

Table of Contents

1.0 Description of the Procedure, Product, or Service 1
1.1 Medical Term Definitions 1

2.0 Eligible Recipients 1
2.1 General Provisions 1

3.0 When the Procedure, Product, or Service Is Covered 2
3.1 General Criteria 2
3.2 Specific Criteria 2

4.0 When the Procedure, Product, or Service Is Not Covered 2
4.1 General Criteria 2
4.2 Specific Criteria 2

5.0 Requirements for and Limitations on Coverage 3
5.1 Prior Approval 3

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 3

7.0 Additional Requirements 3
7.1 Compliance 3

8.0 Policy Implementation/Revision Information 3

Attachment A: Claims-Related Information 4
A. Claim Type 4
B. Diagnosis Codes 4
C. Procedure Code(s) 4
D. Modifiers 4
E. Billing Units 4
F. Place of Service 4
G. Co-payments 4
H. Reimbursement 4

1.0 Description of the Procedure, Product, or Service

Blood harvested from the umbilical cord and placenta shortly after delivery of neonates contains stem and progenitor cells capable of restoring hematopoietic function after myeloablation. A variety of malignant diseases and non-malignant bone marrow disorders are treated with myeloablative therapy followed by infusion of stem and progenitor cells to restore hematopoietic cells and function. Sources of stem cells include allogeneic bone marrow, autologous bone marrow, and peripheral blood. For many patients, no suitable donor is available to provide allogeneic bone marrow. Autologous stem cells may be inappropriate in some patients either due to contamination with malignant cells or due to genetic defects. Thus, the cord blood source of stem cells is needed.

1.1 Medical Term Definitions

- a. Allogeneic: genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism.
- b. Autologous: derived from the same organism, i.e., self donation.
- c. Genetic: hereditary; transferred through the genes from parent to child.
- d. Hematopoietic: pertaining to or effecting the formation of blood cells.
- e. 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.
- f. Myeloablative: treatment designed to destroy most all blood cells and cancer cells.
- g. 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.
- h. Progenitor: a parent or ancestor.
- i. Prophylactic: preventive measures taken before any disease is present.
- j. 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

- a. Cord blood as a source of stem cells may be covered by the NC Health Choice Program when it is determined to be medically necessary because the following criteria are met.
- b. Cord blood as a source of stem cells is covered when:
 1. Transplantation of cord blood stem cells from related or unrelated donors may be considered medically necessary in recipients with an appropriate indication for allogeneic bone marrow transplant but without a hematopoietic stem cell donor with the same or better HLA (Human Leukocyte Antigen) matching characteristics.
 2. Collection and storage of cord blood from a neonate may be considered medically necessary when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant.

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

Cord blood as a source of stem cells is **not covered** by the NC Health Choice Program for:

- a. indications other than those listed in **Subsection 3.2**.
- b. prophylactic collection and storage of cord blood from a neonate is non-covered when proposed for some unspecified future use as an autologous stem-cell transplant in the original donor, or for some unspecified future use as an allogeneic stem cell transplant in a related or unrelated recipient.
- c. services for or related to the search for a donor.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for the use of cord blood as a source of stem cells.

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 Codes				
38205	38206	38230	38240	38242

CPT Codes	
S2140	S2142

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.