

Specialty Pharmacy Program

Amevive® (alefacept)

CLINICAL BACKGROUND

Psoriasis is a chronic inflammatory skin disease. Psoriasis is classified as mild, moderate, or severe, depending on disease activity, location and amount of body surface area (BSA) involved, response to prior treatment, and psychosocial impact. In mild psoriasis, the area involved may be localized to small, discrete areas of the body or less than 3% to 5% of the BSA. Moderate to severe psoriasis may affect a greater BSA, nails, mucous membranes, joints, or the entire body. Psoriasis affecting only a small BSA may still be significant if it causes substantial disruption in daily activities and work or affects crucial body areas such as the hands, feet, face or genitals.

Psoriasis is treated with topical therapies, phototherapy, and systemic agents. Therapies may be used alone or in combination to achieve control of disease. The biologic response modifiers, or biologics, are the newest options for psoriasis management. They work by targeting overactive T-cells that cause skin cells to multiply uncontrollably.

Amevive is a biologic agent that prevents activation of T cells by binding to CD2 receptors on the surface of T cells. Amevive is indicated for adult patients (≥ 16 years of age) with a diagnosis of moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

Amevive reduces CD4+ T cell counts and patients must have a normal CD4+ T cell count and no clinically important infection before initiating therapy. Amevive should not be used in patients with human immunodeficiency virus infection. CD4+ T cell count should be monitored routinely during therapy. Because of the risk for excessive immunosuppression, Amevive should not be used in combination with other biologics or other immunosuppressive agents. Amevive should be used with caution in patients at high risk for cancer.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

Off-Label Indication(s)

Requests for off-label use of Amevive will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.