To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.

Table of Contents

1.0 Description of the Procedure, Product, or Service................................................................. 1

2.0 Eligibility Requirements........................................................................................................... 4
  2.1 Provisions............................................................................................................................ 4
  2.1.1 General................................................................................................................... 4
  2.1.2 Specific .................................................................................................................. 4
  2.2 Special Provisions............................................................................................................... 4
  2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age ................................................................. 4
  2.2.2 EPSDT does not apply to NCHC beneficiaries............................................................. 5
  2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age................................................................. 5

3.0 When the Procedure, Product, or Service Is Covered.............................................................. 6
  3.1 General Criteria Covered.................................................................................................... 6
  3.2 Specific Criteria Covered.................................................................................................... 6
  3.2.1 Specific criteria covered by both Medicaid and NCHC ........................................ 6
  3.2.2 Medicaid Additional Criteria Covered................................................................... 6
  3.2.3 NCHC Additional Criteria Covered...................................................................... 7

4.0 When the Procedure, Product, or Service Is Not Covered...................................................... 7
  4.1 General Criteria Not Covered............................................................................................. 7
  4.2 Specific Criteria Not Covered............................................................................................. 7
  4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC ................................ 7
  4.2.2 Medicaid Additional Criteria Not Covered ............................................................ 7
  4.2.3 NCHC Additional Criteria Not Covered................................................................ 7

5.0 Requirements for and Limitations on Coverage ..................................................................... 8
  5.1 Prior Approval .................................................................................................................... 8
  5.2 Prior Approval Requirements............................................................................................ 8
  5.2.1 General................................................................................................................... 8
  5.2.2 Specific .................................................................................................................. 8
  5.3 Specific Transplant Prior Approval Requirements ............................................................. 8

6.0 Providers Eligible to Bill for the Procedure, Product, or Service............................................ 9
  6.1 Provider Qualifications and Occupational Licensing Entity Regulations.......................... 9
  6.2 Provider Certifications........................................................................................................ 9

7.0 Additional Requirements ........................................................................................................ 9
  7.1 Compliance.......................................................................................................................... 9

8.0 Policy Implementation/Revision Information............................................................................ 10
DRAFT

Attachment A: Claims-Related Information ..............................................................
A. Claim Type ........................................................................................................ 12
B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) .......... 12
C. Code(s) ........................................................................................................... 12
D. Modifiers .......................................................................................................... 13
E. Billing Units ..................................................................................................... 13
F. Place of Service ............................................................................................... 13
G. Co-payments ................................................................................................. 13
H. Reimbursement ............................................................................................... 13
I. Billing for Donor Expenses ............................................................................. 13
1.0 Description of the Procedure, Product, or Service

Hematopoietic Stem-Cell Transplantation
Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in patients who receive bone marrow toxic doses of cytotoxic drugs with or without whole body radiation therapy. Allogeneic HSCT refers to the use of hematopoietic progenitor cells obtained from a donor. They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates.

Immunologic compatibility between infused stem cells and the recipient is a critical factor for achieving a good outcome of allogeneic HSCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the Class I and Class II loci on chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

Preparative Conditioning for Allogeneic Hematopoietic SCT
The conventional practice of allogeneic HSCT involves administration of myelotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to cause bone marrow failure. Reduced-intensity conditioning (RIC) refers to chemotherapy regimens that seek to reduce adverse effects secondary to bone marrow toxicity. These regimens partially eradicate the patient’s hematopoietic ability, thereby allowing for relatively prompt hematopoietic recovery. Patients who undergo RIC with allogeneic HSCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. A number of different cytotoxic regimens, with or without radiotherapy, may be used for RIC allotransplantation. They represent a continuum in their intensity, from nearly totally myeloablative, to minimally myeloablative with lymphoablation.

Genetic Diseases and Acquired Anemias

Hemoglobinopathies
The thalassemias result from mutations in the globin genes, resulting in reduced or absent hemoglobin production, reducing oxygen delivery. The supportive treatment of beta-thalassemia major requires life-long red blood cell transfusions that lead to progressive iron overload and the potential for organ damage and impaired cardiac, hepatic, and endocrine function. The only definitive cure for thalassemia is to correct the genetic defect with allogeneic HSCT.
Sickle cell disease is caused by a single amino acid substitution in the beta chain of hemoglobin, and, unlike thalassemia major, has a variable course of clinical severity. Sickle cell disease typically manifests clinically with anemia, severe painful crises, acute chest syndrome, stroke, chronic pulmonary and renal dysfunction, growth retardation, neurologic deficits, and premature death.

