

Corporate Medical Policy

Alefacept Injection (Amevive)

| | |
|-------------------------|-----------------------------|
| File Name: | alefacept_injection_amevive |
| Origination: | 3/2009 |
| Last CAP Review: | 1/2012 |
| Next CAP Review: | 1/2013 |
| Last Review: | 1/2012 |

Description of Procedure or Service

Plaque psoriasis is the most common form of psoriasis. It is characterized by raised, inflamed, red lesions covered with a silvery-white buildup of dead skin cells (scales). This is found primarily on the trunk, elbows, knees, scalp and finger or toe nails. The cause of psoriasis is related to the immune system, and more specifically, a type of white blood cell called a T lymphocyte or T cell. Normally, T cells travel throughout the body to detect and fight off foreign substances, such as viruses or bacteria. If you have psoriasis, however, the T cells attack healthy skin cells by mistake as if to heal a wound or to fight an infection. Normally, skin cells mature and shed after about a month. In psoriasis, the cell maturation speeds up, taking only three to four days. Because the lower layer of skin cells divides more rapidly than normal, dead cells accumulate in thicker patches on the skin's outermost layer (called the epidermis). Chief complaints of patients with moderate to severe psoriasis include scaling, itching, redness, and tightness of the skin with burning sensations. Exposed skin, especially cracked or bleeding areas, can act as potential sites of infection.

Initial treatment for stable plaque psoriasis is topical, including corticosteroids, emollients, anthralin, tar, retinoids, calcipotriene (Vitamin D analogue), and salicylic acid. Though corticosteroids are the mainstay of topical therapy, continuous use of these agents can cause tachyphylaxis (wearing off effect) and several side effects. Other treatments for plaque psoriasis include phototherapy, immunosuppressants, and systemic retinoids.

Biologic drugs are taken from living material (human, plant, animal, or microorganism). Many biologics act on parts of the body's immune system to prevent inflammatory disorders, including psoriasis. Unlike drugs that suppress the entire immune system, biologics can fight more selectively and target only those chemicals involved in causing psoriasis. Only recently have biologics targeted toward psoriasis begun to emerge as potentially promising new treatment options.

Amevive®(alefacept) is a biologic drug that treats plaque psoriasis and is used either after the conventional treatments mentioned above have failed in continuing to provide benefit or when a patient is not able to receive conventional therapy (drug and phototherapy).

Efficacy of psoriasis therapy is determined by a 75% reduction in the psoriasis area severity index (PASI). PASI scores are based on an assessment of the percentage of involvement of the scalp, trunk, and upper and lower limbs. This is combined with an evaluation of skin erythema (redness), induration (thickness), and scaling. PASI scores can range between 0 and 72, with a score greater than 10-12 considered severe disease. Typically, PASI scores are used in an academic setting. In practice, physician assessment along with patient response, are used to gauge response to treatment.

Amevive® (alefacept) is administered via IM injection in the physician's office.

Alefacept Injection (Amevive)

NOTE*This policy only applies to Amevive® (alefacept) when used for the treatment of moderate to severe plaque psoriasis.**

Please also refer to the following Corporate Medical Policies for treatment of psoriasis:

- Targeted Phototherapy for Psoriasis
- PUVA (Psoralens with Ultraviolet A) Therapy
- Ultraviolet Light Box Therapy in the Home
- Infliximab

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Amevive® (alefacept) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Coverage for Amevive® (alefacept) requires prior review.

When Alefacept Injection (Amevive) is covered

Initial Coverage review for Amevive®(alefacept):

1. Benefits for an initial 3 month period of time may be considered medically necessary for the treatment of moderate to severe plaque psoriasis:
 - a. In patients who are 18 years of age or older; **and**
 - b. In situations where the patient has already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless the patient is not a candidate for phototherapy or phototherapy is not available to the patient; **and**
 - c. In situations where the patient has already been treated with or is not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporin, and acitretin (Soriatane®).

Continuation of coverage for Amevive®(alefacept) beyond 3 months:

1. In situations where treatment continues to provide improvement in the plaque psoriasis, coverage is renewable for an additional 3 months following a 3-month period of time where the patient is not receiving Amevive®(alefacept).
2. Coverage is provided for up to two 3-month treatment cycles per lifetime.

