

## Antipsoriatic Therapy

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

### Impacted Medications

Alefacept Injection (*Amevive*<sup>®</sup>)  
 Ustekinumab (*Stelara*<sup>™</sup>)  
 Refer to separate summaries for adalimumab (*Humira*<sup>®</sup>), etanercept injection (*Enbrel*<sup>®</sup>) and infliximab injection (*Remicade*<sup>®</sup>) for more information on the coverage policies for those medications.

### What They Do and How They Are Used

- Plaque psoriasis is a chronic immune mediated, 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) and an overexpression of Interleukin (IL) -12 and IL-23. TNF and IL-12 and 23 are naturally occurring cytokines 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*<sup>®</sup>, *Enbrel*<sup>®</sup>, etc. 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*<sup>®</sup> (alefacept) and *Raptiva*<sup>®</sup> (efalizumab) inhibit multiple steps of the immune-mediated response involved in psoriasis, including T-cell activation, movement, and attachment to skin cells.
- *Amevive*<sup>®</sup> 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*<sup>®</sup> binds to a subunit attached to T-cells, which prevents activation and movement into skin cells.
- *Stelara*<sup>™</sup> is a monoclonal antibody that binds with high affinity to the p40 subunits of the IL-12 and IL-23.
- 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*<sup>®</sup> (alefacept) is administered via IM injection in the physician's office.
- *Stelara*<sup>™</sup> (ustekinumab) is administered by subcutaneous injection initially and 4 weeks later, followed by 45 mg every 12 weeks. The dosage is increased to 90 mg for patients weighing greater than 100 kg.

### Rationale for Coverage Authorization

To provide coverage for *Amevive*<sup>®</sup> and *Stelara*<sup>™</sup> 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*<sup>®</sup> and *Stelara*<sup>™</sup> is determined through prior authorization for every claim.

### ALERT: Withdrawal of *Raptiva*<sup>®</sup> (Efalizumab) from U.S. Market

- On April 8, 2009, Genentech, Inc., and the FDA announced the voluntary withdrawal of *Raptiva*<sup>®</sup> from the U.S. market.
- The decision was based on three 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*<sup>®</sup> to any new patients and should promptly contact patients currently receiving *Raptiva*<sup>®</sup> to assess the most appropriate treatment alternatives.
- Patients should not abruptly discontinue *Raptiva*<sup>®</sup>, 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*<sup>®</sup> is no longer available as of **June 8, 2009**.

### Coverage Authorization Criteria

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

For Raptiva:

1. Patient must be  $\geq$  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*<sup>®</sup>).
4. Coverage is not provided for the use of more than one biologic drug simultaneously.

For Stelara:

1. The patient is  $\geq$  18 years of age with moderate to severe plaque psoriasis for 6 months or longer, with at least 10% body surface area involvement, and a candidate for phototherapy or systemic therapy.

AND

2. Coverage is not provided for the use of *Stelara* in combination with another biologic drug.

AND

3. The prescriber has screened for the presence of latent TB infection and if appropriate, initiated treatment of latent TB before administering *Stelara*.

Coverage duration:

*Amevive*<sup>®</sup>: Coverage is provided for up to two 3-month treatment cycles per lifetime.

*Stelara*<sup>™</sup>: Coverage is provided for 2 years.

### References

- Bowcock AM, Barker JN. Genetics of psoriasis: the potential impact on new therapies. *J Am Acad Dermatol.* 2003; 49:S51-S56.
- FDA.gov [homepage on the Internet]. Maryland: U.S. Food and Drug Administration; c2009 [updated 2009 Apr 8; cited 2009 Apr 9]. Available from: <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01992.html>.
- Feldman SR. The design of clinical trials in psoriasis: lessons for clinical practice. *J Am Acad Dermatol.* 2003; 49:S62-S65.
- Gene.com. [homepage on the Internet]. San Francisco: Genentech, Inc.; c2009 [updated 2009 Apr 8; cited 2009 Apr 9]. Available from: <http://www.gene.com/gene/news/press-releases/display.do?method=detail&id=12047>.
- Goffe B, Cather JC. Etanercept: an overview. *J Am Acad Dermatol.* 2003; 49:S105-S111.
- Krueger GG, Callis KP. Development and use of alefacept to treat psoriasis. *J Am Acad Dermatol.* 2003; 49:S87-S97.
- Leonardi CL et al. Etanercept as monotherapy in patients with psoriasis. *N Engl J Med.* 2003; 349:2014-2022.
- Leonardi CL. Efalizumab: an overview. *J Am Acad Dermatol.* 2003; 49:S98-S104.
- Mehlig SL, Gordon KB. The immunology of psoriasis and biologic immunotherapy. *J Am Acad Dermatol.* 2003; 49:S44-S50.
- Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 1. overview of psoriasis with biologics. *J Am Acad Dermatol.* 2008 May;58(5):826-850.
- Menter MA, Krueger GC. Psoriasis treatment 2003 at the new millennium: position paper on behalf of the authors. *J Am Acad Dermatol.* 2003; 49:S39-S43.
- Papadopoulos E. Briefing Document: Biologic License Application STN BL 125075/0 for efalizumab for the treatment of moderate to severe chronic plaque psoriasis. 2003.
- Product Information: Alefacept injection (*Amevive*<sup>®</sup> - Biogen) 2005.
- Product Information: Ustekinumab injection (*Stelara*<sup>™</sup> - Centocor Ortho Biotech Inc) 2009.