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1.0 Description of the Procedure, Product, or Service

1.1 Hematopoietic Stem-Cell Transplantation

Hematopoietic stem-cell transplantation (SCT) 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 (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 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 SCT. 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 leg of chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

1.2 Conventional Preparative Conditioning for Hematopoietic SCT

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 mediated by nonself immunologic effector cells that develop 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 rejections and GVHD, which also increases susceptibility of the patient to opportunistic infections.

1.3 Reduced Intensity Conditioning for Allogeneic SCT

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 traditional 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 nonrelapse 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 the Policy, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (traditional) regimens.

1.4 Non-Hodgkin's Lymphoma (NHL)

A heterogeneous group of lymphoproliferative malignancies, NHL usually originates in lymphoid tissue. Historically, uniform treatment of patients with NHL was hampered by the lack of a uniform classification system. In 1982, the Working Formulation (WF) was developed to unify different classification systems into one. The WF divided NHL into low-, intermediate-, and high-grade, with subgroups based on histologic cell type. Since our understanding of NHL has improved, the diagnosis has become more sophisticated and includes the incorporation of new immunophenotyping and genetic techniques. As a result, the WF has become outdated.

European and American pathologists proposed a new classification, the Revised European American Lymphoma (REAL) Classification, and an updated version of the REAL system, the new World Health Organization (WHO) classification. The WHO/REAL classification recognizes three (3) major categories of lymphoid malignancies based on morphology and cell lineage: B-cell neoplasms, T-cell/natural killer (NK)-cell neoplasms, and Hodgkin's lymphoma.

The most recent lymphoma classification is the 2008 WHO Classification:

Mature B-cell neoplasms

- a. Chronic lymphocytic leukemia/small lymphocytic lymphoma
- b. B-cell prolymphocytic leukemia
- c. Splenic marginal zone lymphoma
- d. Hairy cell leukemia
- e. Splenic lymphoma/leukemia, *unclassifiable*
 1. *Splenic diffuse red pulp small B-cell lymphoma**
 2. *Hairy cell leukemia-variant**
- f. Lymphoplasmacytic lymphoma

1. Waldenstrom macroglobulinemia
- g. Heavy chain diseases
 1. Alpha heavy chain disease
 2. Gamma heavy chain disease
 3. Mu heavy chain disease
- h. Plasma cell myeloma
- i. Solitary plasmacytoma of bone
- j. Extranasal plasmacytoma
- k. Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma)
- l. Nodal marginal zone B-cell lymphoma (MZL)
 1. *Pediatric type nodal MZL*
- m. Follicular lymphoma
 1. *Pediatric type follicular lymphoma*
- n. Primary cutaneous follicle center lymphoma
- o. Mantle cell lymphoma
- p. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified
 1. *T cell/histiocyte rich large B-cell lymphoma*
 2. *DLBCL associated with chronic inflammation*
 3. *Epstein-Barr virus (EBV)+ DLBCL of the elderly*
- q. Lymphomatoid granulomatosis
- r. Primary mediastinal (thymic) large B-cell lymphoma
- s. Intravascular large B-cell lymphoma
- t. Primary cutaneous DLBCL, leg type
- u. ALK [anaplastic lymphoma kinase] + large B-cell lymphoma
- v. Plasmablastic lymphoma
- w. Primary effusion lymphoma
- x. Large B-cell lymphoma arising in HHV8-associated multicentric Castleman disease
- y. Burkitt lymphoma
- z. B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma
- aa. *B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and classical Hodgkin's lymphoma*

*These represent provisional entities or provisional subtypes of other neoplasms.

Diseases shown in italics are newly included in the 2008 WHO classification.

Mature T-cell and NK-cell neoplasms

- a. T-cell prolymphocytic leukemia
- b. T-cell large granular lymphocytic leukemia
- c. Chronic lymphoproliferative disorder of NK-cells*
- d. Aggressive NK cell leukemia
- e. Systemic EBV [Epstein-Bar virus]+ T-cell lymphoproliferative disease of childhood (associated with chronic active EBV infection)
- f. Hydroa vacciniforme-like lymphoma
- g. Adult T-cell leukemia/ lymphoma
- h. Extranodal NK/T cell lymphoma, nasal type
- i. Enteropathy-associated T-cell lymphoma

- j. Hepatosplenic T-cell lymphoma
- k. Subcutaneous panniculitis-like T-cell lymphoma
- l. Mycosis fungoides
- m. Sézary syndrome
- n. Primary cutaneous CD30+ T-cell lymphoproliferative disorder
 - 1. *Lymphomatoid papulosis*
 - 2. *Primary cutaneous anaplastic large-cell lymphoma*
- o. Primary cutaneous aggressive epidermotropic CD8+ cytotoxic T-cell lymphoma*
- p. Primary cutaneous gamma-delta T-cell lymphoma
- q. Primary cutaneous small/medium CD4+ T-cell lymphoma*
- r. Peripheral T-cell lymphoma, not otherwise specified
- s. Angioimmunoblastic T-cell lymphoma
- t. Anaplastic large cell lymphoma (ALCL), ALK+
- u. Anaplastic *large cell lymphoma* (ALCL), ALK⁻*

*These represent provisional entities or provisional subtypes of other neoplasms.

