

# MEDICAL POLICY

<p><b>SUBJECT: ALLOGENEIC STEM CELL TRANSPLANTATION</b></p> <p><b>POLICY NUMBER: 7.02.02</b></p> <p><b>CATEGORY: Transplants</b></p>	<p><b>EFFECTIVE DATE: 11/19/99</b></p> <p><b>REVISED DATE: 01/18/01, 03/21/02, 06/19/03, 06/17/04, 05/18/05, 03/16/06, 05/17/07, 07/17/08, 10/29/09, 10/28/10, 12/15/11, 10/18/12, 10/17/13</b></p> <p><b>PAGE: 1 OF: 13</b></p>
<ul style="list-style-type: none"> <li><i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i></li> <li><i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i></li> <li><i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i></li> </ul>	

## **POLICY STATEMENT:**

Based upon our criteria and review of the peer-reviewed literature, high-dose chemotherapy with allogeneic stem cell support has been medically proven to be effective and therefore **medically appropriate** for carefully selected candidates.

Reduced-intensity conditioning (RIC) regimens have been proposed as an alternative to traditional myeloablative conditioning regimens. RIC regimens are being commonly used in older patients as well as in disorders in which traditional myeloablative conditioning regimens are associated with high rates of non-relapse mortality. Hodgkin disease, myeloma, and low-grade lymphoid malignancies have been the diseases most impacted by RIC regimens.

The following is a listing of coverage criteria for different medical conditions.

<b>I. <u>Leukemias:</u></b>	
<b>Medically appropriate indications:</b>	<b>Investigational indications:</b>
<p><b><u>Adult and Pediatric AML:</u></b></p> <ul style="list-style-type: none"> <li>First remission in patients with cytogenetic intermediate or poor-risk disease or other factors that predict poor outcome (please refer to description section of this policy); or</li> <li>Primary refractory or relapsed disease or disease in second or greater remission; or</li> <li>Patients who have relapsed following a prior autologous HSCT and are medically able to tolerate the procedure</li> </ul> <p><b><u>Adult ALL:</u></b></p> <ul style="list-style-type: none"> <li>First complete remission for any risk level; or</li> <li>Primary refractory or relapsed disease or disease in second or greater remission.</li> </ul> <p><b><u>Pediatric ALL:</u></b></p> <ul style="list-style-type: none"> <li>First complete remission but at high risk of relapse (e.g., including but not limited to: age less than 1 year or greater than 9 years at presentation, WBC greater than or equal to 50,000/uL, hypodiploidy (less than 45 chromosomes) t(9:22) or Pro-B, T lineage; or</li> <li>Second or greater remission or refractory disease.</li> </ul> <p><b><u>Chronic myelogenous leukemia (CML)</u></b></p> <ul style="list-style-type: none"> <li>Patients with no hematologic remission after 3 months of imatinib therapy; or</li> <li>Patients with no cytogenetic response or cytogenetic relapse at 6, 12, or 18 months after achieving initial</li> </ul>	<p><b><u>Adult ALL:</u></b></p> <p>To treat relapsing ALL after a prior autologous HSCT</p> <p><b><u>Pediatric ALL:</u></b></p> <ul style="list-style-type: none"> <li>Ultra-high risk patients in first remission</li> <li>Relapsed after prior autologous SCT</li> </ul> <p><b><u>Chronic lymphocytic leukemia (CLL)</u></b> with the exception of the small subset of patients with progressive disease refractory to conventional treatments described in the list of medically appropriate indications.</p>

