

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

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1.0 Description of the Procedure, Product, or Service

Transplantation of allogeneic hematopoietic stem cells derived from bone marrow or peripheral blood, in conjunction with myeloablative chemotherapy, is an established therapy for various malignancies, including acute and chronic leukemias, Hodgkin's disease, and non-Hodgkin's lymphomas. The treatment effect results from chemotherapeutic ablation of malignant cells, as well as an associated immune-mediated graft versus malignancy effect. The conventional practice of allogeneic stem-cell transplants (allo-SCT) involves administration of myelotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at high enough doses to cause bone marrow failure in most patients. While such treatment may eradicate the malignant cells, patients are as likely to die from opportunistic infections, graft-versus-host disease, and organ failure as from the underlying malignancy. Recently, regimens have been developed that seek to reduce treatment-related adverse effects while retaining beneficial (i.e., graft versus malignancy) effects. So-called nonmyeloablative regimens have been tentatively defined as those that do not eradicate the patient's hematopoietic ability, allowing for relatively prompt hematopoietic recovery (e.g., 28 days or less) without a transplant. Examples of such regimens include fludarabine-cyclophosphamide and fludarabine-idarubicin-cytarabine combinations. On engraftment, patients treated with nonmyeloablative regimens will demonstrate mixed chimerism initially. Most will subsequently convert to full-donor chimerism and may be supplemented with donor lymphocyte infusions to further eradicate malignant cells. Nonmyeloablative chemotherapy is now commonly referred to as reduced-intensity conditioning (RIC), with patients also receiving allogeneic stem-cell support. This procedure also has been called "mini-transplant."

Two general categories of patients have been considered candidates for nonmyeloablative allotransplants: those who would otherwise be considered candidates for a conventional myeloablative allotransplant and those who would not. In the former category, nonmyeloablative allotransplants could be considered as a variant of a standard chemotherapy conditioning regimen. In the latter category, nonmyeloablative transplants would be considered a novel approach, either for patients whose comorbidities preclude a standard myeloablative conditioning regimen, or in those with malignancies that have not been shown to be effectively treated with conventional myeloablative allogeneic transplants.

1.1 Medical Term Definitions

- a. Chemotherapy: refers to the treatment of disease by chemical agents; more commonly refers to the use of chemicals that have a specific toxic effect upon cancerous tissue.
- b. Malignant: cancerous, not benign; describes a tumor that invades and destroys the tissues in which it originates and can spread to other sites in the body via the bloodstream and lymphatic system. If untreated, these tumors cause progressive deterioration and death

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

Nonmyeloablative allogeneic transplants of hematopoietic stem cells for treatment of malignancy may be considered medically necessary in recipients who would otherwise meet patient selection criteria for high dose chemotherapy and allogeneic stem cell transplantation.

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

Other applications of nonmyeloablative allogeneic transplants of hematopoietic stem cells for treatment of malignancy are considered investigational. This includes:

- a. the use of nonmyeloablative allogeneic transplants of hematopoietic stem cells for treatment of malignancy in recipients who do not meet the criteria for high-dose chemotherapy and allogeneic stem cell transplant due to either:
 1. age; or
 2. co-morbidities.
- b. as a treatment of other malignancies including:
 1. multiple myeloma
 2. renal cell carcinoma
 3. other solid tumors
 4. autoimmune disease

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior Approval is required for nonmyeloablative allogeneic transplants of hematopoietic stem cells for treatment of malignancy.

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	Throughout	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	38230	38240	38242

HCPCS Code
S2150

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.