IMMUNOTHERAPY, ADOPTIVE

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Adoptive immunotherapy (AIT) is a term describing treatment to boost an individual’s immune system using the individual’s own lymphocytic cells which are treated to become more aggressive at fighting cancer. With AIT, the individual’s lymphocytes are removed from the body, specially treated and reinfused into the body. AIT has been investigated in the treatment of various cancers and viruses. Adoptive immunotherapy may also be referred to as cellular adoptive immunotherapy and adoptive cell transfer.
IMMUNOTHERAPY, ADOPTIVE (cont.)

Description: (cont.)

The transfer (removal, treatment and replacement) of the lymphocytic cells takes places using either adoptive cellular therapy (ACT) or through antigen-loaded dendritic cell infusions. The common steps in ACT are:

- Lymphocyte harvesting from tumor biopsy or peripheral blood
- Reproduction of tumor specific lymphocytes in vitro using various immune modulators
- Selection of lymphocytes with reactivity to common tumor antigens with ELISA
- Lymphodepletion with immunosuppressive agents
- Transfusion of lymphocytes back into the individual

Originally, lymphokine-activated killer cells (LAK) were taken peripherally and activated in vitro with interleukin-2 (IL-2) and other cytokines. Newer techniques include the use of autologous dendritic cells (ADC) or tumor-infiltrating lymphocytes (TIL) or cytokine-induced killer (CIK) cells. If the lymphocytes are harvested from peripheral blood, ADC pulsed with tumor antigens are used to propagate the lymphocytes. If the lymphocytes are collected from the tumor biopsy, these TIL are propagated with IL-2 and OKT3.

Criteria:

- Adoptive immunotherapy is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
IMMUNOTHERAPY, ADOPTIVE (cont.)

Resources:


IMMUNOTHERAPY, ADOPTIVE (cont.)

Resources: (cont.)


