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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. Bone-marrow stem cells may be obtained from the transplant recipient (i.e., autologous SCT) or from a donor (i.e., allogeneic SCT). 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 SCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic SCT. 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.

1.2 Conventional Preparative Conditioning for Hematopoietic SCT

Conventional preparative conditioning for hematopoietic SCT involves administration of myelotoxic agents (e.g., cyclophosphamide, busulfan) with or without total-body irradiation at doses sufficient to cause bone marrow failure. The beneficial treatment effect in this procedure results from chemotherapeutic eradication of malignant cells with an associated immune-mediated graft-versus-malignancy effect. While such treatment may eliminate the malignant cells, patients are as likely to die from opportunistic infections, graft-versus-host disease (GVHD), and/or organ failure as from the underlying malignancy.

Autologous SCT necessitates myeloablative chemotherapy to eradicate cancerous cells from the blood and bone marrow, thus permitting subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic progenitor cells. As a consequence, autologous SCT is typically performed as consolidation therapy when the patient's disease is in complete remission. Patients who undergo autologous SCT are susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

1.3 Reduced Intensity Conditioning for Allogeneic SCT

Reduced-intensity conditioning (RIC) for allogeneic SCT refers to chemotherapy regimens that seek to reduce adverse effects secondary to bone marrow toxicity, while retaining the beneficial graft-versus-malignancy effect of allogeneic transplantation. These regimens do not initially eradicate the patient's hematopoietic ability, allowing relatively prompt hematopoietic recovery (e.g., 28 days or less) even without a transplant. Patients who undergo RIC with allogeneic SCT 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. A number of different cytotoxic regimens, with or without radiotherapy, may be used for RIC allotransplantation. They represent a continuum in their effects, from nearly total myeloablation, to minimal myeloablation with lymphoablation.

1.4 Non-Hodgkin 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 lymphoma.

Within the B-cell and T-cell categories, two subdivisions are recognized: precursor neoplasms, which correspond to the earliest stages of differentiation, and more mature differentiated neoplasms.

1.5 Updated REAL/WHO classification

- a. B-Cell Neoplasms
 1. Precursor B-cell neoplasm: precursor B-acute lymphoblastic leukemia/lymphoblastic lymphoma (LBL).
 2. Peripheral B-cell neoplasms
 - (a) B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma
 - (b) B-cell prolymphocytic leukemia
 - (c) Lymphoplasmacytic lymphoma/immunocytoma
 - (d) Mantle cell lymphoma (MCL)
 - (e) Follicular lymphoma
 - (f) Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphatic tissue (MALT) type
 - (g) Nodal marginal zone B-cell lymphoma (+/- monocytoid B-cells)
 - (h) Splenic marginal zone lymphoma (+/- villous lymphocytes)
 - (i) Hairy-cell leukemia

- (j) Plasmacytoma/plasma cell myeloma
 - (k) Diffuse large B-cell lymphoma
 - (l) Burkitt lymphoma
- b. T-Cell and Putative NK-Cell Neoplasms
- 1. Precursor T-cell neoplasm: precursor T-acute lymphoblastic leukemia/LBL
 - 2. Peripheral T-cell (PTCL) and NK-cell neoplasms
 - (a) T-cell chronic lymphocytic leukemia/prolymphocytic leukemia
 - (b) T-cell granular lymphocytic leukemia
 - (c) Mycosis fungoides/Sézary syndrome
 - (d) Peripheral T-cell lymphoma, not otherwise characterized
 - (e) Hepatosplenic gamma/delta T-cell lymphoma
 - (f) Subcutaneous panniculitis-like T-cell lymphoma
 - (g) Angioimmunoblastic T-cell lymphoma
 - (h) Extranodal T-/NK-cell lymphoma, nasal type
 - (i) Enteropathy-type intestinal T-cell lymphoma
 - (j) Adult T-cell lymphoma/leukemia (human T-lymphotrophic virus [HTLV] 1+)
 - (k) Anaplastic large cell lymphoma, primary systemic type
 - (l) Anaplastic large cell lymphoma, primary cutaneous type
 - (m) Aggressive NK-cell leukemia

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.

The International Lymphoma Classification Project identified the most common NHL subtypes as follows: diffuse large B-cell lymphoma (DLBCL) 31%, follicular lymphoma (FL) 22%, small lymphocytic lymphoma/ chronic lymphocytic leukemia (SLL/CLL) 6%, mantle cell lymphoma (MCL) 6%, peripheral T-cell lymphoma (PTCL) 6%, and marginal zone B-cell lymphoma/mucosa-associated lymphoid tissue (MALT) lymphoma 5%. All other subtypes each represent less than 2% of cases of NHL.

