BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

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AMEVIVE® (alefacept)

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.

Description:

Amevive is an immunosuppressive dimeric fusion protein that consists of the extracellular CD2-binding portion of the human leukocyte function antigen-3 (LFA-3) linked to the Fc (hinge, CH2 and CH3 domains) portion of the human IgG1. Alefacept is produced by recombinant DNA technology in a Chinese Hamster Ovary (CHO) mammalian cell expression system. Amevive interferes with lymphocyte activation by specifically binding to the lymphocyte antigen, CD2, and inhibiting LFA-3/CD2 interaction.

Definitions:

Adult: Age 18 years and older

AMEVIVE (alefacept) (cont.)

Criteria:

See "Resources" section for FDA-approved dosage.

- FDA-approved dosage of Amevive is considered ***medically necessary*** for the treatment of adults with moderately to severely active chronic plaque psoriasis who are candidates for phototherapy or systemic therapy with documentation of **ALL** of the following:

  1. Failure to respond to **ONE** of the following conventional therapies (unless otherwise contraindicated) or an inadequate response (as defined by prescribing provider):

     - Systemic therapy (Cyclosporin **or** Methotrexate **or** Retinoids)
     - PUVA therapy
     - Phototherapy

  2. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  3. CD4+ T Lymphocyte counts are normal. The CD4+ T Lymphocyte counts of individuals receiving Amevive should be monitored every two weeks throughout the course of the 12-week dosing regimen. If CD4+ T Lymphocyte counts are below 250 cells/µL, Amevive dosing should be withheld and weekly monitoring instituted. Amevive should be discontinued if the counts remain below 250 cells/µL for one month.
  4. No evidence of HIV
  5. No evidence of active or history of systemic malignancy
  6. Amevive is not being used concurrently with other immunosuppressive agents, phototherapy or live vaccines
  7. Dosage is not greater than the FDA approved dosing for the labeled indication (refer to dosing table)

- Amevive for all other indications not previously listed or if above criteria not met 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.

Resources:

1. Biologics & Non-TNF Agents Potentially Winners in the New ACR Guidelines for Early & Experienced Rheumatoid Arthritis (RA) Patients. Specialty Pharma Journal. Received 06/11/2012

AMEVIVE (alefacept) (cont.)

Resources: (cont.)

Amevive Package Insert.

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderate to severe chronic plaque psoriasis	Used under the guidance and supervision of a physician. Amevive is administered by intramuscular injection. Dose is 15mg once weekly. The recommended regimen is a course of 12 weekly injections. Retreatment with an additional 12-week course may be initiated provided that CD4+T lymphocyte counts are within the normal range, and a minimum of a 12-week interval has passed since the previous course of treatment.

Adult: Age 18 years and older