Diseases shown in *italics* are newly included in the 2008 WHO classification.

In the United States, B-cell lymphomas represent 80%–85% of cases of NHL, and T-cell lymphomas represent 15%–20%. NK lymphomas are relatively rare.

In general, the NHL can be divided into two prognostic groups, indolent and aggressive. Indolent NHL has a relatively good prognosis, with a median survival of 10 years; however, it is not curable in advanced clinical stages. Early-stage indolent NHL (stage 1 or 2) may be effectively treated with radiation alone. Although indolent NHL is responsive to radiation and chemotherapy, a continuous rate of relapse is seen in advanced stages. These patients can often be re-treated, if their disease remains of the indolent type. Indolent NHL may transform into a more aggressive form, which is generally treated with regimens that are used for aggressive, recurrent NHL. Histologic transformation to higher grade lymphoma occurs in up to 70% of patients with low-grade lymphoma, and median survival with conventional chemotherapy is one year or less.

Follicular lymphoma (FL) is the most common indolent NHL (70%–80% of cases), and often the terms indolent lymphoma and FL are used synonymously. Also included in the indolent NHL are SLL/CLL, lymphoplasmatic lymphoma, marginal zone lymphomas, and cutaneous T-cell lymphoma.

Aggressive NHL has a shorter natural history; however, 30%–60% of these patients can be cured with intensive combination chemotherapy regimens. Aggressive lymphomas include DLBCL, MCL, PTCL, anaplastic large cell lymphoma, and Burkitt's lymphoma.

Oncologists developed a clinical tool to aid in predicting the prognosis of patients with aggressive NHL (specifically DLBCL), referred to as the International Prognostic Index (IPI). Prior to the development of IPI in 1993, prognosis was predominantly based on disease stage.

Based on the number of risk factors present and adjusted for patient age, the IPI defines 4 risk groups: low, low intermediate, high intermediate and high risk, based on 5 significant risk factors prognostic of overall survival (OS):

1. Age older than 60 years
2. Elevated serum lactate dehydrogenase (LDH) level

3. Ann Arbor stage III or IV disease
4. Eastern Cooperative Oncology Group (ECOG) performance status of 2, 3, or 4.
5. Involvement of more than one extranodal site

Risk groups are stratified according to the number of adverse factors as follows: 0 or 1 is low risk, 2 is low intermediate, 3 is high intermediate, and 4 or 5 are high risk.

Patients with two or more risk factors have a less than 50% chance of relapse-free survival and overall survival (OS) at five years. Age-adjusted (aaIPI) and stage-adjusted modifications of this IPI are used for younger patients with localized disease.

Adverse risk factors for age-adjusted IPI include stage III or IV disease, elevated LDH and ECOG performance status greater than 2, and can be calculated as follows: 0 is low risk, 1 is low intermediate, 2 is high intermediate, and 3 is high risk.

With the success of the IPI, a separate prognostic index was developed for FL, which has multiple independent risk factors for relapse after a first complete remission. The proposed and validated Follicular Lymphoma International Prognostic Index (FLIPI) contains five adverse prognostic factors:

1. Age older than 60 years
2. Ann Arbor stage III-IV
3. Hemoglobin level less than 12.0 g/dL
4. More than four lymph node areas involved
5. Elevated serum lactate dehydrogenase (LDH) level

These five factors are used to stratify patients into 3 categories of risk: low [0-1 risk factor], intermediate [2 risk factors], or poor [more than 3 risk factors].

a. Mantle Cell Lymphoma (MCL)

Mantle cell lymphoma (MCL) comprises approximately 6%–8% of NHL, and has been recognized within the past 15 years as a unique lymphoma subtype with a particularly aggressive course. MCL is characterized by a chromosomal translocation t(11;14), and the term mantle cell lymphoma was proposed in 1992 by Banks et al. The number of therapeutic trials are not as numerous for MCL as for other NHL as it was not widely recognized until the REAL classification. MCL shows a strong predilection for elderly men, and the majority of cases (70%) present with disseminated [stage 4] disease and extranodal involvement is common. Localized MCL is quite rare. MCL has a median survival of approximately two – four years, and although most patients achieve remission with first-line therapy, relapse inevitably occurs, often within 12–18 months. MCL is rarely, if ever, cured with conventional therapy, and no standardized therapeutic approach to MCL is used.

