

Title: ustekinumab (Stelara)

Origination: 11/18/09	Revised: 03/30/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Medication Summary

- Ustekinumab (Stelara) is a human interleukin (IL)-12 and -23 antagonist indicated for the treatment of adult Members (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Ustekinumab (Stelara) has been investigated in the treatment of psoriatic arthritis and Crohn's disease, but has not yet received FDA approval for these conditions.
- Ustekinumab (Stelara) is supplied as 45mg/0.5ml vials and is approved for administration by a healthcare provider.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- **Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.**

Exclusions

- Member less than eighteen (18) years of age;
- Concurrent use of multiple biological response modifiers including, but not limited to: Humira (adalimumab), Amevive (alefacept), and Enbrel (etanercept). Only one (1) agent at a time will be covered for the treatment of Plaque Psoriasis;
- Guttate, erythrodermic, or pustular psoriasis;
- Member experiencing acute infection or significant chronic infection including, but not limited to: sepsis, tuberculosis, aplastic anemia, opportunistic infections.

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Procedure:

1.0 Request for *initial therapy* with ustekinumab (Stelara) for **plaque psoriasis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:

1.1 Provider is a dermatologist; **AND**

1.2 Member is at least 18 years of age; **AND**

1.3 Diagnosis of moderate to severe plaque psoriasis for at least six (6) months as evidenced by **at least one (1)** of the following:

1.3.1 Involvement of at least 10% of the body surface area (BSA); **OR**

1.3.1 Psoriasis Area and Severity Index (PASI) Score of 12 or greater; **OR**

1.3.1 Psoriasis leading to incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia);

AND

1.4 Member shows inadequate response to a three (3) to six (6) month minimum trial **OR** is not a candidate for any of the following topical agents:

1.4.1 Anthralin;

1.4.2 Coal Tar Preparations;

1.4.3 Corticosteroids;

1.4.4 Emollients;

1.4.5 Immunosuppressives;

1.4.6 Keratolytics;

1.4.7 Retinoic Acid Derivatives;

1.4.8 Vitamin D Analogues;

AND

1.5 Member shows inadequate response to three (3) to six (6) month minimum trial of an adequate dose **OR** is not a candidate for **at least one (1)** of the following systemic agents:

1.5.1 Immunosuppressives;

1.5.1 Retinoic Acid Derivatives;

1.5.1 Methotrexate;

AND

1.6 Member shows inadequate response to three (3) month to six (6) month minimum trial **OR** is not a candidate for treatment with phototherapy (PUVA);

Procedure, continued:

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1.0 Request for *initial therapy* with Stelara for **plaque psoriasis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following, continued:

AND

1.7 **For Commercial Members only – excludes Medicare or Miami Dade County** Member shows inadequate response, or intolerance to, an adequate dose of Humira (adalimumab) **AND** Enbrel (etanercept);

1.8 If all criteria are met, initial therapy with Stelara may be approved for a total of three (3) injections (5 months of therapy) at the following dosing:

1.8.1 Weight <100kg: 45 mg SQ at weeks 0, 4 and then every 12 weeks; **OR**

1.8.1 Weight >100kg: 90 mg SQ at weeks 0, 4 and then Q12 weeks thereafter.

2.0 Request for *continuation of therapy* beyond initial authorization period for **plaque psoriasis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying a reduction in Member's signs and symptoms (i.e., improvement in body surface area affected, skin lesions, and/or PASI score):

2.1 If criteria are met, Stelara may be approved for up to one (1) year (total of 4 injections) at the following dosing:

2.1.1 Weight <100kg: 45 mg SQ every 12 weeks; **OR**

2.1.1 Weight >100kg: 90 mg SQ every 12 weeks.

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References:

1. Gottlieb A, Menter A, Mendelsohn A, et al. Ustekinumab, a human interleukin 12/23 monoclonal antibody, for psoriatic arthritis: randomized, double-blind, placebo-controlled, crossover trial. *Lancet* 2009;373:633-40.
2. Sandborn WJ, Feagan BG, Fedorak RN, et al. A randomized trial of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with moderate-to-severe Crohn's disease. *Gastroenterology* 2008;135:1130-41.
3. Stelara (ustekinumab) Prescribing information. Centocor Ortho Biotech Inc. Horsham, PA. September 2009.
4. Leonardi CL, Kimball AB, Papp KA, et al. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1) *Lancet* 2008;371: 1665–74.
5. Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, Van Voorhees AS, Elmets CA, Leonardi CL, Beutner KR, Bhushan R, Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol* 2008 May; 58 (5):851-64.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.