The mean age of death for patients with sickle cell disease has been demonstrated as 42 years for males and 48 years for females. Three major therapeutic options are available: chronic blood transfusions, hydroxyurea, and HSCT, the latter being the only possibility for cure.

**Bone marrow failure syndromes**

Aplastic anemia in children is rare, and is most often idiopathic and less commonly due to a hereditary disorder. Inherited syndromes include Fanconi anemia, a rare autosomal recessive disease, characterized by genomic instability, with congenital abnormalities, chromosome breakage, cancer susceptibility, and progressive bone marrow failure leading to pancytopenia and severe aplastic anemia. Frequently this disease terminates in a myelodysplastic syndrome or acute myelogenous leukemia. Most patients with Fanconi anemia succumb to the complications of severe aplastic anemia, leukemia, or solid tumors, with a median survival of 30 years of age. In Fanconi anemia, HSCT is currently the only treatment that definitively restores normal hematopoiesis. Excellent results have been observed with the use of HLA-matched sibling allogeneic HSCT, with cure of the marrow failure and amelioration of the risk of leukemia.

Dyskeratosis congenita is characterized by marked telomere dysregulation with clinical features of reticulated skin hyperpigmentation, nail dystrophy, and oral leukoplakia. Early mortality is associated with bone marrow failure, infections, pulmonary complications, or malignancy.

Mutations affecting ribosome assembly and function are associated with Shwachman-Diamond syndrome, and Diamond-Blackfan anemia. Shwachman-Diamond has clinical features that include pancreatic exocrine insufficiency, skeletal abnormalities and cytopenias with some patients developing aplastic anemia. As with other bone marrow failure syndromes, patients are at increased risk of myelodysplastic syndrome with malignant transformation, especially acute myelogenous leukemia. Diamond-Blackfan anemia is characterized by absent or decreased erythroid precursors in the bone marrow with 30% of patients also having a variety of physical anomalies.

**Primary immunodeficiencies**

The primary immunodeficiencies are a genetically heterogeneous group of diseases that affect distinct components of the immune system. More than 120 gene defects have been described, causing more than 150 disease phenotypes. The most severe defects (collectively known as severe combined immunodeficiency or SCID) cause an absence or dysfunction of T lymphocytes, and sometimes B lymphocytes and natural killer cells. Without treatment, patients with SCID usually die by 12 to 18 months of age. With supportive care, including prophylactic medication, the life span of these patients can be prolonged, but long-term outlook is still poor, with many dying from infectious or inflammatory complications or malignancy by early adulthood. Bone marrow transplant is the only definitive cure, and the treatment of choice for SCID and other primary immunodeficiencies, including Wiskott-Aldrich syndrome and congenital defects of neutrophil function.
Inherited metabolic diseases

Lysosomal storage disorders consist of many different rare diseases caused by a single gene defect, and most are inherited as an autosomal recessive trait. Lysosomal storage disorders are caused by specific enzyme deficiencies that result in defective lysosomal acid hydrolysis of endogenous macromolecules that subsequently accumulate as a toxic substance. Peroxisomal storage disorders arise due to a defect in a membrane transporter protein that leads to defects in the metabolism of long-chain fatty acids. Lysosomal storage disorders and peroxisomal storage disorders affect multiple organ systems, including the central and peripheral nervous systems. These disorders are progressive and often fatal in childhood due to both the accumulation of toxic substrate and a deficiency of the product of the enzyme reaction. Hurler syndrome usually leads to premature death by five years of age.

Exogenous enzyme replacement therapy is available for a limited number of the inherited metabolic diseases; however, these drugs don’t cross the blood-brain barrier, which results in ineffective treatment of the central nervous system. Stem cell transplantation provides a constant source of enzyme replacement from the engrafted donor cells, which are not impeded by the blood-brain barrier. The donor-derived cells can migrate and engraft in many organ systems, giving rise to different types of cells, for example microglial cells in the brain and Kupffer cells in the liver.

