

## Evidence Based Guideline

# Donor Leukocyte Infusion

**File Name:** donor\_leukocyte\_infusion  
**Guideline Number:** EBG.MED1105  
**Origination:** 1/2001  
**Last Review:** 4/2007

**Active guideline, no longer scheduled for routine literature review.**

### Description of Procedure or Service

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Donor [leukocyte](#) infusion (DLI) is a form of adoptive immunotherapy in which a patient with a hematologic malignancy who has previously received an allogeneic bone marrow transplant has relapsed. The leukocytes are obtained from the original bone marrow donor through a [leukapheresis](#) procedure. The principle use of donor leukocyte infusion (also known as donor lymphocyte or buffy coat transfusion) is to induce a graft-versus-tumor response by introducing white blood cells from the donor to the patient. The objective is for the donor leukocyte cells to recognize the cancer cells and destroy them. This differs from a repeat bone marrow transplant in that no chemotherapy is given prior to the infusion and the T-cells (which are part of the body's immune system and fight infection) are not depleted. Donor leukocyte infusion in this situation is considered a salvage therapy at the time of relapse.

Donor leukocyte infusions have been proposed for a variety of hematologic malignancies including chronic myeloid leukemia, multiple myeloma, acute myeloid leukemia, acute lymphocytic leukemia, multiple myeloma, chronic lymphocytic leukemia, myelodysplastic syndromes, Hodgkin's disease, and non-Hodgkin's lymphoma.

Research is also being done related to genetic modification of donor leukocytes. This approach is an attempt to prevent graft-versus-host-disease while preserving the graft-versus-tumor effect.

### Evidence Based Guideline for Donor Leukocyte Infusion

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Donor [leukocyte](#) infusion may be appropriate as treatment for a patient with a hematologic malignancy who has relapsed after a prior [allogeneic](#) bone marrow transplant for Acute Myelogenous Leukemia, Hodgkin's Disease, Chronic Myelogenous Leukemia, and Acute Lymphocytic Leukemia.

See Also:

Bone Marrow Transplant for Acute Myelogenous Leukemia, policy number SUR6090.4

Bone Marrow Transplant for Hodgkin's Disease, policy number SUR6090.12

Bone Marrow Transplant for Chronic Myelogenous Leukemia, policy number SUR6090.8

Bone Marrow Transplant for Acute Lymphocytic Leukemia, policy number SUR6090.3

## Policy: Donor Leukocyte Infusion

### Medical Evidence regarding Donor Leukocyte Infusion indicates it is not recommended in the following situations:

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Donor [leukocyte](#) infusion is not recommended as a treatment for other malignancies that have relapsed after prior allogeneic bone marrow (or stem cell) transplant.

Genetic modification of donor leukocytes is not recommended. The use of genetically modified donor leukocytes continues to be investigated for more efficient gene transfer protocols as well as for its potential use in the treatment of a range of hematological malignancies.

### Benefits Application

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Please refer to certificate for availability of benefit. This guideline 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.

### Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 38242, 86950*

### Medical Term Definitions

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#### **Allogeneic**

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

#### **Leukocytes**

white blood cells.

#### **Leukapheresis**

a process to remove white blood cells from the body. Patients have one large catheter placed in each arm. Blood flows from one arm, through a machine which removes the white blood cells, leaving the red blood cells and fluids. These return to the body through the catheter in the other arm. The white blood cells can be treated, for use in the same patient, or transfusion to another patient.

### Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual, 1/30/1998

Specialty Matched Consultant Advisory Panel - 6/2001

BCBSA Medical Policy Reference Manual, 2/15/2002; 2.03.03

BCBSA Medical Policy Reference Manual, 12/18/02; 2.03.03

Specialty Matched Consultant Advisory Panel - 6/2003

## Policy: Donor Leukocyte Infusion

Specialty Matched Consultant Advisory Panel - 4/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.03, 4/1/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.03, 9/27/05

Specialty Matched Consultant Advisory Panel - 4/2007

### Policy Implementation/Update Information

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- 2/01 Original Policy Issued.
- 6/01 Specialty Matched Consultant Advisory Panel review. No change in criteria.
- 5/02 Policy criteria revised. Added indication under when it is covered to include acute myelogenous leukemia. Removed indications under when it is not covered to include acute myeloid leukemia and chronic lymphocytic leukemia as no longer investigational. Added statement that genetic modification of donor leukocytes is considered investigational.
- 6/03 Specialty Matched Consultant Advisory Panel review. No criteria changes. Code 36520 deleted and code 38242 added to Billing/Coding section.
- 3/04 Benefits Application and Billing/Coding sections updated for consistency.
- 5/5/05 Specialty Matched Consultant Advisory Panel review 4/14/2005. "Description of Procedure or Service" section updated. Under the "When covered" section removed "in the chronic phase" from statement. Under the "When not covered" section added diagnosis "chronic lymphocytic leukemia", no change in statement intent. Added rationale to "Policy Guidelines" section. Key words added. References added.
- 6/2/05 References added.
- 5/21/07 Specialty Matched Consultant Advisory Panel review 4/25/2007. Revised "Description" section. Medical policy changed to evidence based guideline. Status changed to Active guideline, no longer scheduled for routine literature review.

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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.