



PHARMACY PRIOR AUTHORIZATION Clinical Guideline Amevive® (alefacept)

FDA Indications
Plaque psoriasis: Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.
Dosage Forms
<ul style="list-style-type: none"> • IV administration: 7.5 mg single-use vial available in four administration or 1 administration dose packs • IM administration: 15-mg single-use vials available in four administration or 1 administration dose packs
Dosage
<p>7.5 mg given once weekly as an IV bolus or 15 mg given once weekly as an IM injection. The recommended regimen is a course of 12 weekly injections. The CD4 T lymphocyte counts should be monitored every two weeks during the 12-week dosing period and used to guide dosing. Patients should have normal CD4 T lymphocyte counts prior to an initial or a subsequent course of treatment. If CD4 T lymphocyte counts are below 250 cells/μL, treatment should be withheld and weekly monitoring instituted. Amevive should be discontinued if CD4 T lymphocyte counts remain below 250 cells/μL for one month.</p> <p>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.</p>
Authorization Guidelines
<p>Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines to assess the medical necessity of the request for a prescription for Amevive. If the guidelines are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.</p>
<ul style="list-style-type: none"> • For patients with a <u>documented diagnosis</u> of moderate to severe chronic plaque psoriasis who meet all of the following: <ul style="list-style-type: none"> ➤ Has CD4 positive T lymphocyte counts \geq 250 cells/μL ➤ Does not have hypersensitivity to Amevive or any of its components ➤ Does not have human immunodeficiency virus (HIV) infection or acquired immunodeficiency syndrome (AIDS) ➤ No active infections as documented in medical records for patients with a history of recurrent infections or an underlying condition that may predispose them to infections (i.e., advanced or uncontrolled diabetes mellitus, malignancy, immunosuppression [including long term corticosteroid therapy]) ➤ Concurrently not receiving live vaccines. Live virus vaccines should not be given concurrently with alefacept due to the possibility of secondary transmission of infection

by the vaccine.

- No active or latent tuberculosis infection per medical records
- Has a body surface area (BSA) of 10% or more that is affected OR Involvement of < 10% in critical areas (palms, soles, genitals or face) that interferes with daily activities
- Trial and failure of UVB therapy or documentation showing contraindication to therapy;
- Trial and failure of a compliant regimen of methotrexate for three consecutive months or documentation showing contraindication to therapy;
- Trial and failure of a compliant regimen of Enbrel or Humira for three consecutive months or documentation showing contraindication to therapy

Prior Authorization Requirements

Initial Approval

- 3 months (Amevive should be discontinued if the counts remain below 250 cells/ μ L for one month)
- Supporting medical records (e.g., baseline CD4 count)
- Review of Rx history

Renewal

- 3 months
- Break in treatment period of a minimum of a 12-week interval since the previous course of treatment
- Medical records supporting response to therapy and CD4 counts within normal range
- Review of Rx history

References

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4. Kraan MC, van Kuijk AW, Dinant HJ, et al. Alefacept treatment in psoriatic arthritis: Reduction of the effector T cell population in peripheral blood and synovial tissue is associated with improvement of clinical signs of arthritis. *Arthritis Rheum*. 2002;46(10):2776-2784.
5. Gottlieb, A, Korman NJ, Gordon KB et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008;58(5):826-850. Available at: http://www.aad.org/research/_doc/Psosection1.pdf. Accessed March 2, 2009.
6. Gottlieb, A, Korman NJ, Gordon KB et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol*. 2008;58(5):851-864. Available at: http://www.aad.org/research/_doc/PsoPsAsection2.pdf. Accessed March 2, 2009
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