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<p>hematologic response after 3 months of imatinib therapy; or</p> <ul style="list-style-type: none"> <li>• Patients on imatinib therapy who progress to accelerated or blast phase CML.</li> <li>• Patients in the first chronic phase with T315I mutations not sensitive to any tyrosine kinase inhibitors (TKIs)</li> </ul> <p><b><u>Chronic lymphocytic leukemia (CLL)</u></b> in previously treated patients with non response or relapse within 12-24 months:</p> <ul style="list-style-type: none"> <li>• After purine analogues; or</li> <li>• After having achieved a response with intensive therapy; or</li> <li>• With high risk cytogenetic abnormalities (e.g., del (17p) and del(11q))</li> </ul>	
<b>II. <u>Lymphomas:</u></b>	
<b><u>Hodgkin Lymphomas:</u></b>	
<b>Medically appropriate indications:</b> <ul style="list-style-type: none"> <li>• Primary refractory or relapsing after completion of initial course of chemotherapy.</li> <li>• Salvage after failed autologous transplant greater than 6 months</li> </ul>	<b>Investigational indications:</b> <ul style="list-style-type: none"> <li>• Initial therapy for all HL.</li> </ul>
<b><u>Non Hodgkin Lymphoma:</u></b>	
Non Hodgkin Lymphoma (NHL) can be classified as either indolent (low grade) or aggressive (intermediate or high grade).	
<b>Medically appropriate indications:</b> <b><u>Aggressive</u></b> <ul style="list-style-type: none"> <li>• Initial therapy for very high risk Burkitt or Burkitt-like Non Hodgkin Lymphoma.</li> <li>• To consolidate a first complete response in patients with diffuse large B-cell lymphoma but at high or high-intermediate risk of relapse as predicted by the age-adjusted international prognostic index (IPI);</li> <li>• To achieve or consolidate a complete response in a chemosensitive first or second relapse;</li> <li>• As salvage therapy for patients who do not achieve a complete response after full first-line induction chemotherapy;</li> </ul> <b><u>Indolent</u></b> <ul style="list-style-type: none"> <li>• As salvage therapy for patients who do not achieve complete response after a full dose of first-line induction chemotherapy;</li> <li>• To achieve or consolidate complete response for those in a first or subsequent chemosensitive relapse, whether or not their lymphoma has undergone transformation to a higher grade.</li> </ul> <b><u>Mantle Cell Lymphoma</u></b> <ul style="list-style-type: none"> <li>• As salvage therapy</li> </ul> <b><u>Peripheral T-cell Lymphoma</u></b> <ul style="list-style-type: none"> <li>• As salvage therapy</li> </ul>	<b>Investigational indications:</b> <ul style="list-style-type: none"> <li>• Initial therapy for all NHL except Burkitt type.</li> <li>• To consolidate a first complete response for patients with Diffuse Large B-cell lymphoma with a low or low-intermediate risk of relapse as predicted by the IPI</li> <li>• To consolidate a first complete response for indolent NHL subtypes</li> <li>• To treat NHL that progresses or relapses within 6 months after a prior course of high-dose chemotherapy with autologous SCT</li> <li>• Tandem transplants</li> <li>• To consolidate a first remission in Mantle Cell lymphoma</li> <li>• To consolidate a first remission in Peripheral T-Cell lymphoma</li> </ul>

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Examples of lymphomas as described by the World Health Organization (WHO) and the Revised European-American Classification of Lymphoid Neoplasms (REAL). This list is not all-inclusive. \* denotes indolent types of lymphoma while + denotes aggressive type.

