tubes, and prostate gland), tumors of the head and neck, soft tissue sarcoma, thyroid tumors, tumors of the thymus and tumors of unknown primary origin.

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. Myelosuppressive: something that inhibits bone marrow activity, resulting in decreased production of blood cells and platelets.
- i. 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.
- j. 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.
- k. 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.
- l. Stem cells: immature generic blood cells that will mature into the various types of blood cells in the body.
- m. 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.

Most children will be able to get all the services they need under the core (basic) plan of NC Health Choice. A child who qualifies as having special needs may be able to receive additional services not covered by the core plan.

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

Bone marrow transplant, high dose chemotherapy and stem cell support for miscellaneous tumors in adults are covered when they are determined to be medically necessary because the criteria below are met:

- a. HDC and autologous stem cell support may be covered for recipients participating in a clinical trial.

3.3 Policy Guidelines

While some HDC protocols can be administered on an outpatient basis, typically the recipient is hospitalized for management of the marrow ablative complications of the therapy. All recipients receiving whole body radiotherapy, typically those receiving an allogeneic transplant (from donor to patient), will require prolonged hospitalization.

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 miscellaneous tumors in adults is not covered in the following situations:

- a. When the criteria in **Subsection 3.2** are not met.
- b. HDC and autologous or allogeneic stem cell support is considered investigational for other tumors including the following, unless they are part of a clinical trial.
 - 1. Lung cancer, any histology;
 - 2. Colon cancer;
 - 3. Rectal cancer;
 - 4. Pancreas cancer;
 - 5. Gastric cancer;
 - 6. Esophageal cancer;

7. Gall bladder cancer;
8. Cancer of the bile duct;
9. Renal cell cancer;
10. Cervical cancer;
11. Uterine cancer;
12. Cancer of the fallopian tubes;
13. Prostate cancer;
14. Nasopharyngeal cancer;
15. Paranasal sinus cancer;
16. Neuroendocrine tumors;
17. Soft tissue sarcomas;
18. Thyroid tumors;
19. Tumors of the thymus;
20. Tumors of unknown primary origin;
21. Malignant melanoma;
22. Undifferentiated tumors.

4.3 Policy Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for various solid tumors in adults addressed in this policy does not list bone marrow transplant as a treatment option. The National Cancer Institute (NCI) database identified several Phase I, II and III trials related to bone marrow transplants for solid tumors in adults.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for bone marrow transplant for miscellaneous tumors in adults.

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				

HCPSC Codes
S2150

Note: If prior approval has not been obtained, claims will deny.

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.