Antipsoriatic Therapy

### Covered Medications

| Alefacept Injection (Amevive<sup>®</sup>)  
| Ustekinumab (Stelara™) |

Refer to separate summaries for Adalimumab (Humira<sup>®</sup>), Etanercept Injection (Enbrel<sup>®</sup>), and Infliximab injection (Remicade<sup>®</sup>)

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### 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 treatment, 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™, Enbrel®, 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).
- Amevive<sup>®</sup> (alefacept) inhibits 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 on therapy.
- Stelara™ 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™ (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

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### Benefit design

- Coverage for Amevive™, and Stelara™ is determined through prior authorization for every claim

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### Coverage authorization criteria

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

#### Alefacept Injection (Amevive<sup>®</sup>)

1. Patient must be ≥ 18 years of age
   AND
2. Coverage is provided where the patient is under the care or referral of a dermatologist, and
3. 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
4. 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>), and
5. Coverage is not provided for the use of more than one biologic drug simultaneously.
   OR
6. Patient is currently on Amevive and has had significant improvement in his/her condition, and
7. Coverage is provided if the patient has NOT received TWO or more 3 month treatment cycles per lifetime, and
8. Coverage is provided in situations where at least 3 months have elapsed since the patient’s previous Amevive cycle.

**Coverage Duration:** Coverage is provided for up to two 3 month treatment cycles per lifetime.

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Antipsoriatics – Stelara  
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Ustekinumab (Stelara)
Coverage is provided for the treatment of moderate to severe plaque psoriasis in accord with the following criteria:

1. Patient is 18 years of age or older
   AND
2. Patient had a 3 month or longer trial of phototherapy (i.e. broadband, narrowband ultraviolet B) or photochemotherapy (i.e. PUVA) and experienced an inadequate response or intolerance or the patient is not a candidate for phototherapy or photochemotherapy
   OR
3. Patient has been treated and experienced an inadequate response or intolerance, or is not a candidate to other non-biologic systemic therapies such as methotrexate, cyclosporine, or acitretin (Soriatane®)
   AND
4. The patient had a 3 month or longer trial of at least one TNF-inhibitor (i.e. Remicade, Enbrel, or Humira) and experienced an inadequate response or intolerance or the patient is not a candidate for treatment with a TNF-inhibitor.
   AND
5. Patient MUST be evaluated and screened for the presence of latent TB infection PRIOR to initiation of therapy with this drug

Coverage is not provided for the use of more than one biologic drug simultaneously or if there is guttate, pustular, or erythrodermic psoriasis present.

Coverage duration: Coverage is provided for 2 years.

References

- Product Information: Ustekinumab injection (Stelara™ - Centocor Ortho Biotech Inc) 2009.