Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Category: Surgery
***Current Policy Effective Date: 3/1/09**

Title: Autologous Bone Marrow or Stem Cell Transplants (Investigational)

Procedure Code(s): 38241

Description / Background

Bone marrow or peripheral stem cell transplant is a highly specialized process where the bone marrow stem cells are harvested (removed) from the bloodstream and returned or transplanted back into the body after completion of high-dose chemotherapy. Stem cells are immature blood cells which may later develop into either white or red blood cells or platelets. Autologous transplant refers to the individual receiving his/her own cells. A separate donor is not involved.

Before the harvested cells are transplanted back into the body, doses of chemotherapeutic agents several times greater than normal are utilized to aggressively attack the cancer cells. During this process the individual's immune system is also almost totally destroyed with the high dose chemotherapy "killing" the normal cells. The re-infusion of the stored, previously harvested stem cells serves to "rescue" the body from the effects of the high-dose chemotherapy and restore the normal cells and immune system.

In many diseases high-dose chemotherapy and autologous stem cell support have become the standard of care. Investigation continues for high-dose chemotherapy and autologous stem cell support in certain other diseases.

Research studies have **not shown** this process to be effective in the treatment of the diseases addressed in this policy, including but not limited to:
Note: Certain ICD-9 codes may be considered established or experimental/investigational depending on the specific neoplasm involved.

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ICD-9 Codes	Nomenclature	Description
174.0-174.9 175.0, 175.9 172.5, 173.5	Malignant neoplasm of female breast Malignant neoplasm of the male breast Skin of the male or female breast	**Stage I:** See EBMT (Experimental Bone Marrow Transplant) Rider **Stage II Stage III and Stage IV**: See SOCT (Specified Oncology Clinical Trials) and EBMT (Experimental Bone Marrow Transplant) Riders
183.0	Malignant neoplasm of ovary	See SOCT (Specified Oncology Clinical Trials) policy) (BCBSM specific policy)
189.0 *Note: This code may also be considered established depending on the particular neoplasm	Wilm's tumor	Most common primary malignant renal tumor of childhood and is typically treated with a combination of surgery radiation therapy, and chemotherapy. Well encapsulated in early stage and embryonal adenomyosarcoma tumor.
190.5	Retinoblastoma	Most frequent ocular tumor in children, Majority appear to arise spontaneously from retinal germ cells a significant fraction is hereditary.
191.0-191.9 *Note: This code may also be considered established depending on the particular neoplasm	Gliomas	Rapidly growing, pulpy or cystic tumor of the cerebrum or spinal cord. The lesion spreads with pseudopod-like projections. It is composed of a mixture of monocytes, pyriform cells, immature and mature astrocytes and neural ectodermal cells, with fibrous or protoplasmic processes. Types of gliomas are astrocytoma, ependymoma, glioblastoma multiforme, medulloblastoma and oligodendroglioma.
191.5	Ependymoma	A neuroepithelial tumor that may arise throughout the CNS, but is typically contiguous with the ventricular system. In children, the tumor typically arises intracranially, while in adults, a spinal cord location is more common. Ependymomas are distinct from ependymoblastomas due to their more mature histologic differentiation. For this reason, ependymomas are not formally considered primitive neuroectodermal tumors.

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205.1(0-1)	Chronic Myelogenous Leukemia	Myeloproliferative disorder that is easily recognizable because 95% of cases have leukemic cells with a distinctive cytogenetic abnormality called the Philadelphia chromosome, a clonal disorder.
273.3	Waldenström's Macroglobulinemia	A rare chronic cancer that is classified as an indolent type slower growing and causes fewer symptoms than lymphoma. Abnormal plasma cells multiply out of control and interfere with blood flow through the smaller blood vessels.
285.0	Sideroblastic Anemia	A heterogenous group of rare blood disorders characterized by the bone marrow's inability to manufacture normal red blood cells.
Autoimmune Diseases:		
340	Multiple sclerosis	Progressive disease characterized by disseminated demyelination of nerve fibers of the brain and spinal cord. A history of exacerbation and remission of symptoms and the presence of greater than normal amounts of protein in cerebrospinal fluid are characteristic for diagnosis.
710.0	Systemic lupus erythematosus	Chronic inflammatory disease which affects many body systems. Pathophysiology includes severe vasculitis, renal involvement and lesions of the skin and nervous system. The initial manifestation is arthritis and an erythematous rash over the nose and malar eminences, weakness, fatigue and weight loss.
710.1	Scleroderma	Systemic sclerosis - affects the vascular system and characterized by fibrous degenerative changes in the connective tissue of the skin, lungs and internal organs, e.g., esophagus, digestive tract and kidneys.
714.0	Rheumatoid arthritis	Chronic destructive sometimes deforming collagen disease characterized by symmetric inflammation of the synovium and increased synovial exudate, leading to thickening of the synovium and swelling of the joint.

CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:
N/A

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Note:
The codes listed below are considered investigational for the diagnoses listed in this policy but may be considered established in the related policy i.e., Autologous Bone Marrow or Stem Cell Transplants (Established).

