

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	1
1.1	Definitions	4
1.1.1	Hematopoietic Stem Cell Transplantation (HSCT)	4
1.1.2	Relapse.....	5
1.1.3	Primary Refractory Disease.....	5
1.1.4	Salvage Therapy	5
1.1.5	Rescue Transplant.....	5
1.1.6	Tandem Transplants.....	5
2.0	Eligibility Requirements	5
2.1	Provisions.....	5
2.1.1	General.....	5
2.1.2	Specific	5
2.2	Special Provisions.....	6
2.2.1	EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age	6
2.2.2	EPSDT does not apply to NCHC beneficiaries	7
2.2.3	Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age	7
3.0	When the Procedure, Product, or Service Is Covered.....	7
3.1	General Criteria Covered	7
3.2	Specific Criteria Covered.....	7
3.2.1	Specific criteria covered by both Medicaid and NCHC	7
3.2.2	Medicaid Additional Criteria Covered.....	8
3.2.3	NCHC Additional Criteria Covered	8
4.0	When the Procedure, Product, or Service Is Not Covered.....	8
4.1	General Criteria Not Covered	8
4.2	Specific Criteria Not Covered.....	8
4.2.1	Specific Criteria Not Covered by both Medicaid and NCHC.....	8
4.2.2	Medicaid Additional Criteria Not Covered.....	8
4.2.3	NCHC Additional Criteria Not Covered.....	8
5.0	Requirements for and Limitations on Coverage	9
5.1	Prior Approval	9
5.2	Prior Approval Requirements	9
5.2.1	General.....	9
5.2.2	Specific	9
5.3	Specific Transplant Prior Approval Requirements.....	9
6.0	Provider(s) Eligible to Bill for the Procedure, Product, or Service	10
6.1	Provider Qualifications and Occupational Licensing Entity Regulations.....	10
6.2	Provider Certifications	10

**NC Division of Medical Assistance
Hematopoietic Stem-Cell
Transplantation for Solid
Tumors of Childhood**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11A-15
Amended Date: July 1, 2018**

7.0	Additional Requirements	11
7.1	Compliance	11
8.0	Policy Implementation/Revision Information.....	11
Attachment A: Claims-Related Information		13
A.	Claim Type	13
B.	International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)	13
C.	Code(s).....	13
D.	Modifiers.....	13
E.	Billing Units.....	13
F.	Place of Service	13
G.	Co-payments	14
H.	Reimbursement	14
I.	Billing for Donor Expenses	14

Related Clinical Coverage Policies

Refer to <https://dma.ncdhhs.gov/> for the related coverage policies listed below:

11A-6, Allogeneic Hematopoietic and Bone Marrow Transplantation in the Treatment of Germ Cell Tumors

11A-10, Hematopoietic Stem-Cell and Bone Marrow Transplantation for Central Nervous System (CNS)
Embryonal Tumor and Ependymoma

11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells

1A-39, Routine Costs in Clinical Trial Services for Life Threatening Conditions

1.0 Description of the Procedure, Product, or Service

Hematopoietic Stem-Cell Transplantation for Solid Tumors

Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy. Stem cells may be obtained from the transplant recipient (autologous HSCT) or can be harvested from a donor (allogeneic HSCT). Stem cells may be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates.

Autologous HSCT takes advantage of the steep dose-response relationship observed with many chemotherapeutic agents and allows for escalation of chemotherapy doses above those limited by myeloablation. The use of allogeneic HSCT for solid tumors relies on a graft-versus-tumor effect. Allogeneic HSCT is uncommonly used in solid tumors, and may be used if an autologous source cannot be cleared of tumor or cannot be harvested.

Solid Tumors of Childhood

Solid tumors of childhood are defined as those not arising from myeloid or lymphoid cells. Some of the most common solid tumors of childhood are neuroblastoma, Ewing's sarcoma, Ewing's Sarcoma Family of Tumors, Wilms tumor, rhabdomyosarcoma, osteosarcoma, and retinoblastoma.

The prognosis for pediatric solid tumors has improved over the last 2 decades, mostly due to the application of multiagent chemotherapy and improvements in local control therapy (including aggressive surgery and advancements in radiation therapy). However, patients with metastatic, refractory, or recurrent disease continue to have poor prognoses, and these "high-risk" patients are candidates for more aggressive therapy, including autologous HSCT, in an effort to improve event-free survival (EFS) and overall survival (OS).

Descriptions of the solid tumors of childhood that are addressed in this policy are as follows:

Peripheral Neuroblastoma

Neuroblastoma is the most common extracranial solid tumor of childhood with two-thirds of the cases presenting in children younger than 5 years of age. These tumors originate where sympathetic nervous system tissue is present, within the adrenal medulla or paraspinal

sympathetic ganglia. They are remarkable for their broad spectrum of clinical behavior, with some undergoing spontaneous regression, others differentiating into benign tumors, and still others progressing rapidly and resulting in patient death.