Alefacept Injection (Amevive)

When Alefacept Injection (Amevive) is not covered

1. When the criteria stated above are not met.
2. Coverage is not provided for the simultaneous use of more than one biologic drug.
3. Amevive®(alefacept) is contraindicated in and should not be administered to patients infected with HIV. Amevive®(alefacept) reduces CD4+ lymphocyte counts, which might accelerate disease progression or increase complications of disease in these patients.
4. Amevive®(alefacept) is contraindicated in and should not be administered to patients with known hypersensitivity to Amevive®(alefacept) or any of its components.

Policy Guidelines

In the approved labeling for Amevive®(alefacept), the FDA is encouraging physicians to inform patients of the need for regular monitoring of white blood cell counts during therapy and that Amevive®(alefacept) must be administered under the supervision of a physician. Moreover, the approved labeling states that patients should be informed that Amevive®(alefacept) suppresses their immune system, which could increase their chances of developing an infection or malignancy. Therefore, patients should inform their physician promptly if they develop any signs of an infection or malignancy while undergoing a course of treatment with Amevive®(alefacept).

Women of childbearing potential make up a considerable segment of the patient population affected by psoriasis. Because the effect of Amevive®(alefacept) on pregnancy and fetal development, including immune system development, is not known, health care providers are encouraged to enroll patients taking Amevive®(alefacept) who become pregnant into the manufacturer's pregnancy registry by calling 1-866-AMEVIVE (263-8483).

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J0215

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Menter A, Gottlieb A, Feldman SR, 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 May;58(5):826-50.

The U.S. Food and Drug Administration. Center for Drug Evaluation and Research. FDA Talk Paper. FDA Approves First Biologic Therapy for Psoriasis. January 31, 2003. Retrieved on March 4, 2009 from <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01194.html>

Alefacept Injection (Amevive)

The U.S. Food and Drug Administration. Center for Drug Evaluation and Research. Drugs@FDA FDA Approved Drug Products. Label and Approval History for Amevive retrieved on March 4, 2009 from <http://www.fda.gov/cder/foi/label/2006/125036s0711bl.pdf>

Dunn KL, Feldman SR. Alefacept Treatment for Chronic Plaque Psoriasis. *Skin Therapy Lett.* 2010 Apr;15(4):1-3. Retrieved on December 7, 2010 from <http://www.skintherapyletter.com/2010/15.4/1.html>

National Institutes of Health (NIH). Assess the Long-term Effectiveness and Safety of Amevive (Alefacept) in Subjects With Moderate to Severe Chronic Plaque Psoriasis (AWARE-2). Clinical Trial #NCT00795353. Retrieved on December 7, 2010 from <http://www.clinicaltrials.gov/ct2/show/NCT00795353>

Specialty Matched Consultant Advisory Panel review 1/2011

Medical Director Review 1/2012

Specialty Matched Consultant Advisory Panel review 1/2012

Policy Implementation/Update Information

- 3/30/09 New policy developed. Amevive® (alefacept) injection for the treatment of psoriasis requires prior plan approval. Benefits for an initial 3 month period of time may be considered medically necessary: 1) In patients who are 18 years of age or older; and 2) In situations where the patient has already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless the patient is not a candidate for phototherapy or phototherapy is not available to the patient; and 3) In situations where the patient has already been treated with or is not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporin, and acitretin (Soriatane®). Continuation of coverage may be provided (in situations where treatment is continuing to provide improvement in the plaque psoriasis) for an additional 3 months following a 3-month period of time where the patient is not receiving Amevive® (alefacept). Coverage is provided for up to two 3-month treatment cycles per lifetime. Amevive® (alefacept) is not covered when the criteria stated above are not met. Coverage is not provided for the simultaneous use of more than one biologic drug. Amevive®(alefacept) is contraindicated in and should not be administered to patients infected with HIV. Amevive®(alefacept) reduces CD4+ lymphocyte counts, which might accelerate disease progression or increase complications of disease in these patients. Amevive®(alefacept) is contraindicated in and should not be administered to patients with known hypersensitivity to Amevive®(alefacept) or any of its components. Notification given 3/30/09. Effective date 7/1/09. (pmo)
- 6/22/10 Policy Number(s) removed. (amw)
- 2/15/11 Specialty Matched Consultant Advisory Panel review 1/2011. References updated. (mco)
- 2/7/12 Specialty Matched Consultant Advisory Panel review 1/2012. Medical Director review 1/2012. No changes to Policy Statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of

Alefacept Injection (Amevive)

disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.