Other codes (investigational, not medically necessary, etc.):

38241

Billed with:

38204	38206	38207	38208	38209	38210
38211	38212	38213	38214	38215	38220
38221	38230	S2150			

Diagnoses / Medical Conditions

- Chronic Myelogenous Leukemia
- Astrocytomas/Gliomas
- Breast Cancer (male, female)
- Ovarian Cancer
- Multiple Sclerosis
- Systemic lupus erythematosus
- Systemic sclerosis (scleroderma)
- Rheumatoid arthritis
- Primitive neuroectodermal tumors (PNET)
- Ependymoma
- Sideroblastic Anemia
- Waldenström's Macroglobulinemia
- Wilm's tumor
- Retinoblastoma

Medical Policy Statement

Autologous bone marrow and stem cell transplants remain experimental/investigational for the diagnoses listed in this policy and those not listed in the "Autologous Bone Marrow or Blood-Derived Peripheral Stem Cell Transplantation (Established)" policy. The safety and effectiveness of these procedures for these diagnoses have not been proven.

Rationale

Current peer-reviewed medical literature and clinical trials have been insufficient to prove the effectiveness of autologous bone marrow or peripheral stem cell transplants for the listed conditions.

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The National Comprehensive Cancer Network (NCCN) Guidelines recommend stem-cell transplant (SCT) (not specified) is recommended as salvage therapy for Waldenström's Macroglobulinemia only in a clinical trial.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Autologous stem cells (formative cells) are harvested from the patient's own bone marrow or peripheral blood. Chemotherapy and radiotherapy are then given in doses several times greater than the standard therapeutic doses. The most significant adverse effect of high dose chemotherapy and radiation is the depletion of the individual's bone marrow. The administration of the high dose chemotherapy and/or radiotherapy is followed closely by reinfusion of the individual's bone marrow to replenish the bone marrow that was depleted. The safety and effectiveness of these procedures for the diagnoses listed in this policy and those not listed as covered in the related established policy have not been proven and therefore, are experimental/investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

- Autologous Bone Marrow or Stem Cell Transplants - Established
- Allogeneic Bone Marrow or Stem Cell Transplants – Established
- Allogeneic Bone Marrow or Stem Cell Transplants - Investigational

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Medicare Information

National Medicare Policy: "NCD for Stem Cell Transplantation (110.8.1), 1/3/2006.
Autologous bone marrow and peripheral stem cell transplants are reasonable and necessary for the following conditions:

- Acute leukemia in remission
- Resistant non-Hodgkin's lymphomas
- Recurrent or refractory neuroblastoma
- Advanced Hodgkin's disease
- Multiple Myeloma

Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- Acute leukemia, not in remission
- Chronic granulocytic leukemia

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- Solid tumors (other than neuroblastoma)
- Up to October 1, 2000, multiple myeloma
- Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma
- Effective October 1, 2000 no nprimary AL amyloidosis; and
- Effective October 1, 2000, thru March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older

Neither national nor local Medicare address autologous bone marrow nor peripheral stem cell transplants for:

- Autoimmune diseases
- Chronic myelogenous leukemia
- Malignant neoplasm of the male or female breast
- Malignant neoplasm of the ovary
- Gliomas

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

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- Anagnostopoulos, Athanasios, et al., “Autologous or Allogeneic Stem Cell Transplantation in patients with Waldenström’s Macroglobulinemia,” *Biology of Blood and Marrow Transplantation*, Vol. 12, 2006, pp. 845-854.
- Blue Cross Blue Shield Association, “High-Dose Chemotherapy and Autologous Stem-Cell Support for Malignant Astrocytomas and Gliomas," *Medical Policy Reference Manual*, # 8.01.31, Issue 5:2007, Original Policy Date 12/1/99, Last review date 9/18/07.
- Blue Cross Blue Shield Association, “High-Dose Chemotherapy and Hematopoietic Stem-Cell Support for the Treatment of Chronic Myelogenous Leukemia,” *Medical Policy Reference Manual*, # 8.01.30, Issue 6:2008, Original Policy Date 12/1/99, Last review date 6/12/08.
- Blue Cross Blue Shield Association, “High-Dose Chemotherapy and Hematopoietic Stem-Cell Support for Epithelial Ovarian Cancer," *Medical Policy Reference Manual*, # 8.01.23, Issue 6:2007, Original Policy Date 12/01/99, Update 12/13/07.
- Blue Cross Blue Shield Association, “High-Dose Chemotherapy with Autologous Stem-Cell Support for Primitive Neuroectodermal Tumors (PNET) of the CNS and Ependymoma," *Medical Policy Reference Manual*, # 8.01.28, Issue 5:2008, Update 05/08/08.
- Blue Cross Blue Shield Association, “High-Dose Chemotherapy and Autologous Stem Cell Support for Autoimmune Diseases, Including Multiple Sclerosis,” *Medical Policy Reference Manual,* # 8.01.25, Issue 5:2007, Original Policy Date 4/30/00, Update 09/18/07.

