Antipsoriatic Therapy

<table>
<thead>
<tr>
<th>Covered Medications</th>
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</thead>
<tbody>
<tr>
<td>Alefacept Injection (Amevive®)</td>
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<tr>
<td>Efalizumab Injection (Raptiva®)</td>
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</tbody>
</table>

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 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 along with 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.

Benefit design

- Coverage for Amevive® and Raptiva® is determined through prior authorization for every claim
- Coverage is provided for Raptiva® for one 125 mg vial per week with coverage for up to two 125 mg vials per week provided through a coverage review process.
- A quantity of one 15 mg vial of Amevive® per week is covered with no coverage review available for additional quantities.

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 of Raptiva® for 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 psoriasis worsening
- 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](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 up to one 15 mg vial per week for 3 months and renewable (in situations where treatment is continuing to provide improvement in the plaque psoriasis) for an additional 3 months following 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 one 125 mg vial per week. Coverage for an additional quantity (i.e., up to two vials per week) is provided in situations where the patient weighs > 125 kg. 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.

**References**