<b><u>B-cell Neoplasms</u></b> <u>Precursor B-cell Neoplasms</u> <ul style="list-style-type: none"> <li>• Precursor B-lymphoblastic leukemia/lymphoma<sup>+</sup></li> </ul> <u>Mature (Peripheral) B-cell Neoplasms-Predominately Disseminated</u> <ul style="list-style-type: none"> <li>• CLL/SLL<sup>*</sup></li> <li>• B-Prolymphocyte lymphoma<sup>+</sup></li> <li>• Lymphoplasmacytic lymphoma<sup>*</sup></li> <li>• Splenic Marginal Zone lymphoma<sup>*</sup></li> <li>• Hairy cell lymphoma<sup>*</sup></li> <li>• Plasma cell myeloma/plasmacytoma</li> </ul> <u>Mature (Peripheral) B-cell Neoplasms-Primary Extranodal Mucosa-associated lymphoid tissue*</u> <u>Mature (Peripheral) B-cell Neoplasms-Predominantly Nodal</u> <ul style="list-style-type: none"> <li>• Marginal Zone lymphoma<sup>*</sup></li> <li>• Follicular lymphoma<sup>*</sup></li> <li>• Mantle cell lymphoma<sup>+</sup></li> <li>• Diffuse Large B-cell lymphoma (LBCL)<sup>+</sup></li> <li>• Mediastinal LBCL<sup>+</sup></li> <li>• Intravascular LBCL<sup>+</sup></li> <li>• Primary effusion lymphoma<sup>+</sup></li> <li>• Burkitt's lymphoma<sup>+</sup></li> <li>• Lymphomatoid granulomatosis</li> </ul>	<b><u>T- and NK-cell Neoplasms</u></b> <u>Precursor T- and NK-cell Neoplasms</u> <ul style="list-style-type: none"> <li>• Precursor T-lymphoblastic leukemia/lymphoma<sup>+</sup></li> <li>• Blastoid NK lymphoma<sup>+</sup></li> </ul> <u>Mature (Peripheral) T-cell Neoplasms- Predominately Disseminated</u> <ul style="list-style-type: none"> <li>• T-cell Prolymphocytic leukemia<sup>+</sup></li> <li>• T-cell Large Granular Lymphocytic leukemia<sup>*</sup></li> <li>• Aggressive NK-cell leukemia<sup>+</sup></li> <li>• Adult T-cell lymphoma/leukemia-HTLV-1<sup>+</sup></li> </ul> <u>Mature (Peripheral) T-cell Neoplasms- Primary Extranodal</u> <ul style="list-style-type: none"> <li>• Extranodal NK/T-cell lymphoma, nasal type<sup>+</sup></li> <li>• Enteropathy-type T-cell lymphoma<sup>+</sup></li> <li>• Hepatosplenic T-cell lymphoma<sup>+</sup></li> <li>• Subcutaneous panniculitis-like T-cell lymphoma<sup>+</sup></li> <li>• Mycosis fungoides/Sézary syndrome<sup>*</sup></li> <li>• Primary cutaneous anaplastic large-cell lymphoma<sup>+</sup></li> </ul> <u>Mature (Peripheral) T-cell Neoplasms-Predominantly Nodal</u> <ul style="list-style-type: none"> <li>• Peripheral T-cell lymphoma- NOS<sup>+</sup></li> <li>• Angioimmunoblastic T-cell lymphoma<sup>+</sup></li> <li>• Primary systemic anaplastic Large-cell lymphoma<sup>+</sup></li> </ul>
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\*\*International Prognostic Index: Low Risk = 0-1 points, Low Intermediate = 2, High Intermediate = 3, High Risk = 4-5 points

<b>0 points</b>	<b>1 point for presence of each</b>
<ul style="list-style-type: none"> <li>• Age less than 60 years</li> <li>• Tumor stage I or II</li> <li>• Extranodal Involvement (ENI) 0-1</li> <li>• Performance status (PS) Eastern Cooperative Oncology Group (ECOG) 0-1</li> <li>• Lactate dehydrogenase (LDH) normal</li> </ul>	<ul style="list-style-type: none"> <li>• Age greater than 60 years,</li> <li>• Tumor stage III or IV,</li> <li>• ENI greater than 1,</li> <li>• PS (ECOG) 2-4,</li> <li>• LDH greater than normal.</li> </ul>
<b>**International Follicular Lymphoma Prognostic Index: Low Risk = 0-1 points, Intermediate Risk = 2, High Risk= greater than 5 points</b>	
	<b>1 point for presence of each</b> <ul style="list-style-type: none"> <li>• Age greater than or equal to 60 years;</li> <li>• Ann Arbor stage III-IV;</li> <li>• Hemoglobin level less than 12 g/dL;</li> <li>• Serum LDH level greater than the upper limit of normal;</li> <li>• Number of nodal sites greater than or equal to 5</li> </ul>

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### **III. Solid Tumors of Childhood**

Defined as not arising from myeloid or lymphoid cells. The most common are neuroblastoma, Ewing's sarcoma, Wilms' tumor, rhabdomyosarcoma, osteosarcoma, retinoblastoma or germ cell tumor.