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- Blue Cross Blue Shield Association, "High-Dose Chemotherapy with Hematopoietic Stem-Cell Support for Breast Cancer," *Medical Policy Reference Manual*, #8.01.27, Issue 6:2007, Original Policy Date 12/1/99, Update 12/13/07.
- Blue Cross Blue Shield Association, "High-Dose Chemotherapy plus Hematopoietic Stem-Cell Support to Treat Primary Amyloidosis or Waldenström's Macroglobulinemia," *Medical Policy Reference Manual*, # 8.01.42, Issue 9:2008, Original Policy Date 10/9/03, Update 09/11/08.
- Blue Cross Blue Shield Association, "High-Dose Chemotherapy and Hematopoietic Stem-Cell Support for Miscellaneous Solid Tumors in Adults," *Medical Policy Reference Manual*, 8.01.24, Issue 5:2007, Original Policy Date 12/1/99, Update 09/18/07.
- Blue Cross Blue Shield Association, "High-Dose Chemotherapy and Hematopoietic Stem-Cell Support for the Treatment of Chronic Myelogenous Leukemia," *Medical Policy Reference Manual*, 8.01.30, Issue 6:2008, Original Policy Date 12/1/99, Update 06/12/08.
- Blue Cross Blue Shield Association, "High-Dose Chemotherapy and Hematopoietic Stem-Cell Support as a Treatment of Germ-Cell Tumors," *Medical Policy Reference Manual*, 8.01.35, Issue 5:2007, Original Policy Date 4/30/00, Update 09/18/07.
- Burt, R. K., et al., "The promise of hematopoietic stem cell transplantation for autoimmune diseases," *Bone Marrow Transplantation*, Vol. 31, 2003.
- Durando, X., et al., "High-dose BCNU followed by autologous hematopoietic stem cell transplantation in supratentorial high-grade malignant gliomas: a retrospective analysis of 114 patients," *Bone Marrow Transplantation*, Vol. 31, 2003.
- Gertz, Morie, "Waldenstrom Macroglobulinemia: A Review of Therapy," *American Journal of Hematology*, Vol. 79, 2005, pp. 147-157.
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- *Hayes Medical Technology Directory*, "High-Dose Immunosuppressive Therapy with or without Hematopoietic Transplantation for the Treatment of Severe Autoimmune Disease," (HIGH0202.22), Lansdale, PA: HAYES, Inc., 12/28/2005.
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- *Hayes Medical Technology Directory, "*High-Dose Chemotherapy with Autologous Stem Cell Transplantation, Treatment for Breast Cancer," Lansdale, PA, HAYES, Inc., March 24, 2006.
- Reed, E., et al., "Occult tumor cells detected in autologous blood stem cell harvests have no impact on 5 year outcomes for breast cancer patients with 4-9 positive modes treated with adjuvant high-dose therapy and stem cell transplantation," *Bone Marrow Transplantation*, Vol. 31, 2003.
- Tartarone, A., et al., "Should we continue to study high-dose chemotherapy in metastatic breast cancer patients? A critical review of the published data," *Bone Marrow Transplantation,* Vol. 31, 2003.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 29, 2008, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/17/04	5/17/04	6/10/04	Joint policy established. This policy combines the following policies into one combined document: • Autologous BMT for amyloidosis • Autologous BMT for chronic myelogenous leukemia • Autologous BMT for germ cell tumor of the testes • Autologous progenitor stem cell rescue with HDC for rhabdomyosarcoma • Autologous sten cell support for autoimmune diseases
7/15/05	7/15/05	11/9/05	Routine maintenance
11/1/06	8/25/06	9/13/06	Maintenance review
11/1/07	8/21/07	10/22/07	Routine maintenance
3/1/09	12/9/08	12/30/08	Routine maintenance

Next Review: 1st Qtr, 2010

Pre-Consolidation Medical Policy History

Original Policy Date		Comments
BCN	N/A	Revised: N/A
BCBSM	N/A	Revised: N/A

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BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: AUTOLOGOUS BONE MARROW OR STEM CELL TRANSPLANTS (INVESTIGATIONAL)

I. Short Description

Autologous stem cells (formative cells) are harvested from the patient's own bone marrow or peripheral blood. Chemotherapy and radiotherapy are then given in doses several times greater than the standard therapeutic doses. The most significant adverse effect of high dose chemotherapy and radiation is the depletion of the individual's bone marrow. The administration of the high dose chemotherapy and/or radiotherapy is followed closely by reinfusion of the individual's bone marrow to replenish the bone marrow that was depleted. The safety and effectiveness of these procedures for the diagnoses listed in this policy and those not listed as covered in the related established policy have not been proven.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Not covered
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
BlueCaid	Not covered

Note: All services related to the transplant except evaluation services will not be authorized until/unless the transplant is approved.

III. Administrative Guidelines:

N/A

IV. Effective Dates:

Policy updated: 7/15/05, 11/1/06, 11/1/07, 3/1/09
Joint policy effective date: 4/15/04

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