Patients with neuroblastoma are stratified into prognostic risk groups (low, intermediate, and high) that determine treatment plans. Risk variables include age at diagnosis, clinical stage of disease, tumor histology, and certain molecular characteristics, including the presence of the MYCN oncogene.

Amplification of the MYCN oncogene is one of the few prediction markers for adverse outcome. This gene encodes the MYCN transcriptional regulator predominantly expressed in the developing peripheral neural crest. MYCN is vital for proliferation, migration and stem cell homeostasis while decreased levels are associated with terminal neuronal differentiation.

Tumor histology is categorized as favorable or unfavorable, according to the degree of tumor differentiation, proportion of tumor stromal component, and index of cellular proliferation. It is well established that MYCN amplification is associated with rapid tumor progression and a poor prognosis even in the setting of other coexisting favorable factors. Loss of heterozygosity (LOH) at chromosome arms 1p and 11q occurs frequently in neuroblastoma.

Although 1p LOH is associated with MYCN amplification, 11q is usually found in tumors without this abnormality. Some recent studies have shown that 1p LOH and unbalanced 11q LOH are strongly associated with outcome in patients with neuroblastoma and both are independently predictive of worse progression-free survival (PFS) in patients with low- and intermediate-risk disease. Although the use of these LOH markers in assigning treatment in patients is evolving, they may prove useful to stratify treatment.

Clinical stage of disease is based on the International Neuroblastoma Staging System (INSS) as follows:

Stage 1: Localized tumor with complete gross excision, with or without microscopic residual disease; lymph nodes negative for tumor

Stage 2A: Localized tumor with incomplete gross excision; lymph nodes negative for tumor

Stage 2B: Localized tumor with or without complete gross excision, with ipsilateral lymph nodes positive for tumor

Stage 3: Unresectable unilateral tumor infiltrating across the midline, with or without regional lymph node involvement; or localized unilateral tumor with contralateral regional lymph node involvement; or midline tumor with bilateral extension by infiltration or by lymph node involvement

Stage 4: Any primary tumor with dissemination to distant lymph nodes, bone, bone marrow, liver, skin, and/or other organs, except as defined for stage 4S

Stage 4S: Localized primary tumor as defined for stage 1, 2A, or 2B, with dissemination limited to skin, liver, or bone marrow (marrow involvement less than 10%), limited to children younger than 1 year of age

The low-risk group includes patients less than 1 year of age with stage 1, 2, or 4S with favorable histopathologic findings and no MYCN oncogene amplification. **High-risk neuroblastoma** is characterized by an age older than 1 year, disseminated disease, MYCN oncogene amplification, and unfavorable histopathologic findings.

In general, most patients with low-stage disease have excellent outcomes with minimal therapy, and with INSS stage 1 disease, most patients can be treated by surgery alone. Most infants, even with disseminated disease, have favorable outcomes with chemotherapy and surgery. In contrast, most children older than 1 year with advanced-stage disease die due to progressive disease, despite intensive multimodality therapy and relapse remains common. Treatment of recurrent disease is determined by the risk group at the time of diagnosis, and the extent of disease and age of the patient at recurrence.

Ewing's Sarcoma and the Ewing Family of Tumors

Ewing's sarcoma family of tumors (ESFT) encompasses a group of tumors that have in common some degree of neuroglial differentiation and a characteristic underlying molecular pathogenesis (chromosomal translocation). The translocation usually involves chromosome 22 and results in fusion of the EWS gene with one of the members of the ETS family of transcription factors, either FLI1 (90–95%) or ERG (5–10%). These fusion products function as oncogenic aberrant transcription factors. Detection of these fusions is considered to be specific for the ESFT, and helps further validate the diagnosis. Included in ESFT are “classic” Ewing's sarcoma of bone, extrasosseous Ewing's, peripheral primitive neuroectodermal tumor (pPNET), and Askin tumors (chest wall).