Neuroblastoma can be categorized according to the stage and number of copies of the N myc oncogene

<u>Low Risk</u>	<u>Intermediate Risk</u>	<u>High Risk: Stage II and greater than 10 N-myc</u>
Stage I	Stage III and N-myc = 1 and ferritin less than 143 and favorable histology	Stage III; greater than 10 N-myc or ferritin greater than 143 or unfavorable histology
Stage II; N-myc = 1	Stage IV; N-myc = 1 and less than 1 year at diagnosis	Stage IV and greater than 1 year at diagnosis
Stage IVS	Stage III and less than 1 year at diagnosis	Stage IV at less than 1 year at diagnosis and greater than 10 N-myc

<b>Medically appropriate indications:</b>	<b>Investigational indications:</b>
None	<ul style="list-style-type: none"> <li>Salvage allogeneic transplant for relapsing neuroblastoma or other solid tumors <i>after autologous</i> transplant or fail to respond</li> <li>Pediatric solid tumors</li> </ul>

### **IV. Genetic Diseases & Acquired Anemias**

Based upon our criteria and assessment of the peer-reviewed literature treatment with HDC and allogeneic stem cell transplant for the following conditions has been **medically proven** to be effective:

- Sickle cell anemia for children or young adults with either a history of prior stroke or at increased risk of stroke or end-organ damage and with an HLA-identical, related donor. Factors associated with high risk of stroke or end-organ damage include: recurrent chest syndrome, recurrent vaso-occlusive crises, red blood cell alloimmunization on chronic infusion therapy.
- Severe or very severe acquired aplastic anemia (e.g., secondary to drug or toxin exposure)
- Idiopathic acquired aplastic anemia in young patients not responding to immunosuppressive therapy
- Severe inherited bone marrow failure syndromes (e.g., Fanconi anemia, Schwachman-Diamond Syndrome, and Diamond Blackfan syndrome)
- Thalassemia major (Homozygous beta-thalassemia, Hemoglobin E-Thalassemia)
- Wiskott-Aldrich syndrome and other combined immunodeficiencies
- Infantile malignant osteopetrosis (Albers-Schöberg disease or marble bone disease)
- Lysosomal and peroxisomal storage disorders (e.g., Hurler, Maroteaux Lamy variants, and Gaucher disease, metachromatic leukodystrophy, globoid cell leukodystrophy, adrenoleukodystrophy) *except* Hunter, Sanfilippo, and Morquio syndromes
- Severe congenital neutropenia (e.g., Kostmann syndrome);
- Leukocyte adhesion deficiencies;
- X-linked lymphoproliferative syndrome;
- Hemophagocytic lymphohistiocytosis.

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#### **V. Myelodysplastic Diseases**

**Myelodysplastic syndrome (MDS)** refers to a heterogeneous group of hematopoietic disorders characterized by impaired maturation of hematopoietic cells and a tendency to transform into acute myelocytic leukemia. The 2008 WHO classification of MDS includes but is not limited to: refractory anemia (RA), refractory anemia with ring sideroblasts (RARS), refractory cytopenia with multilineage dysplasia (RCMD), refractory cytopenia with ring sideroblasts, refractory anemia with excess blasts 1 and 2 (RAEB 1 and 2), del 5q syndrome, and unclassified myelodysplastic syndrome. **Myeloproliferative disorders** are characterized by the slow but relentless expansion of a clone of cells with the potential evolution into a blast crisis similar to acute myelocytic leukemia. Examples of myeloproliferative disorders include polycythemia vera, primary myelofibrosis, essential thrombocythemia, and chronic myelogenous leukemia (please refer to leukemia section I.) Other less common types of myeloproliferative disorders include chronic neutrophilic leukemia, chronic eosinophilic leukemia, hypereosinophilic leukemia, and mast cell disease.

#### **Conditions eligible for coverage:**

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Myelodysplastic syndrome</li> </ul> | <ul style="list-style-type: none"> <li>• Myeloproliferative disorders</li> </ul> |
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#### **VI. Amyloidosis**

Based upon our criteria and assessment of the peer-reviewed literature, treatment with HDC and allogeneic stem cell transplant for Primary Systemic Amyloidosis has not been medically proven to be effective and therefore is considered **investigational**.

