MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Autologous Hematopoietic (Stem) Cell Transplantation**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, high-dose chemotherapy (HDC) with autologous hematopoietic (stem) cell support has been medically proven to be effective and, therefore, is considered **medically appropriate** for carefully selected candidates. The following is a listing of coverage criteria for different medical conditions.

I. Leukemias:	
Medically appropriate indications:	**Investigational indications:**
Adult Acute Lymphoblastic Leukemia (ALL): • In first remission at high risk of relapse (e.g., age greater than 35 years, and leukocytosis at presentation of greater than 30,000/µL (B-cell lineage), greater than 100,000/µL (T-cell lineage), or poor prognosis genetic abnormalities (e.g., presence of Philadelphia chromosome, extramedullary disease, and time to attain complete remission longer than four weeks). **Pediatric ALL**: • In first complete remission but at high risk of relapse (e.g., age, WBC greater than or equal to 50,000/ul,	**Adult ALL:** • In second or greater remission or with refractory disease **Small lymphocytic leukemia (SLL)** **Chronic myelogenous leukemia (CML)**

hypodiploidy (less than 45 chromosomes) t(9:22) or *BCR/ABL* fusion t(4;11*) or MLL/AF4* fusion • In second or greater remission or refractory ALL. **Chronic lymphocytic leukemia (CLL)** • Response to initial therapy • Allogeneic HST contraindicated (e.g., lack of suitable donor)	
II. Lymphomas	
Hodgkin Lymphoma (HL):	
Medically appropriate indications: • Primary refractory or relapsing after completion of an initial or subsequent course of chemotherapy	**Investigational indications:** • Initial therapy for all HLs to consolidate a first complete remission • A second autologous hematopoietic (stem) cell transplant for relapsed lymphoma after a prior autologous transplant
Non-Hodgkin Lymphoma (NHL):	
NHL can be classified as either indolent (low-grade) or aggressive (intermediate- or high-grade)	
Medically appropriate indications:	**Investigational indications:**
Aggressive • Salvage therapy when a complete response after full first-line induction chemotherapy is not achieved • To achieve or consolidate a complete or partial response in a chemo-sensitive first or second relapse • To consolidate a first complete or partial response in patients with Diffuse Large B-cell lymphoma at high- or high-intermediate risk of relapse, as predicted by the IPI** • Primary therapy for intermediate or aggressive subtypes with high International Prognostic Index** (IPI) score and for Burkitt-like Ki-67 positive NHL Salvage therapy when a complete response after full first-line induction chemotherapy is not achieved for low- or high-risk Burkitt lymphoma **Indolent** • Salvage therapy for patients who do not achieve a complete response after a full dose of first-line induction chemotherapy • To achieve or consolidate a complete or partial response for those in a first or subsequent chemo-sensitive relapse, whether or not their lymphoma has undergone transformation to a higher grade **Waldenstrom's macroglobinemia** • Salvage therapy for patients with chemo sensitive Waldenstrom macroglobulinemia	• Initial therapy for all other subgroups of NHL, except intermediate or aggressive subtypes with high international prognostic index **(**IPI) score** as listed in the medically appropriated indications • 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** • To consolidate a first complete response for those with indolent lymphoma subtypes • Tandem transplants • As salvage therapy for Mantle Cell lymphoma

Mantle Cell Lymphoma

- To consolidate a first remission (complete or partial)

Peripheral T Cell Lymphoma (e.g., Mycosis fungoides/ Sezary syndrome, primary cutaneous anaplastic large-cell lymphoma)

- To consolidate a first remission in high-risk Peripheral T-Cell Lymphoma
- As salvage therapy

Primary CNS Lymphoma

- To consolidate a first remission
- As salvage therapy for relapsed or refractory primary CNS Lymphoma

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-cell Neoplasms

Precursor B-cell Neoplasms

- Precursor B-lymphoblastic leukemia/lymphoma+

Mature (Peripheral) B-cell Neoplasms-Predominately Disseminated

- CLL/SLL*
- B-Prolymphocyte lymphoma+
- Lymphoplasmacytic lymphoma*(includes Waldenstrom's Macroglobulinemia)
- Splenic Marginal Zone lymphoma*
- Hairy cell lymphoma*
- Plasma cell myeloma/plasmacytoma

Mature (Peripheral) B-cell Neoplasms-Primary Extra nodal Mucosa-associated lymphoid tissue*

