

**DRAFT**

**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.**

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**NC Medicaid  
Hematopoietic Stem-Cell ~~or Bone~~  
Marrow Transplantation for Acute  
Lymphoblastic Leukemia (ALL)**

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

**DRAFT**

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**Related Clinical Coverage Policies**

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

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**

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. Bone marrow stem cells may be obtained from the transplant recipient (i.e., autologous HSCT) or from a donor (i.e., allogeneic HSCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

Immunologic compatibility between infused stem cells and the recipient is not an issue in autologous HSCT. However, immunologic compatibility between donor and patient 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 HLA A, B, and DR loci on each arm of chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci.

### **Conventional Preparative Conditioning for HSCT**

The success of autologous HSCT is predicated on the ability of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the patient prior to undergoing bone marrow ablation. As a consequence, autologous HSCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HSCT are susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

The conventional (“classical”) practice of allogeneic HSCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that develops after engraftment of allogeneic stem cells within the patient’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease

without the use of pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allogeneic HSCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections.

### **Reduced-Intensity Conditioning for Allogeneic HSCT**

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in conventional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden, but also to minimize as much as possible associated treatment-related morbidity and non-relapse mortality (NRM) in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of NRM and relapse due to residual disease. RIC regimens can be viewed as a continuum in effects, from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. 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, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For the purposes of this Policy, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be non-myeloablative, as opposed to fully myeloablative (conventional) regimens.

Some patients for whom a conventional myeloablative allogeneic HSCT could be curative may be considered candidates for reduced-intensity conditioning (RIC) allogeneic HSCT. These include those patients whose age (typically older than 60 years) or co-morbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude the use of a standard myeloablative conditioning regimen.

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for non-Hodgkin’s lymphoma indicate autologous or allogeneic HSCT is appropriate for treatment of poor-risk patients with Lymphoblastic lymphoma (i.e. when disease is considered systemic).

The ideal allogeneic donors for HLA are identical siblings, matching at the HLA-a, B, and DR loci (6 of 6). Related donors mismatched at one locus are also considered suitable donors. A matched unrelated donor identified through the National Marrow donor Registry is typically the next option considered. Recently there has been interest in haploidentical donors, typically a parent or a child of a patient, where usually there is sharing of only 3 of the 6 major histocompatibility antigens. The majority of the recipients will have such a donor; however, the risk of graft-versus-host disease and overall morbidity of the procedure may be severe, and experience with the donors is not as extensive as that with matched donors.

## **Acute Lymphoblastic Leukemia (ALL)**

### **Childhood ALL**

ALL is the most common cancer diagnosed in children and represents almost 25% of cancers in children younger than 15 years. Complete remission of disease is now typically achieved with

pediatric chemotherapy regimens in approximately 95% of children with ALL, with up to 85% long-term survival rates. Survival rates have improved with the identification of effective drugs and combination chemotherapy through large, randomized trials, integration of presymptomatic central nervous system prophylaxis, and intensification and risk-based stratification of treatment.

ALL is a heterogeneous disease with different genetic alterations resulting in distinct biologic subtypes. Patients are stratified according to certain clinical and genetic risk factors that predict outcome, with risk-adapted therapy tailoring treatment based on the predicted risk of relapse. Two of the most important factors predictive of risk are patient age and white blood cell count (WBC) at diagnosis. Certain genetic characteristics of the leukemic cells strongly influence prognosis.

**Clinical and biologic factors predicting clinical outcome can be summarized as follows:**

Factor	Favorable	Unfavorable
Age at diagnosis	1-9 years	Less than 1 or greater than 9 years
Sex	Female	Male
WBC count	Less than 50,000/ $\mu$ L	Greater than 50,000/ $\mu$ L
Genotype	Hyperdiploidy (greater than 50 chromosomes) t(12;21) or TEL/AML 1 fusion	Hypodiploidy (less than 45 chromosomes) t(9;22) or BCR/ABL fusion t(4;11) or MLL/AF4 fusion
Immunophenotype	Common, preB	ProB, T-lineage

**Adult ALL**

ALL accounts for approximately 20% of acute leukemias in adults. Approximately 60%–80% of adults with ALL can be expected to achieve complete remission after induction chemotherapy; however, only 35%–40% can be expected to survive 2 years. Differences in the frequency of genetic abnormalities that characterize adult ALL versus childhood ALL, help to explain the outcome differences between the two groups. For example, the “good prognosis” genetic abnormalities like hyperdiploidy and t(12;21) are seen much less commonly in adult ALL, whereas they are some of the most common in childhood ALL. Conversely, “poor prognosis” genetic abnormalities like the Philadelphia chromosome t[9;22] are seen in 25%–30% of adult ALL but infrequently in childhood ALL. Other adverse prognostic factors in adult ALL include age greater than 35 years, poor performance status, male sex, and leukocytosis at presentation of greater than 30,000/ $\mu$ L (B-cell lineage) and greater than 100,000/ $\mu$ L (T-cell lineage).

