

## Corporate Medical Policy

### Adoptive Immunotherapy

**File Name:** adoptive\_immunotherapy  
**Policy Number:** MED1010  
**Origination:** 11/1993  
**Last Review:** 3/2008  
**Next Review:** 3/2010

#### Description of Procedure or Service

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Adoptive immunotherapy (AIT) is a cancer treatment in which a patient's white blood cells are taken out of the body, specially treated, and then injected back into the body to help the body's immune system fight cancer. There are three types of adoptive immunotherapy.

- ◆ 1. Lymphokine - activated killer (LAK) cell therapy: The patient's white blood cells are taken from the person's blood by a process called [leukopheresis](#). The cells are then treated in the lab with interleukin-2 (IL-2) to produce LAK cells. The stimulated cells are then injected back into the patient to help the body's immune system fight the cancer.
- ◆ 2. Tumor-infiltrating lymphocyte (TIL) therapy: White blood cells are dissected from tumors that have been surgically removed from the patient. The white blood cells are then treated with interleukin-2 (IL-2). They are stimulated by the interleukin-2 to become more aggressive at fighting the cancer. The cells are then injected back into the patient's body.
- ◆ 3. Autolymphocyte therapy (ALT) (transfer of specific immune cells): Special white blood cells, identified as [T-cells](#) or [dendritic cells](#) are collected from the patient. [T-cells](#) are exposed in the lab to a combination of OKT3 monoclonal antibodies and interleukin-2 (IL-2). The cells are then injected back into the patient to help the body's immune system fight the cancer. A variation to this process uses [dendritic cells](#) exposed to a variety of [antigens](#). When reinfused back to the patient these [dendritic cells](#) act as potent immunostimulators to the native [T-cells](#) again helping the body to fight the cancer.

#### Policy

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**BCBSNC will not provide coverage for Adoptive Immunotherapy. It is considered investigational. 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

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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.

## Policy: Adoptive Immunotherapy

### When Adoptive Immunotherapy is covered

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Not applicable. It is considered investigational and BCBSNC does not cover investigational services.

### When Adoptive Immunotherapy is not covered

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When it is considered investigational. BCBSNC does not provide coverage for investigational services, including the following:

1. For adoptive immunotherapy with lymphokine-activated killer (LAK) cells or tumor infiltrating lymphocytes (TILs) or [antigen](#)-loaded [dendritic cells](#) for advanced renal cell carcinoma, melanoma or other malignancies
2. For Autolymphocyte therapy (ALT) using peripheral [T-cells](#) stimulated with OKT3 monoclonal antibody in conjunction with IL-2
3. For any other applications of adoptive immunotherapy

### Policy Guidelines

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A recent literature search did not find any published studies that has shown conclusive scientific evidence of safety and efficacy for use of adoptive immunotherapy. There are several NIH sponsored phase I and II trials utilizing various immunotherapy sources for a variety of cancers. However, all the current trials are in their early phases and the long term effect on health outcomes are unknown at this time.

### 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 Code: S2107*

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

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Key Words: Adoptive immunotherapy for advanced renal cell carcinoma, cancer, immune system, MED1010.

## Medical Term Definitions

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### Antigen

any substance that the body regards as foreign or potentially dangerous. The body produces antibodies

### Dendritic Cells

develop from large white blood cells and reside mainly in tissues. Newly developed dendritic cells ingest and break [antigens](#) into fragments so that other immune cells can recognize them—an activity called [antigen](#) processing. A dendritic cell matures after it is stimulated and moves to the lymph nodes to generate a specific immune response.

### Leukopheresis

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.

### T-cells

a type of white blood cell (lymphocyte). It is called T-cell because it is derived from the thymus gland. Its function is to control cell mediated immune reactions.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual - 12/95

BCBSA Medical Policy Reference Manual - 4/98

Medical Policy Advisory Group - 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

Specialty Matched Consultant Advisory Panel - 6/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 12/17/03.

ECRI. (1994) Interleukin-2 for the treatment of renal cell carcinoma. Executive Briefing. Retrieved on 4/7/2004 from [https://members.ecri.org/members/\\_elements/exec\\_brief/exec\\_docs/oexb36.asp](https://members.ecri.org/members/_elements/exec_brief/exec_docs/oexb36.asp).

ECRI. (1994) Interleukin-2 for the treatment of malignant melanoma. Executive Briefing. Retrieved on 4/7/2004 from [https://members.ecri.org/members/\\_elements/exec\\_brief/exec\\_docs/oexb35.asp](https://members.ecri.org/members/_elements/exec_brief/exec_docs/oexb35.asp).

Specialty Matched Consultant Advisory Panel - 5/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 3/15/05.

Specialty Matched Consultant Advisory Panel - 3/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 3/7/06.

Specialty Matched Consultant Advisory Panel - 3/2008

## Policy: Adoptive Immunotherapy

### Policy Implementation/Update Information

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- 11/93 Evaluated: Investigational in treatment of advanced renal cell carcinoma
- 7/96 Reaffirmed: National Association reviewed 12/95. No changes.
- 3/99 Revised: Added investigational indications. Reaffirmed by MPAG.
- 6/99 Reformatted, Description of Procedure or Service revised, Medical Term Definitions added.
- 7/00 System coding changes.
- 10/00 Specialty Matched Consultant Advisory Panel review. No change recommended in criteria. Medical Policy Advisory Group review. No change in criteria. Approve.
- 11/01 Coding format change.
- 6/02 Specialty Matched Consultant Advisory Panel. No changes. Approve.
- 1/03 Code S2107 added and code 36520 deleted from Billing/Coding section. System coding changes.
- 12/03 Benefits Application and Billing/Coding Sections updated for consistency.
- 6/10/04 Specialty Matched Consultant Advisory Panel review. No change to criteria. References added. Notification given 6/10/2004. Effective date 8/12/2004.
- 4/10/06 Specialty Matched Consultant Advisory Panel review 3/15/2006. No change to policy. Added information pertaining to dendritic cells to "Description of Procedure or Service" section. Added reference to dendritic cells under #1 in the "When not covered" section. Rationale added to "Policy Guidelines" section. References added.
- 6/2/08 Specialty Matched Consultant Advisory Panel review 3/17/2008. No change to policy statement. Added reference to Clinical Trials policy in "Policy" section. References added.

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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.

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