Mature (Peripheral) B-cell Neoplasms-Predominantly Nodal

- Marginal Zone lymphoma*
- Follicular lymphoma*
- Mantle cell lymphoma+
- Intravascular LBCL+
- Primary effusion lymphoma+
- Burkitt's lymphoma+
- Lymphomatoid granulomatosis

T- and NK-cell Neoplasms

Precursor T- and NK-cell Neoplasms

- Precursor T-lymphoblastic leukemia/ lymphoma+
- Blastoid NK lymphoma+

Mature (Peripheral) T-cell Neoplasms- Predominately Disseminated

- T-cell Prolymphocytic leukemia+
- T-cell Large Granular Lymphocytic leukemia*
- Aggressive NK-cell leukemia+ Adult T-cell lymphoma/leukemia-HTLV-1++

Mature (Peripheral) T-cell Neoplasms- Primary Extra nodal

- Extra nodal NK/T-cell lymphoma, nasal type+
- Enteropathy-type T-cell lymphoma+
- Hepatosplenic T-cell lymphoma+
- Subcutaneous panniculitis-like T-cell lymphoma+
- Mycosis fungoides/Sezary syndrome*
- Primary cutaneous anaplastic large-cell lymphoma+

Mature (Peripheral) T-cell Neoplasms-Predominantly Nodal

- Peripheral T-cell lymphoma- NOS+
- Angioimmunoblastic T-cell lymphoma+

Primary systemic anaplastic Large-cell lymphoma+

**International Prognostic Index: Low Risk = 0-1 points, Low Intermediate = 2, High Intermediate = 3, High Risk = 4-5 points

0 points	**1 point for presence of each**
• Age less than 60 years • Tumor stage I or II • Extra nodal Involvement (ENI) 0-1 • Performance status (PS) Eastern Cooperative Oncology Group (ECOG) 0-1 • Lactate dehydrogenase (LDH) normal	• Age greater than 60 years • Tumor stage III or IV • ENI greater than 1 • PS (ECOG) 2-4 • LDH greater than normal

**International Follicular Lymphoma Prognostic Index: Low Risk = 0-1 points, Intermediate Risk = 2, High Risk= greater than 5 points

	1 point for presence of each
	• Age greater than or equal to 60 years • Ann Arbor stage III-IV • Hemoglobin level less than 12 g/dL • Serum LDH level greater than the upper limit of normal • Number of nodal sites greater than or equal to 5

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, or retinoblastoma. Neuroblastoma is classified into low-, intermediate- and high-risk, based on the stage and the number of copies of the N-myc oncogene.

Low Risk	Intermediate Risk	High Risk
Stage I Stage II; N-myc = 1 Stage IVS	Stage III and N-myc = 1 and ferritin less than 143 and favorable histology Stage IV and N-myc =1 and less than 1 year at diagnosis Stage III and less than 1 year at diagnosis	Stage II and greater than 10 N-myc Stage III; greater than 10 N-myc or ferritin greater than143 or unfavorable histology Stage IV and greater than 1 year at diagnosis Stage IV at greater than 1year at diagnosis and greater than 10 N-myc

Medically appropriate indications:	**Investigational indications:**
• Initial treatment of high-risk neuroblastoma • Primary refractory or recurrent neuroblastoma • Initial treatment of high-risk Ewing's sarcoma • Recurrent or refractory Ewing's sarcoma • Tandem transplantation for high-risk neuroblastoma • Metastatic retinoblastoma	• Initial treatment of low- or intermediate-risk Ewing's sarcoma and neuroblastoma • Treatment of Wilms' tumor, rhabdomyosarcoma, osteosarcoma, retinoblastoma without metastasis • Tandem or multiple transplants for treatment of pediatric solid tumors (except high risk neuroblastoma)

IV. Germ Cell Tumors

Comprise the vast majority of primary testicular neoplasms, although can also arise in the ovary and in extragonadal locations.