Allogeneic HSCT has been primarily used to treat the inherited metabolic diseases that belong to the lysosomal and peroxisomal storage disorders. The first stem-cell transplant for an inherited metabolic disease was performed in 1980 in a patient with Hurler syndrome. Since that time, more than 1,000 transplants have been performed worldwide.

Infantile malignant osteopetrosis

Osteopetrosis is a condition caused by defects in osteoclast development and/or function. The osteoclast (the cell that functions in the breakdown and resorption of bone tissue) is known to be part of the hematopoietic family and shares a common progenitor with the macrophage in the bone marrow. Osteopetrosis is a heterogeneous group of heritable disorders, resulting in several different types of variable severity. The most severely affected patients are those with infantile malignant osteopetrosis. Patients with infantile malignant osteopetrosis suffer from dense bone, including a heavy head with frontal bossing, exophthalmos, blindness by approximately 6 months of age, and severe hematologic malfunction with bone marrow failure. Seventy percent of these patients die before the age of six, often of recurrent infections. HSCT is the only curative therapy for this fatal disease.

Hematopoietic stem-cell transplantation for autoimmune disease, such as rheumatoid arthritis or multiple sclerosis, is considered separately in policy, Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases.
2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in Section 3.0 of this policy.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

a. Medicaid
   None Apply.

b. NCHC
   None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

   Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

   This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

   Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service
requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider’s documentation shows that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.

2. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within Section 3.0 of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.
3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered
Medicaid and NCHC shall cover the procedure, product, or service related to this policy when 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 beneficiary’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 statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary’s caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC
Medicaid and NCHC shall cover Allogeneic Hematopoietic Stem Cell & Bone Marrow Transplantation for Genetic Diseases and Acquired Anemias with the following disorders:

a. Hemoglobinopathies
   1. Sickle cell anemia for children or young adults with either a history of prior stroke or at increased risk of stroke or end-organ damage.
   2. Homozygous beta-thalassemia (i.e., thalassemia major).

b. Bone marrow failure syndromes
   1. Aplastic anemia including hereditary (e.g. Fanconi anemia, dyskeratosis congenita, Shwachman-Diamond, Diamond-Blackfan) or acquired (e.g., secondary to drug or toxin exposure) forms.

c. Primary immunodeficiencies
   1. Absent or defective T-cell function (e.g., severe combined immunodeficiency, Wiskott-Aldrich syndrome, X-linked lymphoproliferative syndrome).
   2. Absent or defective natural killer function (e.g. Chediak-Higashi syndrome).
   3. Absent or defective neutrophil function (e.g. Kostmann syndrome, chronic granulomatous disease, leukocyte adhesion defect).

d. Inherited metabolic disease
   1. Lysosomal and peroxisomal storage disorders except Hunter, Sanfilippo, and Morquio syndromes.

e. Genetic disorders affecting skeletal tissue
   1. Infantile malignant osteopetrosis (Albers-Schonberg disease or marble bone disease).

3.2.2 Medicaid Additional Criteria Covered
None Apply.
3.2.3 NCHC Additional Criteria Covered
None Apply.

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

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered
Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:
  a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;
  b. the beneficiary does not meet the criteria listed in Section 3.0;
  c. the procedure, product, or service duplicates another provider’s procedure, product, or service; or
  d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC
Medicaid and NCHC shall not cover Allogeneic Hematopoietic Stem Cell & Bone Marrow Transplantation for Genetic Diseases and Acquired Anemias in the following situations:
  a. For diagnoses other than those covered in Subsection 3.2; or
  b. When the beneficiary’s psychosocial history limits the beneficiary’s ability to comply with pre- and post-transplant medical care; or
  c. When current beneficiary or caretaker non-compliance would make compliance with a disciplined medical regime improbable.

4.2.2 Medicaid Additional Criteria Not Covered
None Apply.

4.2.3 NCHC Additional Criteria Not Covered
a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
   1. No services for long-term care.
   2. No nonemergency medical transportation.
   3. No EPSDT.
   4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”
5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for Allogeneic Hematopoietic Stem Cell & Bone Marrow Transplantation for Genetic Diseases and Acquired Anemias. The provider shall obtain prior approval before rendering Allogeneic Hematopoietic Stem Cell & Bone Marrow Transplantation for Genetic Diseases and Acquired Anemias.