#### **VI. Other Malignant Conditions:**

Based upon our criteria and assessment of the peer-reviewed literature, treatment with HDC and allogeneic stem cell transplant for the following malignant conditions has not been medically proven to be effective and therefore is considered **investigational**:

- |  |                          |
|--|--------------------------|
| • <b>Germ Cell Tumors</b>  |                          |
| • <b>Primitive Neuroectodermal Tumor (PNET)</b> (e.g., ependymoma, and other PNETs)  |                          |
| • <b>Medulloblastoma</b>   |                          |
| • <b>Multiple Myeloma</b> as primary treatment or a prior failed course of autologous HSCT or relapse after autologous SCT |                          |
| • <b>Breast Cancer</b>   |                          |
| • <b>Other malignant conditions and diseases</b>   |                          |
| • Epithelial ovarian cancer  | • Colon cancer           |
| • Lung cancer, any histology   | • Rectal cancer          |
| • Pancreas cancer  | • Stomach cancer         |
| • Esophageal cancer  | • Gall bladder cancer    |
| • Cancer of the bile duct  | • Renal cell cancer      |
| • Cervical cancer  | • Uterine cancer         |
| • Cancer of the fallopian tubes  | • Prostate cancer        |
| • Nasopharyngeal cancer  | • Paranasal sinus cancer |
| • Neuroendocrine tumors  | • Soft tissue sarcomas   |
| • Thyroid tumors   | • Tumors of the thymus   |
| • Tumors of unknown primary origin   | • Malignant Melanoma     |

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## **VI. Non-malignant Diseases**

### **Autoimmune Diseases**

Based upon our criteria and assessment of the peer-reviewed literature, treatment with HDC and allogeneic stem cell transplant for the following autoimmune conditions has not been medically proven to be effective and therefore is considered **investigational**:

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• Autoimmune diseases, including but not limited to, rheumatoid arthritis</li> </ul> | <ul style="list-style-type: none"> <li>• Systemic lupus erythematosus (SLE)</li> </ul> |
| <ul style="list-style-type: none"> <li>• Systemic sclerosis (e.g., scleroderma)</li> </ul>                                  | <ul style="list-style-type: none"> <li>• Multiple sclerosis</li> </ul>                 |

*Refer to Corporate Medical Policy# 11.01.03 regarding Experimental and Investigational Services.*

## **POLICY GUIDELINES:**

### **Pre-Transplant Evaluation Guidelines:**

#### **I. Clinical Evaluation:**

- A. Confirmation of diagnosis;
- B. Identification of comorbidities;
- C. Treatment of co-morbidities;
- D. Current assessment of co-morbidities;
- E. Consult notes (if applicable).

#### **II. Psycho-Social Evaluation:**

- A. Karnofsky performance score;
- B. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).

#### **III. Dental Evaluation.**

#### **IV. Lab Tests:**

- A. CBC, metabolic profile;
- B. Serologies: CMV, Hepatitis B and C;
- C. HIV testing.

#### **V. Cardiac Assessment:**

- A. 12 lead EKG;
- B. Stress echo or MUGA scan.

#### **VI. Pulmonary Assessment:**

- A. Chest x-ray;
- B. Pulmonary function tests (PFTs).

#### **VII. Age Appropriate Screening Tests:**

- A. Age greater than or equal to 50 years:
  1. Colonoscopy (within 10 years); or
  2. Flexible sigmoidoscopy (within 5 years); or
  3. Guaiac stool testing (within 1 year); or
  4. Rationale of contraindication to testing (if applicable).
- B. Women Age 21-70 years: Pap Smear (within 3 years).
- C. Women Age greater than or equal to 40 years: Mammogram (within 2 years)

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#### Recipient Selection Guidelines:

Each individual considered for allogeneic stem cell transplant will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

#### DESCRIPTION:

Stem cells differ from other blood cells in that they are capable of both unlimited self-renewal and differentiation to form white blood cells, red blood cells or platelets. Stem cells can be collected from two sources: direct aspiration of bone marrow *or* through a pheresis procedure to harvest peripheral blood stem cells (PBSC). Prior to harvesting the stems cells, pretreatment with drugs called "growth factors" or "colony stimulating factors" are given to the donor to enhance stem cell production. The harvested stem cells are then cryopreserved until transplanted.

