

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	1
1.1	Medical Term Definitions.....	2
2.0	Eligible Recipients.....	3
2.1	General Provisions.....	3
3.0	When the Procedure, Product, or Service Is Covered.....	3
3.1	General Criteria.....	3
3.2	Specific Criteria.....	3
4.0	When the Procedure, Product, or Service Is Not Covered.....	3
4.1	General Criteria.....	3
4.2	Specific Criteria.....	4
5.0	Requirements for and Limitations on Coverage.....	4
5.1	Prior Approval.....	4
5.2	Continuation of Coverage for Amevive (Alefacept) Beyond 3 Months.....	4
6.0	Providers Eligible to Bill for the Procedure, Product, or Service.....	4
7.0	Additional Requirements.....	4
7.1	Compliance.....	4
7.2	Other.....	5
	Policy Implementation/Revision Information.....	5
	Attachment A: Claims-Related Information.....	6
A.	Claim Type.....	6
B.	Diagnosis Codes.....	6
C.	Procedure Code(s).....	6
D.	Modifiers.....	6
E.	Billing Units.....	6
F.	Place of Service.....	6
G.	Co-payments.....	6
H.	Reimbursement.....	6

1.0 Description of the Procedure, Product, 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 recipients 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® (alefcept) 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 recipient 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 recipient response, are used to gauge response to treatment.

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

In the approved labeling for Amevive® (alefcept), the FDA is encouraging physicians to inform recipients of the need for regular monitoring of white blood cell counts during therapy and that Amevive® (alefcept) must be administered under the supervision of a physician. Moreover, the approved labeling states that recipients should be informed that Amevive® (alefcept) suppresses

their immune system, which could increase their chances of developing an infection or malignancy. Therefore, recipients should inform their physician promptly if they develop any signs of an infection or malignancy while undergoing a course of treatment with Amevive®(alefacept).

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

1.1 Medical Term Definitions

- a. Accelerate: to cause to move faster or speed up.
- b. Bacteria: single-celled microorganisms which can exist either as independent (free-living) organisms or as parasites (dependent upon another organism for life).
- c. Corticosteroids: drugs that reduce inflammation and the turnover of skin cells, and suppress the immune system. Available in different strengths, topical corticosteroids (cortisone) are usually applied twice a day.
- d. Emollient: an agent that softens or soothes the skin.
- e. Hypersensitivity, allergy: the body's over-reaction to a foreign substance.
- f. Immune system: the bodily system that protects the body from foreign substances, cells, and tissues by producing the immune response and that includes especially the thymus, spleen, lymph nodes, special deposits of lymphoid tissue (as in the gastrointestinal tract and bone marrow), lymphocytes including the B cells and T cells, and antibodies.
- g. Immunosuppressant: an agent that can suppress or prevent the immune response. Immunosuppressants are used to prevent rejection of a transplanted organ and to treat autoimmune diseases such as psoriasis, rheumatoid arthritis, and Crohn's disease. Some treatments for cancer act as immunosuppressants. Also called an immunodepressant.
- h. Phototherapy: treatment with light.
- i. Suppress: to curtail or inhibit the activity of something, such as the immune system.
- j. Systemic treatment: treatment that reaches cells throughout the body by traveling through the bloodstream; treatment that affects the body's whole system; re: psoriasis, involves taking medicines by mouth or injection that treat the whole immune system.
- k. T cells: a type of white blood cell (lymphocyte) that is of key importance to the immune system and is at the core of adaptive immunity, the system that tailors the body's immune response to specific pathogens. T cells are like soldiers who search out and destroy the targeted invaders. T cells are also known as T lymphocytes. The "T" stands for "thymus" -- the organ in which these cells mature. As opposed to B cells which mature in the bone marrow.
- l. Topical: applied locally or to the skin, affecting only the area to which it is applied.
- m. Virus: the causative agent of an infectious disease.
- n. White blood cell: any of the blood cells that are colorless, lack hemoglobin, contain a nucleus, and include the lymphocytes, monocytes, neutrophils, eosinophils, and basophils.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Benefits for Amevive®(alefacept) for an initial 3 month period of time may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when ALL of the following criteria are met:

- a. The recipient is 18 years of age or older;
- b. The recipient has already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless the recipient is not a candidate for phototherapy or phototherapy is not available to the recipient; **AND**
- c. The recipient 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®)."

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Benefits for Amevive® (alefacept) may not be covered:

- a. When the criteria in **Subsection 3.2** are not met
- b. Coverage is not provided for the simultaneous use of more than one biologic drug.
- c. Amevive® (alefacept) is contraindicated in and should not be administered to recipients infected with HIV. Amevive® (alefacept) reduces CD4+ lymphocyte counts, which might accelerate disease progression or increase complications of disease in these recipients.
- d. Amevive® (alefacept) is contraindicated in and should not be administered to recipients with known hypersensitivity to Amevive® (alefacept) or any of its components.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for Alefacept Injection (Amevive)

5.2 Continuation of Coverage for Amevive (Alefacept) Beyond 3 Months

- a. In situations where treatment is continuing to provide improvement in the plaque psoriasis, coverage for Amevive® (alefacept) may be renewable for an additional three (3) months following a three (3) month period of time when the recipient is not receiving Amevive® (alefacept).
- b. Coverage is limited to a maximum of two (2) three-month treatment cycles per lifetime.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

7.2 Other

Women of childbearing potential make up a considerable segment of the recipient 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 recipients taking Amevive®(alefacept) who become pregnant into the manufacturer's pregnancy registry by calling 1-866-AMEVIVE (263-8483).

Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

ICD-9-CM
696.1

C. Procedure Code(s)

HCPCS Code
J0215

Note: Refer to Subsection 5.1

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Office

G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

H. Reimbursement

Coverage is limited to a maximum of two (2) three-month treatment cycles per lifetime. The second cycle must follow a three-month rest from treatment.