

Antipsoriatic Therapy

To initiate a Coverage Review, Call 1 800 753-2851

Covered Medications

Alefacept injection (*Amevive*[®])
 Efalizumab injection (*Raptiva*[®])
 Refer to separate summaries for adalimumab (*Humira*[®]), etanercept injection (*Enbrel*[®]) and infliximab injection (*Remicade*[®]) for more information on the coverage policies for those medications.

What They Do and How They Are Used

- Plaque psoriasis is a chronic skin disorder characterized by red, scaly, raised lesions that tend to form on the scalp, limbs, back and genitalia. 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.
- Psoriasis is equally common in men and women, and it has a bimodal peak of onset. The largest peak occurs between 20 and 30 years of age, and a smaller peak is noticed between 50 and 60 years of age.
- Psoriasis is recognized as an immune system–mediated disease. Plaques consist primarily of T-cells, which are responsible for starting the changes seen in psoriasis and the maintenance of skin plaques. Plaques also contain a high level of tumor necrosis factor (TNF). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.
- 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.
- Biological treatments such as *Amevive*[®], *Raptiva*[®], *Enbrel*[®], *Humira*[®] and *Remicade*[®] are used either after these conventional treatments have failed in continuing to provide benefit or when a patient is not able to receive conventional therapy (drug and phototherapy).
- Both *Amevive*[®] (alefacept) and *Raptiva*[®] (efalizumab) inhibit multiple steps of the immune-mediated response involved in psoriasis, including T-cell activation, movement and attachment to skin cells.
- *Amevive*[®] exhibits its effect by binding to a specific receptor on the T-cell, which may explain its toxicity and need to monitor T-cell counts weekly while on therapy.
- *Raptiva*[®] binds to a subunit attached to T-cells, which prevents activation and movement into skin cells.
- 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 and patient response are used to gauge response to treatment.
- *Amevive*[®] (alefacept) is administered via IM injection in the physician's office.
- *Raptiva*[®] (efalizumab) is administered by subcutaneous injection once weekly.

Rationale for Coverage Authorization

To provide coverage for *Amevive*[®] and *Raptiva*[®] in situations where the use of other systemic therapies and phototherapy for the treatment of moderate to severe plaque psoriasis is not an option.

Benefit Design

- Coverage for *Amevive*[®] and *Raptiva*[®] is determined through prior authorization for every claim.

ALERT: Withdrawal of *Raptiva*[®] (efalizumab) from U.S. Market

- On April 8, 2009, Genentech, Inc., and the FDA announced the voluntary withdrawal of *Raptiva*[®] from the U.S. market.
- The decision was based on 3 reports of *Raptiva*'s association with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and usually fatal brain disease of the central nervous system.
- Effective immediately, physicians should not issue prescriptions for *Raptiva*[®] to any new patients and should promptly contact patients currently receiving *Raptiva*[®] to assess the most appropriate treatment alternatives.
- Patients should not abruptly discontinue *Raptiva*[®], since this may lead to severe worsening of psoriasis.
- Copies of the notification letters are available on the Genentech Web site by clicking on the *Raptiva* link at <http://www.gene.com/gene/products> and physicians with questions may contact Genentech Medical Communications at 1-800-821-8590.

➤ *Raptiva*[®] will no longer be available beginning **June 8, 2009**

Coverage Authorization Criteria

Coverage is provided for the treatment of plaque psoriasis in accord with the following criteria:

1. Patient must be ≥18 years of age
AND

2. Coverage is provided 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. Coverage is provided 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), cyclosporine and acitretin (*Soriatane*[®]).

4. Coverage is not provided for the use of more than one biologic drug simultaneously.

Coverage duration:

Amevive[®]: Coverage is provided for 3 months and renewable (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*[®].

Coverage is provided for up to two 3-month treatment cycles per lifetime.

Raptiva[®]: Coverage is provided for 6 months and renewable for 6 months in situations where treatment with *Raptiva*[®] is continuing to provide improvement in the plaque psoriasis.

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- Product information: efalizumab injection (*Raptiva*[®]—Genentech) 2005.