In allogeneic stem cell transplantation cells are obtained from a matched related or unrelated donor. The more closely matched the donor to the recipient's tissue type, the more favorable the outcome for the transplant. Allogeneic stem cell transplants are associated with potential complications and benefits. One complication that may develop is graft-vs-host disease (GVHD). In GVHD, the donor cells may attack the recipient tissue which could eventually lead to death. A potential benefit, the graft-vs-tumor effect, arises when the donor cells attack the recipient tissue. This effect may account for lower relapse rates.

Classification of the risk of disease for acute myeloid leukemia is has been identified in the National Comprehensive Cancer Network treatment guidelines (2013). Risk is based on cytogenetic stratification of good, intermediate and poor-risk AML. Treatment depends on which risk category of the disease.

<u>Risk Status</u>	<u>Cytogenetics</u>	<u>Molecular Abnormalities</u>
Better-risk	<ul style="list-style-type: none"> <li>• inv(16)</li> <li>• t(8;21)</li> <li>• t(16;16)</li> <li>• t(15;17)</li> </ul>	<ul style="list-style-type: none"> <li>• Normal cytogenetics with NPM1 mutation in the absence of FLT3-ITD or isolated biallelic CEBPA mutation</li> </ul>
Intermediate risk	<ul style="list-style-type: none"> <li>• Normal cytogenetics</li> <li>• +8 alone</li> <li>• t(9;11)</li> <li>• Other non-defined</li> </ul>	<ul style="list-style-type: none"> <li>• t(8;21)</li> <li>• inv(16)</li> <li>• t(16;16): with</li> <li>• c-KIT mutation *</li> </ul>
Poor-risk	<ul style="list-style-type: none"> <li>• Complex (greater than or equal to 3 clonal chromosomal abnormalities)</li> <li>• -5</li> <li>• -7</li> <li>• 5q-</li> <li>• 7q-</li> <li>• 11q23 – non t(9;11),</li> <li>• Inv(3)</li> <li>• t(3;3)</li> <li>• t(6;9)</li> <li>• t(9;22)</li> </ul>	<ul style="list-style-type: none"> <li>• Normal cytogenetics with FLT3 ITD mutation**</li> </ul>

\*Emerging data indicates that the presence of c-KIT mutations in patients with t (8; 21) and to a lesser extent inv (16) confers a higher risk of relapse. These patients should be considered for clinical trials, if available.

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**\*\*FLT3-ITD mutations are considered to confer a significantly poorer outcome in patients with normal karyotype, and these patients should be considered for clinical trials where available. There is controversy as to whether FLT3-TKD mutations carry an equally poor prognosis.**

Reduced-intensity conditioning (RIC) 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 eradicate the patient's hematopoietic ability, thereby allowing for 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 totally myeloablative to minimally myeloablative with lymphoablation.

Non-Hodgkin Lymphomas (NHLs) are often divided into two groups, indolent and aggressive depending on the types of affected cells and the rate of growth of the cells. Indolent Non-Hodgkin Lymphomas (NHLs) tend to grow and spread slowly with few symptoms. They are low-grade cancers which are often very responsive to treatments like chemotherapy, radiation, and immunotherapy. However treatment is often deferred until the patient becomes symptomatic. The goal of treatment is often management as indolent lymphomas are rarely cured, unless it is diagnosed when still localized. Thus, treatment options are more varied with no standardization. Aggressive Non-Hodgkin Lymphomas (NHLs) are fast growing and are described as intermediate or high grade. They can be treated with chemotherapy, radiotherapy, monoclonal antibody therapy or a combination. The decision on the exact course of treatment is usually decided on a number of factors such as, the stage of the disease, the number of nodes involved, the presence of lymphoma in other organs, and age.