Medically appropriate indications:	**Investigational indications:**
• Germ cell tumors that do not achieve complete remission, (e.g., refractory germ cell tumors or those exhibiting a partial response)	• Initial treatment (e.g., in lieu of an initial course of conventional chemotherapy) of a poor risk germ cell tumor or as a treatment following first relapse (e.g., in lieu of a course of conventional chemotherapy)

• Unfavorable prognostic factors as initial treatment of first relapse (i.e., without a course of conventional-dose salvage chemotherapy) and in patients with platinum-refractory disease • Tandem or sequential autologous HCT either as salvage therapy or with platinum-refractory disease	
V. Multiple Myeloma	
Medically appropriate indications:	**Investigational indications:**
• Single treatment for newly diagnosed or responsive multiple myeloma • Second autologous HCT to treat responsive myeloma that has relapsed after a durable complete or partial remission following an initial autologous transplant • Tandem transplantation with an initial round of autologous hematopoietic (stem) cell transplantation (HCT) followed by a non-marrow-ablative conditioning regimen and allogeneic hematopoietic (stem) cell transplantation to treat high-risk or with very resistant disease (e.g., Stage 3 diagnosis ISS (International Staging System), cytogenetic abnormalities, specific gene expression patterns, elevated lactate dehydrogenase level (LDH) and the presence of extramedullary disease at diagnosis) multiple myeloma patients preferably in a clinical trial.	
VI. Amyloidosis	
Medically appropriate conditions:	**Investigational indications:**
• Amyloidosis with involvement of fewer than 2 organ systems • Amyloid cardiac involvement is NOT an absolute contraindication to proceeding to BMT. Interventricular septal thickness and ejection fraction should be measured with all patients.	• Amyloidosis with involvement of greater than 2 organ systems
VII. Primitive Neuroectodermal Tumor (PNET)	
PNET include neuroblastoma arising in the central nervous system, ependymoblastoma, or pineal blastoma. All show a similar histology and are principally distinguished by their site of origin.	
Medically appropriate conditions:	**Investigational indications:**
• Recurrent medulloblastoma and other primitive neuroectodermal tumors (PNETs) • As consolidation therapy for previously untreated embryonal tumors (PNET) of the central nervous system that show partial or complete response to induction chemotherapy, or stable disease after induction therapy; Recurrent embryonal tumors	• Treatment of ependymoma • Tandem transplant for patients with medulloblastoma, other PNETs of the CNS, or ependymoma
VIII. Other Malignant Conditions	
Based upon our criteria and review of the peer-reviewed literature, treatment with HDC and autologous hematopoietic (stem) cell transplant for the following malignant conditions has not been medically proven to be effective and therefore is considered **investigational:**	

Breast cancer	Colon cancer
Epithelial ovarian cancer	Rectal cancer
Lung cancer, any histology	Stomach cancer
Pancreas cancer	Gall bladder cancer
Esophageal cancer	Renal cell cancer
Cancer or the bile duct	Uterine cancer
Cervical cancer	Prostate cancer
Cancer of the fallopian tubes	Paranasal sinus cancer
Nasopharyngeal cancer	Soft tissue sarcomas
Neuroendocrine tumors	Tumors of the thymus
Thyroid tumors	Tumors of unknown primary origin
Malignant astrocytoma's and gliomas including glioblastoma multiforme and oligodendroglioma	Malignant Melanoma
IX. Non-malignant Diseases	
Autoimmune Diseases	
Medically appropriate indications:	**Investigational indications:**
Systemic sclerosis (e.g., scleroderma) is medically necessary for the treatment of adults less than 60 years of age at risk of organ failure when **ALL** of the following conditions are met. 1. Systemic sclerosis (scleroderma) for five years or less 2. Modified Rodnan Scale Scores greater than 15 3. History of less than six months of treatment with cyclophosphamide 4. No active gastric antral vascular ectasia 5. Internal organ involvement, which may include: • Cardiac-abnormal electrocardiogram OR • Pulmonary-Active interstitial lung disease (e.g. ground-glass opacities on computed tomography of the chest, decline of forced vital capacity (FVC) of greater than 10% in last 12 months OR • Renal- scleroderma-related renal disease	Rheumatoid and juvenile idiopathic arthritis Systemic lupus erythematosus (SLE) Multiple sclerosis Type 1 diabetes mellitus Chronic inflammatory demyelinating polyneuropathy Crohn's disease

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: Guaiac stool testing (within one year)
   B. Women Age 21-65 years: Pap Smear (within three years)
   C. Women Age greater than or equal to 40 years: Mammogram (within two years)

Recipient Selection Guidelines:

Each individual considered for autologous 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" may be given to enhance stem cell production. The harvested stem cells are then cryopreserved until transplanted.