There had been no generally established prognostic index for patients with MCL. Application of the IPI or FLIPI system to patients with MCL showed serious limitations, which included no separation of some important risk groups. In addition, some of the individual IPI and FLIPI risk factors, including number of extranodal sites and number of involved nodal areas showed no prognostic relevance, and

hemoglobin showed no independent prognostic relevance in patients with MCL. Therefore, a new prognostic index for patients with MCL was developed, and should prove useful in comparing clinical trial results for MCL.

1. MCL international prognostic index (MIPI):
 - A. Age
 - B. ECOG performance status
 - C. Serum LDH (calculated as a ratio of LDH to a laboratory's upper limit of normal)
 - D. White blood cell count (WBC)
 - i. Zero points each are assigned for age younger than 50 years, ECOG performance 0–1, LDH ratio less than 0.67, WBC less than 6,700
 - ii. One point each for age 50–59 years, LDH ratio 0.67–0.99, WBC 6,700–9,999.
 - iii. Two points each for age 60–69 years, ECOG 2–4, LDH ratio 1.00–1.49, WBC 10,000–14,999
 - iv. Three points each for age 70 years or older, LDH ratio 1.5 or greater, WBC 15,000 or more
2. MIPI allows separation of three groups with significantly different prognoses:
 - A. 0 – 3 points=low risk, 44% of patients, median OS not reached and a five-year OS rate of 60%
 - B. 4 - 5 points=intermediate risk, 35% of patients, median OS 51 months
 - C. 6 - 11 points=high risk, 21% of patients, median OS 29 months

b. Peripheral T-Cell Lymphoma (PTCL)

The majority of peripheral T-cell lymphomas are aggressive and fall into the category of PTCL, unspecified (PTCL-u) or not otherwise specified (PTCL-NOS), angioimmunoblastic or anaplastic large cell which, combined make up approximately 60–70% of T-cell lymphomas. PTCLs are less responsive to standard chemotherapy than DLBCLs and carry a worse prognosis than aggressive B-cell counterparts. Survival rates at 5 years with standard chemotherapy regimens range from 20-35%. The poor results with conventional chemotherapy have prompted exploration of the role of HSCT as therapy.

1.5 Staging

The Ann Arbor staging classification is commonly used for the staging of lymphomas and is the scheme defined in the American Joint Committee on Cancer (AJCC) Manual for Staging Cancer. Originally developed for Hodgkin's disease, this staging scheme was later expanded to include non-Hodgkin's lymphoma.

Staging of Lymphoma: Ann Arbor Classification:

- a. Stage I: Involvement of a single lymph node region (I) or of a single extralymphatic organ or site (IE)
- b. Stage II: Involvement of 2 or more lymph node regions on the same side of the diaphragm (II) or localized involvement of extralymphatic organ or site and of one or more lymph node regions on the same side of the diaphragm (IIE).
- c. Stage III: Involvement of lymph node regions on both sides of the diaphragm (III) which may also be accompanied by localized involvement of extralymphatic organ or site (IIIE) or by involvement of the spleen (IIIS) or both (IIISE)
- d. Stage IV: Diffuse or disseminated involvement of one or more extralymphatic organs or tissues with or without associated lymph node enlargement.

2.0 Eligible Recipients

2.1 General Provisions

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

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- a. that is unsafe, ineffective, or experimental/investigational.

- b. 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/or 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 will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

3.0 When the Procedure, Product, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

3.1 General Criteria

Medicaid covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

N.C. Medicaid covers HSCT for non-Hodgkin's lymphoma in the following situations:

- a. For patients with non-Hodgkin's lymphoma (NHL) B-cell subtypes considered aggressive (except mantle cell lymphoma), either allogeneic hematopoietic stem cell transplantation (HSCT) using a myeloablative conditioning regimen or autologous HSCT may be considered medically necessary:
 1. as salvage therapy for patients who do not achieve a complete remission (CR) after first-line treatment (induction) with a full course of standard-dose chemotherapy;
 2. to achieve or consolidate a CR for those in a chemosensitive first or subsequent relapse; or
 3. to consolidate a first CR in patients with diffuse large B-cell lymphoma, with an age adjusted International Prognostic Index score that predicts a high- or high-intermediate risk of relapse.
- b. For patients with mantle cell lymphoma:
 1. Autologous HSCT may be considered medically necessary to consolidate a first remission.
 2. Allogeneic HSCT, myeloablative or reduced-intensity conditioning, may be considered medically necessary as salvage therapy.
- c. For patients with NHL B-cell subtypes considered indolent, either allogeneic HSCT using a myeloablative conditioning regimen or autologous HSCT may be considered medically necessary:
 1. as salvage therapy for patients who do not achieve CR after first-line treatment (induction) with a full course of standard-dose chemotherapy; or
 2. to achieve or consolidate CR for those in a first or subsequent chemosensitive relapse, whether or not their lymphoma has undergone transformation to a higher grade.
- d. Reduced-intensity conditioning allogeneic HSCT may be considered medically necessary as a treatment of NHL in patients who meet criteria for an allogeneic HSCT but who do not qualify for a myeloablative allogeneic HSCT (see Policy Guidelines).
- e. For patients with peripheral T-cell lymphoma:
 1. Autologous HSCT may be considered medically necessary to consolidate a first complete remission in high-risk peripheral T-cell lymphoma. (see Policy Guidelines)
 2. Autologous or allogeneic HSCT (myeloablative or reduced-intensity conditioning) may be considered medically necessary as salvage therapy.

