Adoptive Immunotherapy

DESCRIPTION

The spontaneous regression of certain cancers supports the idea that an individual's immune system is sometimes capable of delaying tumor progression and, on rare occasions, can eliminate tumors altogether. These observations have led to research into various immunologic therapies designed to stimulate the individual's own immune system. Adoptive immunotherapy is a method of activating lymphocytes and/or other types of cells for the treatment of cancer and other diseases. Cells are removed from the individual, processed, and reinfused.

These therapies can be categorized into active specific (e.g., increasing select populations of cytotoxic T lymphocytes with specific reactivity to tumor antigens), active non-specific (i.e., the use of interleukin-2 to increase the number of activated lymphocytes), and passive immunotherapy (i.e., transfer of specific immune cells such as cytotoxic T-lymphocytes or lymphokine-activated killer cells to produce antibodies). Protocols vary, but usually include these common steps:

1. Lymphocyte harvesting (either from peripheral blood or from tumor biopsy)
2. Propagation of tumor-specific lymphocytes in vitro using various immune modulators
3. Selection of lymphocytes with reactivity to tumor antigens with enzyme-linked immunosorbent assay
4. Lymphodepletion of the host with immunosuppressive agents
5. Adoptive transfer (i.e., transfusion) of lymphocytes back into the tumor-bearing host

The proposal is to add words or statements in red and delete words or statements with a strike through

POLICY

- ~~Adoptive immunotherapy, using adoptive cellular therapy for the administration of cytotoxic T lymphocytes, cytokine-induced killer cells, tumor-infiltrating lymphocytes, antigen-loaded autologous dendritic cells, or genetically engineered T cells for treatment of malignancy, is considered ***investigational.***~~
- Adoptive immunotherapy techniques intended to enhance autoimmune effects, including, but not limited to, the following is considered ***investigational***:
  - Cancers associated with Epstein-Barr virus
  - Cytomegalovirus-associated cancers
  - Nasopharyngeal cancer
  - Renal Cell carcinoma
  - Gastric cancer
  - Colorectal Cancer
  - Hepatocellular carcinoma
  - Non-small lung cancer
  - Melanoma
  - Glioblastoma multiforme
  - Medullary thyroid cancer
  - Pancreatic cancer
  - Treatment of cancer using autologous tumor antigen-specific TCR-engineered T cells

  (**Note:** except for therapies (e.g., axicabtagene ciloleucel (Yescarta™), and tisagenlecleucel (Kymriah®) that are addressed separately in BCBST pharmacy policies as ***medically necessary***)

IMPORTANT REMINDERS

This document has been classified as public information

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

~~The evidence for adoptive immunotherapy in individuals with various types of cancer includes randomized controlled trials (RCTs), nonrandomized comparative studies, and uncontrolled trials. The impact of adoptive immunotherapy on health outcomes (e.g., increased survival, improved quality of life) has yet to be clarified. Current guidelines from the National Comprehensive Cancer Network (NCCN) do not include recommendations for adoptive immunotherapy.~~ The evidence supporting adoptive immunotherapy varies according to the type of cellular therapy, malignancy, and clinical indication. Certain adoptive cellular therapies have received FDA approval for specific malignancies and individual populations. For other applications, available evidence remains insufficient to determine that adoptive immunotherapy improves net health outcomes; therefore, these uses are considered investigational.

SOURCES

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EFFECTIVE DATE

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