Prior Approval is required for HSCT and bone marrow transplantation in the treatment of germ cell tumors.

If prior approval has been given for Allogeneic Hematopoietic Stem Cell Transplantation for Genetic Diseases and Acquired Anemias, actual donor transplant-related medical expenses (procuring, harvesting, short-term storing and all associated laboratory costs) are covered. HSCT, DMA shall reimburse for the following transplant-related donor medical expenses: procuring, harvesting, short-term storing and all associated laboratory costs.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and

b. all health records and any other records that support the beneficiary has met the specific criteria in Subsection 3.2 of this policy.

5.2.2 Specific

None Apply.

5.3 Specific Transplant Prior Approval Requirements

The provider(s) shall submit the following to the NC Medicaid transplant nurse consultant:

a. Letter of medical necessity signed by the attending transplant physician, which documents indications for transplant, regimens and dates, the social history and the transplant evaluation;

b. All health care records and any other records that support the beneficiary has met the specific criteria in Subsection 3.2 of this policy including:

1. Lab results (less than three months old) to include Complete Blood Count (CBC), complete electrolytes, liver enzymes, Prothrombin Time (PT), International Normalized Ratio (INR), glucose and A1C (Glycated Hemoglobin if Type I or Type II diabetic), and blood type;

2. Serologies: to include Human Immunodeficiency Virus (HIV), Hepatitis panel, Rapid Plasma Reagin (RPR), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Varicella, Rubella, Herpes Simplex Virus (HSV) I/II, and toxoplasmosis. (Positive serology results may be reported that are greater than three months old);

3. Diagnostic studies (less than six months old) required in a complete packet include:
A. Cardiac: Echocardiogram, Electrocardiogram (ECG), and/or cardiac catheterization as appropriate for beneficiary’s clinical status;
B. Pulmonary: Pulmonary Function Test if beneficiary has cardiac or pulmonary issues, or a history of smoking; and
C. Chest x-ray for all transplant candidates;
4. Other diagnostic tests may be requested as appropriate;
5. Beneficiary’s height and weight
6. All diagnostic and procedure results, including bone marrow aspiration (not more than six months old)
c. Complete psychological and social evaluation to include:
   1. beneficiary’s medical compliance;
   2. beneficiary’s support network;
   3. post-transplant care plan, with identification of primary and secondary care providers; and
   4. history of mental health issues/substance use/legal issues
d. Beneficiaries with a psychiatric history are required to have an evaluation by a psychiatrist with expertise in evaluating the specific psychiatric issues that relate to transplant candidates.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:
a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations
None Apply.

6.2 Provider Certifications
None Apply.

7.0 Additional Requirements
Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:
a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid’s clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

c. FDA approved procedures, products, and devices for implantation must be utilized.

d. A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary’s medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

Revision Information:

<table>
<thead>
<tr>
<th>Date</th>
<th>Section Revised</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/1/05</td>
<td>Entire Policy</td>
<td>Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.</td>
</tr>
<tr>
<td>9/1/05</td>
<td>Subsection 2.2</td>
<td>The special provision related to EPSDT was revised.</td>
</tr>
<tr>
<td>12/1/05</td>
<td>Subsection 2.2</td>
<td>The web address for DMA’s EDPST policy instructions was added to this section.</td>
</tr>
<tr>
<td>12/1/06</td>
<td>Subsection 2.2</td>
<td>The special provision related to EPSDT was revised.</td>
</tr>
<tr>
<td>12/1/06</td>
<td>Sections 3.0 and 4.0</td>
<td>A note regarding EPSDT was added to these sections.</td>
</tr>
<tr>
<td>5/1/07</td>
<td>Sections 2 through 4</td>
<td>EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.</td>
</tr>
<tr>
<td>5/1/07</td>
<td>Attachment A</td>
<td>Added UB-04 as an accepted claims form.</td>
</tr>
<tr>
<td>7/1/10</td>
<td>Throughout</td>
<td>Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.</td>
</tr>
<tr>
<td>1/1/12</td>
<td>throughout</td>
<td>Policy updated to reflect current community standards and changing transplant protocols.</td>
</tr>
<tr>
<td>3/12/12</td>
<td>Throughout</td>
<td>To be equivalent where applicable to NC DMA’s Clinical Coverage Policy # 11A-5 under Session Law 2011-145, § 10.41.(b)</td>
</tr>
<tr>
<td>3/12/12</td>
<td>Throughout</td>
<td>Technical changes to merge Medicaid and NCHC current coverage into one policy.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>All Sections and Attachments</td>
<td>Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.</td>
</tr>
<tr>
<td>03/01/2017</td>
<td>Attachment A, Section B</td>
<td>Revised and Updated ICD-10 codes.</td>
</tr>
<tr>
<td>Date</td>
<td>Section Revised</td>
<td>Change</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>03/15/2019</td>
<td>Table of Contents</td>
<td>Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”</td>
</tr>
<tr>
<td>03/15/2019</td>
<td>All Sections and Attachments</td>
<td>Updated policy template language.</td>
</tr>
<tr>
<td></td>
<td>Throughout</td>
<td>Removed “&amp; Bone Marrow” from title.</td>
</tr>
<tr>
<td></td>
<td><strong>Section 5.3</strong></td>
<td>“Indications for transplant” added to letter of medical necessity requirements. Added “panel” to Hepatitis panel to reflect verbiage in the State Plan.</td>
</tr>
<tr>
<td></td>
<td><strong>Section 7.0</strong></td>
<td>Removed the following statements: FDA approved procedures, products, and devices for implantation must be utilized. A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary’s medical record and made available for review upon request. This text is not applicable to this policy.</td>
</tr>
<tr>
<td></td>
<td><strong>Attachment A</strong></td>
<td>Added the UB-04 as an accepted claims form. Removed all CPT, HCPCS, and ICD-10 codes.</td>
</tr>
</tbody>
</table>
Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

<table>
<thead>
<tr>
<th>ICD-10-Procedure Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30230G0</td>
</tr>
<tr>
<td>30230G4</td>
</tr>
<tr>
<td>30230Y4</td>
</tr>
<tr>
<td>30233G0</td>
</tr>
<tr>
<td>30233G4</td>
</tr>
<tr>
<td>30233Y4</td>
</tr>
<tr>
<td>30240G0</td>
</tr>
<tr>
<td>30240G4</td>
</tr>
<tr>
<td>30240Y4</td>
</tr>
<tr>
<td>30243G0</td>
</tr>
<tr>
<td>30243G4</td>
</tr>
<tr>
<td>30243Y4</td>
</tr>
<tr>
<td>30250G0</td>
</tr>
<tr>
<td>30250G1</td>
</tr>
<tr>
<td>30250Y1</td>
</tr>
<tr>
<td>30253G0</td>
</tr>
<tr>
<td>30253G1</td>
</tr>
<tr>
<td>30253Y1</td>
</tr>
<tr>
<td>30260G0</td>
</tr>
<tr>
<td>30260G1</td>
</tr>
<tr>
<td>30263G0</td>
</tr>
<tr>
<td>30263G1</td>
</tr>
<tr>
<td>30263Y1</td>
</tr>
</tbody>
</table>

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

<table>
<thead>
<tr>
<th>CPT-Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>38205</td>
</tr>
<tr>
<td>38230</td>
</tr>
<tr>
<td>38240</td>
</tr>
<tr>
<td>38242</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS-Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2150</td>
</tr>
</tbody>
</table>
Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Inpatient hospital, Outpatient hospital.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

I. Billing for Donor Expenses

1. Billing for Donor Expenses for Medicaid Beneficiaries
   Donor transplant-related medical expenses are billed on the Medicaid beneficiary’s transplant claim using the beneficiary’s Medicaid identification number.
   Medicaid reimburses only for the actual donor’s transplant-related medical expenses. Medicaid does not reimburse for unsuccessful donor searches.

2. Billing for Donor Expenses for NCHC Beneficiaries
   Donor transplant-related medical expenses donors are billed on the NCHC beneficiary’s transplant claim.
   NCHC reimburses only for the actual donor’s transplant-related medical expenses. NCHC does not reimburse for unsuccessful donor searches.