### **RATIONALE:**

Published studies demonstrate that allogeneic stem cell and bone marrow transplantation improve health outcomes for patients with certain diagnoses who meet specific criteria. Improved outcomes have been achieved outside the investigational setting for those patients. Available evidence does not demonstrate improved outcomes in other diagnoses and/or where listed criteria are not met.

### **CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<b><u>CPT:</u></b>	38205	Blood derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
	38210	Specific cell depletion within harvest, T-cell depletion
	38212	red blood cell removal
	38213	platelet depletion
	38230	Bone marrow harvesting for transplantation
	38240	Bone marrow or blood-derived peripheral stem cell transplantation: allogeneic
	38242	allogeneic donor lymphocyte infusions
	38243	Hematopoietic progenitor cell (HPC);HPC boost

*Proprietary Information of Excellus Health Plan, Inc.*



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86812-86822, HLA typing (code range)  
81370-81383

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**HCPCS:** S2150 Bone marrow or blood-derived peripheral stem cell harvesting and transplantation, allogeneic or autologous, including pheresis, high-dose chemotherapy, and 28 days of post-transplant care (including drugs; hospitalization; medical surgical, diagnostic and emergency services)

**ICD9:**

204.1	Chronic lymphocytic leukemia
201	Hodgkin's disease
200	Lymphoma code range
202.0	Nodular lymphoma
158.0	Malignant neoplasm of retroperitoneum
164.2 - 164.9	Malignant neoplasm of mediastinum (code range)
186	Malignant neoplasm of testis
191	Malignant neoplasm of brain
203	Multiple myeloma
174	Malignant neoplasm of the female breast
162	Malignant neoplasm of lung
159	Malignant neoplasm of intestine
171	Malignant neoplasm of connective and other soft tissue
340	Multiple sclerosis
710	Systemic lupus erythematosus
710.1	Systemic sclerosis
714	Rheumatoid arthritis
272.7	Lipidoses (includes mucopolipidosis)
277.5	Mucopolysaccharidosis
279.12	Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
282.4	Thalassemias
284.0 -284 .9	Aplastic anemia (code range)
282.6 - 282.69	Sickle-cell anemia (code range)
238.7	Myelofibrosis or myelodysplastic syndrome

**ICD10:**

C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs (code range)
C33	Malignant neoplasm of trachea

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C34.00-C34.92	Malignant neoplasm of bronchus and lung (code range)
C38.1-C38.8	Malignant neoplasm of mediastinum and pleura (code range)
C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system (code range)
C48.0	Malignant neoplasm of retroperitoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue (code range)
C50.011-C50.919	Malignant neoplasm of breast (code range)
C62.00-C62.92	Malignant neoplasm of testis (code range)
C71.0-C71.9	Malignant neoplasm of brain (code range)
C81.00-C81.99	Hodgkin lymphoma (code range)
C82.00-C82.59	Follicular lymphoma (code range)
C82.60-C82.99	Cutaneous follicle center lymphoma
C83.00-C83.99	Non-follicular lymphoma (code range)
C84.60-C84.79	Anaplastic large cell lymphoma, ALK-positive (code range)
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.2-C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas (code range)
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms (code range)
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type (code range)
C94.40-C94.42	Acute panmyelosis with myelofibrosis (code range)
C94.6	Myelodysplastic disease, not classified
D46.0-D46.9	Myelodysplastic syndromes (code range)
D46.A-D46.Z	Refractory cytopenia with multilineage dysplasia (code range)
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D56.0-D56.9	Thalassemia (code range)
D57.00-D57.819	Sickle-cell disorders (code range)
D60.0-D61.9	Acquired pure red cell aplasia [erythroblastopenia] (code range)

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D81.0-D82.0	Combined immunodeficiencies (code range)
E75.21-E75.3	Other sphingolipidosis (code range)
E76.01-E76.03	Disorders of glycosaminoglycan metabolism (code range)
E77.0-E77.9	Disorders of glycoprotein metabolism (code range)
G35	Multiple sclerosis
M32.0-M32.9	Systemic lupus erythematosus (SLE) (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)

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\*key articles

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently a National Coverage Determination (NCD) for Stem Cell Transplantation. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=45&ncdver=5&bc=AgAAgAAAAAA&>