Most commonly diagnosed in adolescence, ESFT can be found in bone (most commonly) or soft tissue; however, the spectrum of ESFT has also been described in various organ systems. Ewing's is the second most common primary malignant bone tumor. The most common primary sites are the pelvic bones, the long bones of the lower extremities, and the bones of the chest wall. Current therapy for Ewing's sarcoma favors induction chemotherapy, with local control consisting of surgery and/or radiation (dependent on tumor size and location), followed by adjuvant chemotherapy. Multiagent chemotherapy, surgery, and radiation therapy have improved the PFS in patients with localized disease to 60%–70%. The presence of metastatic disease is the most unfavorable prognostic feature, and the outcome for patients presenting with metastatic disease is poor, with 20%–30% PFS. Other adverse prognostic factors that may categorize a patient as having “high-risk” Ewing's are tumor location (e.g., patients with pelvic primaries have worse outcomes), larger tumor size, and older age of the patient. However, “high-risk” Ewing's has not always been consistently defined in the literature. Thirty to forty percent of patients with ESFT experience disease recurrence and patients with recurrent disease have a 5-year EFS and OS rate of less than 10%.

Rhabdomyosarcoma

Rhabdomyosarcoma (RMS), the most common soft tissue sarcoma of childhood, shows skeletal muscle differentiation. The most common primary sites are the head and neck (e.g., parameningeal, orbital, and pharyngeal), genitourinary tract, and extremities. Most children with RMS present with localized disease, and with conventional multimodal therapy, the cure rate in this group is 70%–80%. However, approximately 15% of children present with metastatic disease, and despite the introduction of new drugs and intensified treatment, the 5-year survival is 20%–30% for this “high-risk” group.

Wilms Tumor

Wilms tumor, the most common primary malignant renal tumor of childhood, is highly sensitive to chemotherapy and radiation, and current cure rates exceed 85%. Ten to 15% of patients with favorable histology and 50% of patients with anaplastic tumors experience tumor progression or relapse. Similar to newly diagnosed Wilms, relapsed Wilms tumor is a heterogeneous disease, and current treatment strategies stratify intensity and scheduling of the treatment modalities based on prognostic features. For newly diagnosed disease, the most important prognostic features are stage and histology. Similar risk-adapted strategies are being attempted for the 15% of patients who experience relapse. Success rates after relapse range from 25%–45%.

For patients with adverse prognostic factors (histologically anaplastic tumors, relapse less than 6–12 months after nephrectomy, second or subsequent relapse, relapse within the radiation field, bone or brain metastases) event-free survival is less than 15%. However, recent trials with HDC and autologous HSCT have reported 3- or 4-year OS rates from 60%–73%.

Osteosarcoma

Osteosarcoma is a primary malignant bone tumor that is characterized by formation of bone or osteoid by the tumor cells. Osteosarcoma occurs predominantly in the appendicular skeleton of adolescents. In children and adolescents, more than 50% of these tumors arise from bones around the knee. The prognosis of localized osteosarcoma has greatly improved over the last 30 years with OS rates increasing from 10% with surgery alone (usually amputation) to 70% with the introduction of neoadjuvant chemotherapy and limb-sparing surgery. However, 30%–40% of patients with non-metastatic osteosarcoma of the extremities experience recurrent disease, most commonly in the lungs. Mean 5-year post-relapse survival rate is approximately 28%, with some groups having a 0% OS rate. Prognostic factors for recurrence include site and size of the primary tumor, presence of metastases at the time of diagnosis, resection adequacy, and tumor response to preoperative chemotherapy (measured as percent of tumor necrosis in the resection specimen). Overall EFS for patients with metastatic disease at diagnosis is about 20%–30%.

Retinoblastoma

Retinoblastoma is the most common primary tumor of the eye in children. It may occur as a heritable (40%) or nonheritable (60%) tumor. Cases may be unilateral or bilateral, with bilateral tumor almost always occurring in the heritable type. The type of treatment depends on the extent of disease. Retinoblastoma is usually confined to the eye, and with current therapy has at least a 90% cure rate. However, once disease has spread beyond the eye, survival rates drop significantly; 5-year disease-free survival is reported to be less than 10% in those with extraocular disease. Extraocular disease may be localized to the soft tissues surrounding the eye, or to the optic nerve, extending beyond the margin of resection. Further extension may result in involvement of the brain and meninges, with subsequent seeding of the cerebrospinal fluid, as well as distant metastases to the lungs, bone, and bone marrow. Stage 4a disease is defined as distant metastatic disease not involving the central nervous system (CNS), and stage 4b is defined as metastatic disease to the CNS.

1.1 Definitions

1.1.1 Hematopoietic Stem Cell Transplantation (HSCT)

Refers to any source of stem cells, i.e., autologous, allogeneic, syngeneic, or umbilical cord blood.

1.1.2 Relapse

Tumor recurrence after a prior complete response.

1.1.3 Primary Refractory Disease

A tumor that does not achieve a complete remission after initial standard-dose chemotherapy.

1.1.4 Salvage Therapy

Treatment that is given after the cancer has not responded to other treatments.