In autologous (stem) cell transplantation (AuSCT) a portion of the patient's own stem cells are re-infused intravenously to rescue the patient by re-establishing his/her bone marrow which has been eradicated after high dose chemotherapy (HDC) and/or total body irradiation has been given to destroy the malignant cells. Tandem transplantation is defined as two planned courses of high-dose chemotherapy with stem cell support.

Classification of the risk of disease for acute myeloid leukemia has been identified in the National Comprehensive Cancer Network treatment guidelines 2020. Risk is based on cytogenetic stratification of good, intermediate, and poor-risk AML. Treatment depends on the risk category of the disease.

Risk Status	Cytogenetics	Molecular Abnormalities
Favorable risk	Core binding factor: • inv(16) • t(8;21) • t(16;16) • t(15;17)	• Normal cytogenetics • NPM1 mutation in the absence of FLT3-ITD or isolated biallelic CEBPA mutation

Intermediate risk	• Normal cytogenetics • +8 • t(9;11) • Other non-defined	
Poor-risk	• Complex (greater than or equal to 3 clonal chromosomal abnormalities • Monosomal karyotype • -5 • -7 • 5q- • 7q- • 11q23 – non t(9;11) • Inv(3) • t(3;3) • t(6;9) • t(9;22)	• Normal cytogenetics with FLT3 ITD mutation** • TP53 mutation

**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.

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 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 dependent 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.

The 2019 European Society for Blood and Marrow Transplantation (EBMT) Handbook documents studies have shown that individuals with systemic sclerosis benefit only marginally from standard immunosuppressive drugs and cyclophosphamide (medication used as chemotherapy and to suppress the immune system). Indications for auto-HSCT in systemic sclerosis have increased since three successive randomized trials, namely, ASSIST (2011), ASTIS (2014) and SCOT (2018), have now demonstrated that auto-HSCT is superior to Cyclophosphamide for early rapidly progressive systemic sclerosis in terms of long-term survival as well as improvement of lung function and skin fibrosis. Current guidelines recommend auto-HSCT for patients with early diffuse systemic sclerosis with a modified Rodnan skin score ≥15 plus major organ involvement in respiratory, cardiovascular or renal systems and treatment should be performed in accredited centers where combined expertise from systemic sclerosis disease specialist and dedicated transplant team can assess and follow patients.

RATIONALE

Published studies demonstrate that autologous (stem) hematopoietic 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

- *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.*

CPT Codes

Code	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38210	Transplant preparation of hematopoietic progenitor cells; Specific cell depletion within harvest, T-cell depletion
38211	tumor cell depletion
38212	red blood cell removal
38213	platelet depletion
38232	Bone marrow harvesting for transplantation, autologous
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

HCPCS Codes

Code	Description
S2150	Bone marrow or blood-derived stem cells (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, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post-transplant care in the global definition

ICD10 Codes

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

Code	Description
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-C82.99	Follicular lymphoma (code range)
C83.00-C83.09	Non-follicular lymphoma (code range)
C83.10-C83.19	Mantle cell lymphoma (code range)
C83.30-C83.39	Diffuse large B-cell lymphoma (code range)
C83.50-C83.59	Lymphoblastic (diffuse) lymphoma (code range)
C83.70-C83.79	Burkitt lymphoma (code range)
C83.80-C83.99	Other non-follicular lymphoma (code range)
C84.60-C84.79	Anaplastic large cell lymphoma, ALK-positive or ALK-negative (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)
E85.0-E85.9	Amyloidosis (code range)
G35	Multiple sclerosis
M05.00-M05.09	Felty's syndrome (code range)
M05.20-M05.29	Rheumatoid vasculitis with rheumatoid arthritis (code range)
M05.30-M05.39	Rheumatoid heart disease with rheumatoid arthritis (code range)
M05.40-M05.59	Rheumatoid myopathy with rheumatoid arthritis (code range)
M05.60-M06.09	Rheumatoid arthritis with involvement of other organs and systems (code range)
M06.1	Adult-onset Still's disease
M06.4	Inflammatory polyarthropathy
M06.80-M06.9	Other specified rheumatoid arthritis (code range)
M08.00-M08.99	Juvenile arthritis (code range)
M12.00-M12.09	Other and unspecified arthropathy (code range)
M32.0-M32.9	Systemic lupus erythematosus (SLE) (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)

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*Key Article

KEY WORDS

Autologous bone marrow transplant, Autologous stem cell transplant

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Stem Cell Transplantation. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=366&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d&