3.3 Policy Guidelines

- a. Reduced-intensity conditioning (RIC) would be considered an option in recipients who meet criteria for an allogeneic hematopoietic stem-cell transplant (HSCT) but whose age (typically older than 55 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy) preclude use of a standard conditioning regimen.

- b. In recipients who qualify for a myeloablative allogeneic hematopoietic SCT on the basis of overall health and disease status, allogeneic HSCT using either myeloablative or RIC may be considered. However, a myeloablative conditioning regimen with allogeneic HSCT may benefit younger recipients with good performance status and minimal comorbidities more than allogeneic HSCT with RIC.
- c. The term **salvage therapy** describes chemotherapy given to recipients who have either: 1) failed to achieve complete remission after initial treatment for newly diagnosed lymphoma; or 2) relapsed after an initial complete remission.
- d. A **chemosensitive relapse** is defined as relapsed non-Hodgkin's's lymphoma that does not progress during or immediately after standard-dose induction chemotherapy (i.e., achieves stable disease or a partial response.)
- e. **Transformation** describes a lymphoma whose histologic pattern has evolved to a higher grade lymphoma. Transformed lymphomas typically evolve from a nodular pattern to a diffuse pattern.
- f. **Tandem transplants** usually are defined as the planned administration of 2 successive cycles of high-dose myeloablative chemotherapy, each followed by infusion of autologous hematopoietic stem cells, whether or not there is evidence of persistent disease following the first treatment cycle. Sometimes, the second cycle may use non-myeloablative immunosuppressive conditioning followed by infusion of allogeneic stem cells.

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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria

Medicaid does not cover hematopoietic stem-cell or bone marrow transplantation for non-Hodgkin's lymphoma in the following situations

- a. For recipients with mantle cell lymphoma:
 1. Autologous HSCT is considered investigational as salvage therapy.
 2. Allogeneic HSCT is considered investigational to consolidate a first remission.
- b. Either autologous HSCT or allogeneic HSCT is considered investigational:
 1. as initial therapy (i.e., without a full course of standard-dose induction chemotherapy) for any NHL;
 2. to consolidate a first complete remission (CR) for patients with diffuse large B-cell lymphoma and an International Prognostic Index score that predicts a low- or low-intermediate risk of relapse;
 3. to consolidate a first complete remission (CR) for those with indolent NHL B-cell subtypes.
- c. Tandem transplants are considered investigational to treat patients with any stage, grade, or subtype of NHL.
- d. For recipients with peripheral T-cell lymphoma, allogeneic HSCT is considered investigational to consolidate a first remission

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

5.1 Prior Approval

Prior approval is required for hematopoietic stem-cell transplant for non-Hodgkin's lymphoma.

If prior approval has been given for stem cell transplant, actual donor expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered.

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

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

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.
3/1/12	Entire Policy	Policy updated to reflect current community standards and changing transplant protocols

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)	Description
38205	Blood derived Hemopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood derived Hemopoietic progenitor cell harvesting for transplantation, per collection; Autologous
38230	Bone Marrow harvesting for transplantation
38240	Bone marrow or peripheral stem cell transplantation; allogeneic
38241	Bone marrow or peripheral stem cell transplantation; Autologous
38242	Allogeneic donor lymphocyte infusions

ICD-9 Procedure Codes	Description
41.00	Bone marrow transplant
41.01	Autologous bone marrow transplant
41.03	Allogeneic bone marrow transplant
41.04	Autologous (hematopoietic) stem cell transplant
41.05	Allogeneic (hematopoietic) stem cell transplant

HCPCS Code(s)	Description
S2150	Bone Marrow or blood derived stem cell (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications including pheresis and cell preparation, /storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical/surgical; and the number of days of pre and post transplant care in the global definition.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payments are not required for hematopoietic stem-cell transplant for non-Hodgkin's lymphoma.

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

Medicaid reimburses only for the actual donor's expenses. Medicaid does not reimburse for unsuccessful donor searches.