**1.1 Definitions**

**1.1.1 Donor Lymphocyte Infusion (DLI)**

A type of therapy in which lymphocytes from the blood of a donor are given to a beneficiary who has already received a stem cell transplant from the same donor. The donor lymphocytes may kill remaining cancer cells.

None Apply.

## 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

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 Hematopoietic stem-cell ~~or bone marrow~~ transplantation for ALL when the beneficiary meets the following specific criteria:

##### Children

- a. Allogeneic or autologous stem cell transplantation may be considered medically necessary as a treatment of childhood ALL in first complete remission but at high risk of relapse. High risk of relapse following initial complete remission is indicated by the presence of at least **one** of the following:
  1. Poor response to initial therapy including poor response to prednisone prophase defined as an absolute blast count of 1,000/ $\mu$ L or greater, or
  2. Poor treatment response to induction therapy at 6 weeks with high risk having greater than or equal to 1% minimal residual disease measured by flow cytometry, or
  3. All children with T-cell phenotype, or
  4. Patients with either the t(9;22) or t(4;11) regardless of early response measures.
- b. Autologous or allogeneic stem cell transplantation support may be considered medically necessary as a treatment of childhood ALL in second or greater remission or refractory ALL;
- c. **Allogeneic HSCT is considered medically necessary to treat relapsing ALL after a prior autologous HSCT.**

##### Adults

- a. Autologous hematopoietic stem cell transplantation may be considered medically necessary as a treatment of adult ALL in first complete remission but at high risk of relapse. High risk of relapse following initial complete remission is indicated by the presence of at least one of the following:
  1. age greater than 35 years,

2. leukocytosis at presentation of greater than 30,000/ $\mu$ L (B-cell lineage) and greater than 100,000/ $\mu$ L (T-cell lineage),
  3. Extramedullary disease, particularly CNS,
  4. "Poor prognosis" genetic abnormalities like the Philadelphia chromosome t(9;22),
  5. Time to attain complete remission longer than 4 weeks.
- b. Allogeneic hematopoietic stem cell transplantation may be considered medically necessary as a treatment of adult ALL in first complete remission for any risk level.
  - c. Allogeneic hematopoietic stem cell transplantation may be considered medically necessary as a treatment of adult ALL in second or greater remission, or in patients with relapsed or refractory ALL.
  - d. Reduced-intensity conditioning allogeneic HSCT may be considered medically necessary as a treatment of ALL in patients who are in complete marrow and extramedullary first or second remission, and who, for medical reasons would be unable to tolerate a standard myeloablative conditioning regimen. These include patients whose age (typically older than 60 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude use of a standard myeloablative conditioning regimen.
  - e. High dose chemotherapy with allogeneic stem cell support may be considered medically necessary as a treatment in adults with Progenitor-B cell ALL.
  - f. Allogeneic HSCT is considered medically necessary to treat relapsing ALL after a prior autologous HSCT.

#### **Adult or Child**

- a. Donor lymphocyte infusion (DLI) (refer to Section 1.1) is considered medically necessary and, therefore, covered following allogeneic hematopoietic stem cell transplantation (HSCT) that is medically necessary for the treatment of ALL that has relapsed or is refractory, to prevent relapse in the setting of a high risk of relapse, or to convert an individual from mixed to full donor chimerism.

### **3.2.2 Policy Guidelines**

Acute lymphoblastic leukemia (ALL) is a heterogeneous disease with different genetic variations resulting in distinct biologic subtypes. Patients are stratified to risk-adapted therapy according to certain clinical and genetic risk factors that predict outcome. Therapy may include hematopoietic stem cell transplantation (HSCT). For individuals who have childhood ALL in first complete remission at high risk of relapse, subsequent remission, or refractory ALL who receive autologous or allogeneic HSCT, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. For children in high risk ALL in first complete remission (CR1) or relapsed ALL, studies suggest that HSCT is associated with fewer relapses but higher death rates due to treatment-related toxicity. However, for a subset of high-risk patients in second complete remission or beyond or with relapsed disease, HSCT is a treatment option. This conclusion is further supported by an evidence-based systematic review of the literature and position statement from

the American Society for Blood and Marrow Transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have adult ALL in first complete remission, subsequent remission, or refractory ALL who receive autologous or allogeneic HSCT, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Current evidence supports the use of autologous HSCT for adults with high-risk ALL in first complete remission, or myeloablative allogeneic HSCT (allo-HSCT) for adults with any risk level ALL, whose health status is sufficient to tolerate the procedure. Reduced-intensity conditioning (RIC) alloHSCT may be considered for patients who demonstrate complete marrow and extramedullary first or second remission and who could be expected to benefit from a myeloablative allo-HSCT, but for medical reasons would not tolerate a myeloablative conditioning regimen. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Allo-HSCT after failed autologous HSCT has been shown to be of clinical benefit in other hematologic malignancies and is potentially curative. In addition, clinical input has supported use of allogeneic HSCT to treat relapsing ALL after a failed prior autologous HSCT, particularly with RIC regimens, in adults or children. Thus, this indication may be considered medically necessary.

