

NC Medicaid Hematopoietic Stem Cell Transplantation Clinical Coverage Policy No: 11A-16 for Chronic Lymphocytic Leukemia (CLL) Amended Date: August 15, 2023 and Small Lymphocytic Lymphoma (SLL)	Medicaid
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To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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**Hematopoietic Stem Cell Transplantation Clinical Coverage Policy No: 11A-16
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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.

Hematopoietic stem cells may be obtained from the transplant recipient (autologous HSCT) or from a donor (allogeneic HSCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood 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). Cord blood is discussed in greater detail in the “Placental and Umbilical Cord Blood as a Source of Stem Cells” 11A-14.

Immunologic compatibility between infused hematopoietic 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 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 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.

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.

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 total 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 nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are neoplasms of hematopoietic origin characterized by the accumulation of lymphocytes with a mature, generally well-differentiated morphology. In CLL, these cells accumulate in blood, bone marrow, lymph nodes, and spleen, while in SLL they are generally confined to lymph nodes.

CLL and SLL share many common features and are often referred to as blood and tissue counterparts of each other, respectively. Both tend to present as asymptomatic enlargement of the lymph nodes, tend to be indolent in nature, but can undergo transformation to a more aggressive form of disease (e.g., Richter's transformation). The median age at diagnosis of CLL is approximately 72 years, but it may present in younger individuals, often as poor-risk disease with significantly reduced life expectancy.

Treatment regimens used for CLL are generally the same as those used for SLL, and outcomes of treatment are comparable for the two diseases. Both low- and intermediate-risk CLL and SLL demonstrate relatively good prognoses with median survivals of 6 to 10 years, while the median survival of high-risk CLL or SLL may be only 2 years (refer to Guidelines). Although typically responsive to initial therapy, CLL and SLL are rarely cured by conventional therapy, and nearly all patients ultimately die of their disease. This natural history prompted investigation of hematopoietic stem-cell transplantation as a possible curative regimen.

Highlights of changes in 2016 WHO classification

Entity/category	Change
CLL/SLL	<ul style="list-style-type: none"> • Cytopenias or disease-related symptoms are now insufficient to make a diagnosis of CLL with <math>5 \times 10^9/L</math> PB CLL cells. • Large/confluent and/or highly proliferative proliferation centers are adverse prognostic indicators. • Mutations of potential clinical relevance, such as <i>TP53</i>, <i>NOTCH1</i>, <i>SF3B1</i>, <i>ATM</i>, and <i>BIRC3</i>, have been recognized.

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.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
- b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

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

- a. **Medicaid**
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/>

3.0 When the Procedure, Product, or Service Is Covered

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

3.1 General Criteria Covered

Medicaid 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 Medicaid

Medicaid shall cover allogeneic HSCT for CLL and SLL using either a myeloablative or reduced-intensity pretransplant conditioning regimen to treat CLL or SLL in beneficiaries with markers of poor-risk disease (refer to Policy Guidelines in **Subsection 3.2.4**).

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 CLL 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 Medicaid Additional Criteria Covered

None Apply.

3.2.3 Policy Guidelines

Staging and Prognosis of CLL and SLL

Two scoring systems are used to determine stage and prognosis of patients with CLL or SLL. As outlined in **Table 1**, the Rai and Binet staging systems classify patients into 3 risk groups with different prognoses and are used to make therapeutic decisions.

Table 1. Rai and Binet Classification for CLL or SLL

Rai State	Risk	Description	Median Survival (yr)	Binet Stage	Description	Median Survival (yr)
0	Low	Lymphocytosis	greater than 10	A	3 or fewer lymphoid areas, normal hemoglobin and platelets	greater than 10

I	Intermediate	Lymphocytosis plus lymphadenopathy	7-9	B	3 or more lymphoid areas, normal hemoglobin and platelets	7
II	Intermediate	Lymphocytosis plus splenomegaly plus/minus lymphadenopathy	7-9			
III	High	Lymphocytosis plus anemia plus/minus lymphadenopathy or splenomegaly	1.5-5	C	Any number of lymphoid areas, anemia, thrombocytopenia	5
IV	High	Lymphocytosis plus thrombocytopenia plus/minus anemia, splenomegaly, or lymphadenopathy	1.5-5			

lymphocytosis = lymphocytes greater than 15 x 10⁹/L for 4 wks; anemia = hemoglobin less than 110 g/L; thrombocytopenia = platelets less than 100 x 10⁹/L

