

Corporate Medical Policy

Bone Marrow Transplant for Autoimmune Diseases

File Name: bone_marrow_transplant_for_autoimmune_diseases
Policy Number: SUR6090.6
Origination: 2/2001
Last Review: 11/2008
Next Review: 11/2010

Description of Procedure or Service

This policy addresses high-dose chemotherapy with [hematopoietic stem-cell](#) support as a treatment of autoimmune diseases. Bone marrow transplants typically include high-dose chemotherapy (HDC).

"High-dose chemotherapy" (HDC) involves the administration of [cytotoxic agents](#) for the treatment of cancer. It uses doses several times greater than the standard therapeutic dose. In some cases, whole body or localized radiotherapy is also given and is included in the term HDC. The rationale for HDC is that many [cytotoxic agents](#) act according to a [steep dose-response curve](#). Thus, small increments in dosage will result in relatively large increases in tumor cell kill. Increasing the dosage also increases the incidence and severity of adverse effects related primarily to bone marrow [ablation](#) (e.g., [opportunistic](#) infections, hemorrhage, organ failure).

Various techniques have been developed to counter the [myelosuppressive](#) effects, and secondary susceptibility to infections of HDC regimens. The main technique is the infusion into the patient of [hematopoietic stem cells](#) to repopulate the bone marrow. [Hematopoietic stem cells](#) are primitive cells capable of replication and formation into mature blood cells. [Stem cells](#) can be [harvested](#) from three sources:

1. Bone marrow cells: Bone marrow [stem cells](#) can be [harvested](#) from a related or unrelated donor.
2. Peripheral [stem cells](#): [Stem cells](#) may be [harvested](#) from the peripheral blood circulation. This may involve several pheresis procedures. Pheresis involves withdrawing blood from a donor in which a portion containing [stem cells](#) is separated and retained with the remainder retransfused back to the donor.
3. [Umbilical cord](#): Blood [harvested](#) from the [umbilical cord](#) and [placenta](#) shortly after the delivery of neonates contains [stem cells](#). Although cord blood is an [allogeneic](#) source, these [stem cells](#) are associated with a lower incidence of rejection or graft versus host disease.

When [harvested](#) from and infused back into the same patient, [stem cells](#) are referred to as [autologous](#). [Stem cells harvested](#) from a healthy, [histocompatible](#) donor and infused into a patient are referred to as [allogeneic](#).

There are over 40 disorders that are recognized as having an autoimmune pathogenesis. Immune suppression is a common treatment strategy for many of these diseases, but some patients do not respond or cannot tolerate long-term immunosuppression. For a select group of patients, HDC with [autologous stem cell](#) support has been investigated as a curative technique.

Policy

BCBSNC will not provide coverage for Bone Marrow Transplant (BMT), high dose chemotherapy

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and [stem cell](#) support for Autoimmune Diseases because it is considered investigational. There is insufficient evidence to objectively conclude that there is a sustainable positive effect on health outcome. BCBSNC does not cover investigational services.

Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.

Benefits Application

Please refer to certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

There may be certificates which exclude benefits for transplantation or for specific diagnoses.

Services for or related to the search for a donor are not covered.

When Bone Marrow Transplant for Autoimmune Diseases are covered

Not applicable.

When Bone Marrow Transplant for Autoimmune Diseases are not covered

HDC and [autologous](#) or [allogeneic stem cell](#) support is considered investigational as a treatment of autoimmune diseases, including, but not limited to: rheumatoid arthritis, systemic lupus erythematosus (SLE), systemic sclerosis (i.e., scleroderma), and multiple sclerosis.

Policy Guidelines

Burt et al recently published results from a large single institute study of 50 patients with systemic lupus erythematosus (SLE) who underwent non-myeloablative autologous bone marrow transplant. The outcomes appear to justify the need for a randomized trial comparing immunosuppression plus autologous bone marrow transplant to standard of care. There are several clinical trials currently recruiting or planned for the study of BMT for scleroderma, lupus, and multiple sclerosis. **R**ecruitment is in process for a phase II/III randomized, open-label multicenter study for patients with severe systemic sclerosis (NCT00545038). Longer term follow-up is needed before conclusions can be reached from study findings.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 38205, 38206, 38230, 38240, 38241, 38242, S2150

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Policy Key Words

Key Words: Bone Marrow Transplant, BMT, Autoimmune Diseases, Rheumatoid Arthritis, Systemic Lupus Erythematosus, SLE, Systemic Sclerosis, Scleroderma, Multiple Sclerosis, High Dose Chemotherapy, HDC, Stem Cell Support, SCS, Autologous, Allogeneic, SUR6090.5

Medical Term Definitions

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.

Allogeneic

genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism.

Autologous

derived from the same organism, i.e., self donation

Cytotoxic agents

drugs which possess a specific destructive action on certain cells; often used to refer to drugs used to fight cancer, such as chemotherapy.

Harvesting

to remove tissues or cells from a donor and preserve for transplantation.

Hematopoietic

pertaining to or effecting the formation of blood cells.

Histocompatible

tissue compatible; donor and recipient are well enough matched that a transplant will be easily accepted.

Myelosuppressive

something that inhibits bone marrow activity, resulting in decreased production of blood cells and platelets.

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.

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.

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Steep dose-response curve

a theory in delivery of cytotoxic agents that small increments in dosage will result in relatively large increases in tumor cell kill.

Stem cells

immature generic blood cells that will mature into the various types of blood cells in the body.

Umbilical cord

a flexible structure through which the umbilical arteries and vein pass and which connects the fetus to the placenta.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 12/1/1999

BCBSA TEC Evaluation, Tab 1, June 2000

BCBSA Medical Policy Reference Manual, 8/18/2000

ECRI Health Technology Assessment; Executive Briefings, Sept. 2000; No. 93

BCBSA TEC Evaluation 2001

BCBSA Medical Policy Reference Manual, 2/15/2002; 8.01.25

Specialty Matched Consultant Advisory Panel - 11/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.25, 7/15/2004

Specialty Matched Consultant Advisory Panel - 11/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.25, 4/25/06

Specialty Matched Consultant Advisory Panel - 11/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.25, 9/11/08

Specialty Matched Consultant Advisory Panel - 11/2008

Policy Implementation/Update Information

1/01 Specialty Matched Consultant Advisory Group.

2/01 Original policy issued.

5/02 Policy statement reaffirmed and reference sources added. Codes 38220 and 38221 added to Billing and Coding section.

2/03 Specialty Matched Consultant Advisory Panel review 11/2002. No change in criteria. Codes 86812-86822 removed; codes 38231 and 86915 deleted and codes 38242, 38205 and 38206 added to the Billing/Coding section. System coding changes.

1/04 Benefits Application and Billing/Coding sections updated for consistency.

2/04 Individual CPT codes listed for CPT code ranges 38240-38242 under Billing/Coding section.

7/29/04 HCPCS code S2150 added to Billing/Coding section.

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- 12/9/04 Specialty Matched Consultant Advisory Panel review 11/29/2004. No change to criteria. Description of Procedure or Service revised. Rationale added in Policy Guidelines section. Policy number added to Policy Key Words section. Hematopoietic and Opportunistic added to Definitions. References added.
- 12/11/06 Specialty Matched Consultant Advisory Panel review 11/6/06. No changes to policy statement. Added the following statement to the "Policy" section; Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions. Updated rationale in "Policy Guidelines" section. References added.
- 12/22/08 Specialty Matched Consultant Advisory Panel review 11/13/2008. No change to policy statement. "Policy Guidelines" section updated. References added.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.