As noted in Section 1.0, there is no clear age cut-off that distinguishes adults from children with ALL.

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 beneficiaries receiving whole body radiotherapy, typically those receiving an allogeneic transplant (from donor to recipient), will require prolonged hospitalization.

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for non-Hodgkin's lymphoma indicate autologous or allogeneic HSCT is appropriate for treatment of poor risk patients with lymphoblastic lymphoma (i.e., when disease is considered to be systemic).

The ideal allogeneic donors are HLA-identical siblings, matched at the HLA-A, B, and DR loci (6 of 6). Related donors mismatched at one locus are also considered suitable donors. A matched, unrelated donor identified through the National Marrow Donor Registry is typically the next option considered. Recently, there has been interest in haploidentical donors, typically a parent or a child of the patient, where usually there is sharing of only 3 of the 6 major histocompatibility antigens. The majority of patients will have such a donor; however, the risk of graft-versus-host disease and overall morbidity of the procedure may be severe, and experience with these donors is not as extensive as that with matched donors.

### 3.2.3 Medicaid Additional Criteria Covered

None Apply.

### 3.2.4 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 Hematopoietic stem-cell ~~or bone marrow~~ transplantation for ALL ~~is not covered~~ in the following situations:

##### ~~Children~~

- a. ~~Allogeneic HSCT to treat relapsing ALL after a prior autologous HSCT;~~

##### Adults

- a. Autologous HSCT to treat adult ALL in second or greater remission or those with refractory disease. ~~and~~
- b. ~~Allogeneic HSCT to treat relapsing ALL after a prior autologous SCT.~~

##### Adult or Child

- a. when the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care.
- b. 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 Hematopoietic Stem Cell Transplantation for Acute Lymphoblastic Leukemia (ALL) ~~all transplants, including bone marrow transplant for ALL~~. The provider shall obtain prior approval before rendering Hematopoietic Stem Cell Transplantation for Acute Lymphoblastic Leukemia (ALL) ~~for all transplants, including bone marrow transplant for ALL~~.

If prior approval has been given for Hematopoietic Stem Cell Transplantation for Acute Lymphoblastic Leukemia (ALL) ~~stem cell transplants~~, actual donor transplant-related medical expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered.

If prior approval has been given for allogeneic HSCT for Acute Lymphoblastic Leukemia (ALL) and a donor lymphocyte infusion (DLI) is later indicated (refer to Section 3.2), separate prior approval shall not be required for the DLI 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 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).

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

### Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
7/1/10	Throughout	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.
1/1/12	Throughout	Policy updated to reflect current community standards and changing transplant protocols.
1/1/12	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11A-1 under Session Law 2011-145 § 10.41.(b)
3/12/12	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
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	Replaced and updated ICD-10 codes
03/15/2019	Table of Contents	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."
03/15/2019	All Sections and Attachments	Updated policy template language.
	<u>Throughout</u>	<u>Removed "or Bone Marrow" from title of policy.</u>
	<u>Section 1.1</u>	<u>Definition added for donor lymphocyte infusion (DLI).</u>
	<u>Section 3.2.1</u>	<u>Allogenic HSCT is considered medically necessary to treat relapsing ALL after a prior autologous HSCT for both children and adults. These criteria added to coverage. Added criteria regarding DLI coverage.</u>
	<u>Section 3.2.2</u>	<u>Policy Guidelines brought up to date for standards of care for treatment of adult and child ALL.</u>

	<u>Section 4.2.1</u>	<u>Allogeneic HSCT to treat relapsing ALL after a prior autologous HSCT removed from non-coverage for adult and child ALL.</u>
	<u>Section 5.1</u>	<u>Added text that if PA has been given for allogeneic HSCT and DLI is later indicated, separate PA is not required for the DLI procedure.</u>
	<u>Section 5.3</u>	<u>“Indications for transplant” added to letter of medical necessity requirements. Added “panel” to Hepatitis panel to reflect verbiage in the State Plan.</u>
	<u>Attachment A</u>	<u>Added the UB-04 as an accepted claims form. Removed all CPT, HCPCS, and ICD-10 codes.</u>

### 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.

ICD-10 Code(s)			
30230AZ	30233Y4	30243Y0	30253Y1
30230G0	30240AZ	30243Y4	30260G0
30230G4	30240G0	30250G0	30260G1
30230Y0	30240G4	30250G1	30260Y0
30230Y4	30240Y0	30250Y0	30260Y1
30233AZ	30240Y4	30250Y1	30263G0
30233G0	30243AZ	30253G0	30263G1
30233G4	30243G0	30253G1	30263Y0
30233Y0	30243G4	30253Y0	30263Y1

**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.

CPT Code(s)
38205
38206
38230
38232
38240
38241
38242

HCPCS Code(s)
S2150

**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.