Several subtypes of NHL have emerged with the REAL/WHO classification with unique clinical and biologic features, and they will be addressed separately throughout the policy, when necessary (specifically MCL and PTCL).

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 one (1) or two (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 (1) year or less. 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, lymphoplasmacytoid 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 four (4) risk groups: low, low intermediate, high intermediate and high risk, based on five (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 two (2), three (3), or four (4)
5. Involvement of more than one (1) extranodal site

Risk groups are stratified according to the number of adverse factors as follows: zero (0) or one (1) is low risk, two (2) is low intermediate, three (3) is high intermediate, and four (4) or five (5) are high risk.

Patients with two (2) or more risk factors have a less than 50% chance of relapse-free survival and overall survival (OS) at five (5) 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 >2 , and can be calculated as follows: zero (0) is low risk, one (1) is low intermediate, two (2) is high intermediate, and three (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 (5) 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 (4) lymph node areas involved
5. Elevated serum lactate dehydrogenase (LDH) level

These five (5) factors are used to stratify patients into 3 categories of risk: low [zero (0)-one (1) risk factor], intermediate [two (2) risk factors], or poor [more than three (3) risk factors].

c. 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 four (4)] disease and extranodal involvement is common. Localized MCL is quite rare. MCL has a median survival of approximately two (2)–four (4) 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 (0) 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 (1) point each for age 50–59 years, LDH ratio 0.67–0.99, WBC 6,700–9,999.
 - (iii) Two (2) points each for age 60–69 years, ECOG 2–4, LDH ratio 1.00–1.49, WBC 10,000–14,999

- (iv) Three (3) 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 (3) groups with significantly different prognoses:
 - (a) zero (0)–three (3) points=low risk, 44% of patients, median OS not reached and a five (5)-year OS rate of 60%
 - (b) four (4)–five (5) points=intermediate risk, 35% of patients, median OS 51 months
 - (c) six (6)–11 points=high risk, 21% of patients, median OS 29 months
- d. Peripheral T-Cell Lymphoma (PTCL)

Immature T-cell lymphomas are generally treated on leukemia protocols, whereas mature (peripheral) T-cell lymphomas are usually treated with chemotherapy regimens similar to those used in DLBCL.

PTCLs are less responsive to standard chemotherapy than DLBCLs and therefore carry a worse prognosis. The poor results with conventional chemotherapy have prompted exploration of the role of HDC/SCT as first-line consolidation therapy.

1.6 Staging

The Ann Arbor staging classification is commonly used for the staging of lymphomas and is the scheme defined in the 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.

1.7 Medical Term Definitions

- a. Ablation: the removal of tissue or an abnormal growth, usually by cutting; may also refer to a very high dose of treatment that is calculated to kill a tumor.
- b. Allogeneic: genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism
- c. Autologous: derived from the same organism, i.e., self donation.

- d. Hematopoietic: pertaining to or effecting the formation of blood cells.
- e. Malignant: cancerous, not benign; describes a tumor that invades and destroys the tissues in which it originates and can spread to other sites in the body via the bloodstream and lymphatic system. If untreated, these tumors cause progressive deterioration and death.
- f. Neoplasm: new and abnormal growth, specifically growth of tissue in which the growth is uncontrolled and progressive. May be benign or cancerous.
- g. Opportunistic: a microorganism that does not usually cause disease but that, under certain circumstances such as impaired immune system due to other diseases or drug treatment becomes pathogenic.
- h. Placenta: Temporary organ formed from both fetal and maternal tissues that provides nutrients and oxygen to the developing fetus, carries away fetal metabolic wastes, and produces the hormones of pregnancy.
- i. Stem cells: immature generic blood cells that will mature into the various types of blood cells in the body.
- j. Umbilical cord: a flexible structure through which the umbilical arteries and vein pass and which connects the fetus to the placenta.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC 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; **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

Hematopoietic stem-cell transplantation for Non Hodgkin's Lymphomas is covered under the NC Health Choice Program when it is determined to be medically necessary because the following criteria are met:

- a. Allogeneic stem-cell transplant (SCT) using myeloablative conditioning regimen or autologous stemcell transplant may be considered medically necessary in recipients with non-Hodgkin's lymphoma (NHL) subtypes that are classed as aggressive in any of the following circumstances:
 1. As salvage therapy for recipients who do not achieve a complete remission after first-line treatment (induction) with a full course of standard-dose chemotherapy;
 2. To consolidate a first complete remission for recipients with diffuse large B-cell lymphoma with an age-adjusted International Prognostic Index (IPI) score that predicts a high- or high-intermediate risk of relapse; **OR**
 3. To achieve or consolidate complete remission for those in a chemosensitive first or subsequent relapse.
- b. Allogeneic stem-cell transplant using myeloablative conditioning regimen or autologous stem-cell transplant may be considered medically necessary in recipients with Non-Hodgkin's lymphoma subtypes who are classified as indolent in any of the following circumstances:
 1. As salvage therapy for recipients who do not achieve a complete remission after first-line treatment (induction) with a full course of standard-dose chemotherapy; **OR**
 2. To achieve or consolidate complete remission for those in first or subsequent chemosensitive relapse, whether or not their lymphoma has undergone transformation to a higher grade.
- c. Autologous stem-cell may be considered medically necessary in recipients with mantle cell lymphoma to consolidate a first remission.
- d. Reduced-intensity conditioning allogeneic stem-cell transplantation may be considered medically necessary as a treatment of non-Hodgkin's lymphoma in recipients who meet the criteria above for an allogeneic stem-cell transplant but who do not qualify for a myeloablative allogeneic stem-cell transplant.

3.3 Policy Guidelines

- a. While some high dose chemotherapy (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 recipients receiving whole body radiotherapy, typically those receiving an allogeneic transplant (from donor to recipient), will require prolonged hospitalization.
- b. Reduced-intensity conditioning (RIC) would be considered an option in recipients who meet criteria for an allogeneic stem-cell transplant (SCT) but whose comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy) preclude use of a standard conditioning regimen.
- c. In recipients who qualify for a myeloablative allogeneic hematopoietic SCT on the basis of overall health and disease status, allogeneic SCT using either myeloablative or RIC may be considered. However, a myeloablative conditioning regimen with allogeneic SCT may benefit younger recipients with good performance status and minimal comorbidities more than allogeneic SCT with RIC.

- d. Few NHL recipients are considered eligible for allotransplant relatively soon after a failed autotransplant. Thus, it is unlikely that prospective trials will ever be conducted to rigorously compare outcomes of this strategy with alternatives. Nevertheless, retrospective studies report long-term disease-free survival for a minority of recipients treated this way. Note that a second transplant (autologous or allogeneic) may be considered to manage relapsed NHL, if the initial autotransplant was followed by a long disease-free interval.
- e. Chemosensitive relapse is defined as relapsed Non-Hodgkin's Lymphoma that does not progress during or immediately after standard-dose induction chemotherapy and achieves stable disease or a partial response.
- f. 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.
- g. 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.
- h. Transformation: a lymphoma whose histologic pattern has evolved to a higher grade lymphoma. Transformed lymphomas typically evolve from a nodular pattern to a diffuse pattern.

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

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 or investigational.

4.2 Specific Criteria

Hematopoietic Stem-Cell Transplant for Non Hodgkin's Lymphomas is not covered in the following situations:

- a. Either autologous stem-cell transplant or allogeneic stem-cell transplant is considered investigational in the following:
 - 1. As initial therapy without a full course of standard-dose induction chemotherapy for all types of Non-Hodgkin's Lymphoma;
 - 2. To consolidate a first complete remission for recipients with diffuse large B-cell lymphoma and an International Prognostic Index (IPI) score that predicts a low or low-intermediate risk of relapse;

3. To consolidate a first complete remission for those with indolent Non-Hodgkin's Lymphoma subtypes; and
 4. For peripheral T-cell lymphoma (PTCL) at any stage of disease.
- b. Tandem transplants with any stage, grade, or sub-type of Non-Hodgkin's Lymphoma are considered investigational.
 - c. Allogeneic stem-cell transplant is considered investigational when Non-Hodgkin's Lymphoma progresses or relapses soon after a prior course of high-dose chemotherapy with autologous stem-cell transplant. (Note: This policy statement is based on a strict evidence-based analysis on outcomes of allotransplants after a failed autotransplant.)

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for hematopoietic stem-cell transplant for Non Hodgkin's Lymphomas.

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 NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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

7.1 Compliance

Providers must 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: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

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

C. Procedure Code(s)

CPT Codes				
38205	38206	38230	38240	38241
38242				

HCPCS Code
S2150

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-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.