1.1.5 Rescue Transplant

A method of replacing blood-forming stem cells that were destroyed by treatment with high doses of anticancer drugs or radiation therapy. The stem cells help the bone marrow recover and make healthy blood cells. A rescue transplant may allow more chemotherapy or radiation therapy to be given so that more cancer cells are killed. It is usually done using the patient's own stem cells that were saved before treatment. Also called stem cell rescue.

1.1.6 Tandem Transplants

A transplant technique where the preplanned intent for therapy involves sequential hematopoietic stem cell transplants.

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://dma.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

The Division of Medical Assistance (DMA) 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 DMA 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

- a. Medicaid and NCHC shall cover single autologous HSCT when it is determined to be medically necessary for:
 1. initial treatment of high-risk neuroblastoma;
 2. recurrent or refractory neuroblastoma;
 3. initial treatment of high-risk Ewing's sarcoma;
 4. recurrent or refractory Ewing's sarcoma; and
 5. metastatic retinoblastoma.
- b. Medicaid and NCHC shall cover planned tandem autologous hematopoietic stem-cell transplantation when it is determined to be medically necessary for high-risk, refractory, or relapsed neuroblastoma. Refer to **Section 1.0** for high-risk neuroblastoma.

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 HSCT for solid tumors of childhood for **ALL** of the following:

- a. Single or tandem autologous hematopoietic stem-cell transplantation as initial treatment of low- or intermediate-risk neuroblastoma, initial treatment of low- or intermediate-risk Ewing's sarcoma, and for other solid tumors of childhood such as:
 1. rhabdomyosarcoma;
 2. Wilms tumor;
 3. osteosarcoma; and
 4. retinoblastoma without metastasis.
- b. Tandem autologous hematopoietic stem-cell transplantation for the treatment of all other types of pediatric solid tumors except high-risk neuroblastoma, as noted above;
- c. Salvage allogeneic hematopoietic stem-cell transplantation for pediatric solid tumors that relapse after autologous transplant or fail to respond;
- d. Allogeneic (myeloablative or nonmyeloablative) hematopoietic stem-cell transplantation for treatment of pediatric solid tumors.

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 HSCT for solid tumors of childhood. The provider shall obtain prior approval before rendering HSCT for solid tumors of childhood.

If prior approval has been given for HSCT, DMA shall reimburse for the following transplant-related donor medical expenses: **procuring, harvesting, short-term storage and all associated laboratory costs.**

All applicable Medicaid and NCHC policies and procedures must be followed in addition to the ones listed in this procedure.

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 DMA 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 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, or 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 Provider(s) 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:
- All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements;
 - All DMA'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);

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
07/01/2005	Entire Policy	Medicaid policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	Medicaid: The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	Medicaid: The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	Medicaid: The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0 and 4.0	Medicaid: A note regarding EPSDT was added to these sections.
05/01/2007	Sections 2 through 4	Medicaid: EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
05/01/2007	Attachment A	Medicaid: Added the UB-04 as an accepted claim form
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	Medicaid: The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0 and 4.0	Medicaid: A note regarding EPSDT was added to these sections.
07/01/2010	Throughout	NCHC: 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.
03/01/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11A-15 under Session Law 2011-145 § 10.41.(b)
03/01/2012	Entire Policy	Policy updated to reflect current community standards and changing transplant protocols.
03/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.

Date	Section Revised	Change
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/01/2017	Attachment A, Section B	ICD-10 updated code revisions.
07/01/2018	Section 1.0	Added information on MYCN oncogene.
07/01/2018	Section 1.1	Added definitions for HSCT, relapse, refractory disease, salvage therapy, rescue therapy, and tandem transplants.
07/01/2018	Section 3.2.1	Added coverage for planned tandem autologous SCT for neuroblastoma. Added coverage for single autologous SCT for metastatic retinoblastoma.
07/01/2018	Section 3.2.4	Section removed as information is now out of date.
07/01/2018	Section 4.2.1	Added allogenic stem cell transplantation to non-coverage. Added HSCT for retinoblastoma without metastasis to non-coverage.
07/01/2018	Section 4.2.4	Section removed as information is now out of date.
07/01/2018	Section 5.3(b)(2)	Added “panel” after Hepatitis to reflect terminology in the State Plan. Added “indications for transplant” to the letter of medical necessity requirements.
07/01/2018	Section 7.1	Removed requirement that a statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices be retained. Removed statement that FDA approved procedures, products, and devices for implantation must be utilized.
07/01/2018	Attachment A, Section B	ICD-10 codes removed.
07/01/2018	Attachment A, Section C	CPT and HCPCS codes removed.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA'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)

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.

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.

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

Providers 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, Attachment 4.18-A, page 1, located at <https://dma.ncdhhs.gov/>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Providers shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://dma.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.