Along with the stage, there are other factors that help predict a person's outlook. These factors are not part of formal staging systems (at least at this time) but are often taken into account when looking at possible treatment options. Factors that tend to be linked with shorter survival time are called **adverse prognostic factors**. Those that predict longer survival are **favorable prognostic factors**.

Adverse prognostic factors	Favorable prognostic factors
<ul style="list-style-type: none"> • Diffuse pattern of bone marrow involvement (more widespread replacement of normal marrow by leukemia) • Advanced age • Deletions of parts of chromosomes 17 or 11 • Trisomy 12 in the CLL cells • High blood levels of certain substances, such as beta-2-microglobulin • Lymphocyte doubling time (the time it takes for the lymphocyte count to double) of less than 1 year • Increased fraction of prolymphocytes (an early form of the lymphocyte) in the blood • High proportion of CLL cells containing ZAP-70 (20% or more) or CD38 (30% or more) • CLL cells with unchanged (not mutated) gene for the immunoglobulin heavy chain variable region (IGHV) 	<ul style="list-style-type: none"> • Non-diffuse (nodular or interstitial) pattern of bone marrow involvement • Deletion of part of chromosome 13 (with no other chromosome abnormalities) • Low proportion of CLL cells containing ZAP-70 (less than 20%) or CD38 (less than 30%) • CLL cells with a mutated gene for IGHV

- CLL cells don't have the TP53 gene

Certain prognostic factors such as the presence or absence of ZAP-70, CD38, and a mutated gene for IGHV help divide cases of CLL into 2 groups, slow growing and fast growing. People with the slower growing kind of CLL tend to live longer and may be able to delay treatment longer as well.

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 a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

- Medicaid shall not cover the procedure, product, or service related to this policy when:
- the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
 - the beneficiary does not meet the criteria listed in **Section 3.0**;
 - the procedure, product, or service duplicates another provider's procedure, product, or service;
 - or 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 Medicaid

Medicaid shall not cover HSCT for CLL and SLL in the following situations:

- Allogeneic HSCT to treat CLL or SLL except as noted in **Subsection 3.2** of this policy;
- Autologous HSCT to treat CLL or SLL.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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 shall not require prior approval for Hematopoietic Stem Cell Transplantation for CLL and SLL.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

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 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 a Medicaid Beneficiary 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: March 1, 2012

Revision Information:

Date	Section Revised	Reason for Change
03/01/2012	Throughout	Initial Promulgation of New Service Coverage
03/01/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11A-16 under Session Law 2011-145 § 10.41.(b)
03/01/2012	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	ICD-10 update codes revised.
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.
10/01/2019	Throughout	Added "Transplantation" to title.
10/01/2019	Section 1.0	Added updates to the 2016 WHO classifications.
10/01/2019	Section 1.1	Definition added for donor lymphocyte infusion.
10/01/2019	Section 3.2.1	Criteria added for DLI coverage.
10/01/2019	Section 3.2.4	Added text discussing adverse and favorable prognostic factors.
10/01/2019	Section 5.1	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.
10/01/2019	Section 5.3	"Indications for transplant" added to letter of medical necessity requirements. Added "panel" to Hepatitis panel to reflect verbiage in the State Plan.
10/01/2019	Section 7.0	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.
10/01/2019	Attachment A	Added the UB-04 as an accepted claims form. Removed all CPT, HCPCS, and ICD-10 codes.
01/15/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your

**NC Medicaid
Hematopoietic Stem-Cell Transplantation for
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**Medicaid
Clinical Coverage Policy No: 11A-16
Amended Date: August 15, 2023**

		PHP.”
01/15/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
07/01/2021	Section 5.0	Prior approval requirement removed.
8/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 8/15/2023 with an effective date of 4/1/2023.

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:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

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:

<https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices>

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

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.