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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 neuroectodermal tumors and ependymoma. 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 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 patient are referred to as allogeneic.

Primitive neuroepithelial tumors include medulloblastoma, neuroblastoma arising in the central nervous system, ependymblastoma, or pineoblastoma. Medulloblastoma is the most common type of primitive neuroectodermal tumor (PNET). Treatment options focus on optimal surgical resection with or without radiation therapy.

Ependymoma is a neuroepithelial tumor arising throughout the central nervous system. Ependymomas are not considered a member of the PNET family.

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. Refractory: not responding to treatment
- l. 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.
- m. Stem cells: immature generic blood cells that will mature into the various types of blood cells in the body.
- n. 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

Bone marrow transplant, high dose chemotherapy and stem cell support for primitive neuroectodermal tumors (PNET) are covered under the NC Health Choice Program when they are determined to be medically necessary because the following medical criteria are met:

- a. HDC (with or without associated radiotherapy) and autologous stem cell support may be considered medically necessary for the treatment of recurrent or residual medulloblastoma and other primitive neuroectodermal tumors (PNET's), including ependymblastoma, neuroblastoma, and pinealoblastoma.

3.3 Other Medical Policy Guidelines

- a. Residual tumor is defined as a tumor that does not achieve a complete response after initial therapy. This includes partial responses (for this condition less than complete but greater than 50% response) and refractory disease (for this condition less than a 50% response).
- b. 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 recipient), 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

- a. Bone Marrow Transplant, high dose chemotherapy and stem cell support for ependymoma is not covered because it is considered investigational. There is insufficient evidence to objectively conclude that there is a sustainable positive effect on health outcome. The NC Health Choice Program does not cover investigational services.

- b. Bone marrow transplant for neuroectodermal tumors and ependymoma is not covered in the following situations:
1. HDC (with or without associated radiotherapy) and autologous stem cell support is considered investigational as a treatment of ependymoma, or to consolidate a complete remission after initial therapy for medulloblastoma and other PNET's of the CNS.
 2. HDC (with or without associated radiotherapy) and allogeneic stem cell support is considered investigational as a treatment of medulloblastoma, PNET's or ependymoma.
 3. Multiple-cycle HDC (with or without associated radiotherapy) and autologous stem-cell support (i.e., tandem transplants) is investigational in all recipients with medulloblastoma, other PNETs of the CNS, or ependymoma.

Note: If the medical criteria are not met, some recipients may be eligible for coverage under a clinical trial.

4.3 Policy Guidelines

A recent literature search failed to find any new data on the outcomes of HDC with hematopoietic stem cell support for recipients with ependymoma. The 2008 National Comprehensive Cancer Network Guidelines on Central Nervous System Tumors do not list HDC with stem cell support as a treatment option for recipients with ependymoma. There are currently no clinical trials focusing specifically on this treatment for ependymoma. However, there are several ongoing Phase III randomized clinical trials for PNETs.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for all transplants, including bone marrow transplant for neuroectodermal tumors and ependymoma.

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.”

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 Code(s)				
38205	38206	38230	38240	38241
38242				

HCPCS Code
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

G. Co-payments

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

H. Reimbursement

Providers must bill their usual and customary charges.