

## Corporate Medical Policy

### Ustekinumab (Stelara)

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<b>Origination:</b>	02/2010
<b>Last CAP Review:</b>	1/2012
<b>Next CAP Review:</b>	1/2013
<b>Last Review:</b>	1/2012

#### Description of Procedure or Service

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Plaque psoriasis is the most common form of psoriasis. It is characterized by raised, inflamed, red lesions covered with a silvery-white buildup of dead skin cells (scales). These are found primarily on the trunk, elbows, knees, scalp and finger or toe nails. The cause of psoriasis is related to the immune system, and more specifically, a type of white blood cell called a T lymphocyte or T cell. Normally, T-cells travel throughout the body to detect and fight off foreign substances, such as viruses or bacteria. If you have psoriasis, however, the T-cells attack healthy skin cells by mistake as if to heal a wound or to fight an infection. Normally, skin cells mature and shed after about a month. In psoriasis, the cell maturation speeds up, taking only three to four days. Because the lower layer of skin cells divides more rapidly than normal, dead cells accumulate in thicker patches on the skin's outermost layer (called the epidermis). 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.

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.

Ustekinumab (Stelara™) is a human IgG1 $\kappa$  monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL23 cytokines. IL-12 and IL23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4<sup>+</sup> T-cell differentiation and activation. In *in vitro* models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12  $\beta$ 1.

Ustekinumab (Stelara™) is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Please also refer to the following related Corporate Medical Policies for treatment of psoriasis:

- Targeted Phototherapy for Psoriasis
- PUVA (Psoralens with Ultraviolet A) Therapy
- Ultraviolet Light Box Therapy in the Home
- Infliximab
- Alefacept

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

# Ustekinumab (Stelara)

## Policy

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**BCBSNC will provide coverage for Ustekinumab (Stelara™) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

Coverage for Ustekinumab (Stelara™) requires prior review.

## When Ustekinumab (Stelara™) is covered

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Ustekinumab (Stelara™) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients who:

- are 18 years of age or older; and
- have 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
- have already been treated with or are not a candidate for any other systemic treatment such as methotrexate (oral or IM), cyclosporin, or acitretin (Soriatane®).

## When Ustekinumab (Stelara™) is not covered

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When the criteria listed above are not met.

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

## Policy Guidelines

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Ustekinumab (Stelara™) should only be administered by a healthcare provider to patients who will be closely monitored and have regular follow-up visits with a physician.

Since Ustekinumab (Stelara™) may increase the risk of infections and reactivation of latent infections, it should not be given to patients with any clinically important active infection and should not be administered until the infection resolves or is adequately treated.

Patients should be evaluated for tuberculosis infection prior to initiating treatment with Ustekinumab (Stelara™). It should not be given to patients with active TB. Anti-tuberculosis therapy should be considered in patients with a past history of latent or active tuberculosis when an adequate course of treatment cannot be confirmed prior to initiation of Ustekinumab (Stelara™).

Ustekinumab (Stelara™) is an immunosuppressant and may increase the risk of malignancy.

Prior to initiating therapy with Ustekinumab (Stelara™), patients should receive all immunizations appropriate for age as recommended by current immunization guidelines. Patients being treated with Ustekinumab (Stelara™) should not receive live vaccines.

# Ustekinumab (Stelara)

According to the Food and Drug Administration (FDA) approved labeling for Ustekinumab, the dose should not exceed 90 mg every 12 weeks (maintenance). Allow up to 90 mg at 4 weeks after the initial dose only.

The approved labeling does not describe circumstances in which dosages above this maximum would be considered safe and effective.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: J3357*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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U.S. Food and Drug Administration. Prescribing information. Retrieved 1/29/2010 from [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/125261lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/125261lbl.pdf)

U.S. Food and Drug Administration. Approval letter, BLA 125261/0 dated September 25, 2009. [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#apphist](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist)

U.S. Food and Drug Administration. Center for Drug Evaluation and Research. Application number: 125261. Summary Review. Retrieved 1/29/2010 from [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#apphist](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist)

Schafer JA, Kjesbo NK, Gleason PP. Formulary Review of 2 New Biologic Agents: Tocilizumab for Rheumatoid Arthritis and Ustekinumab for Plaque Psoriasis. *J Manag Care Pharm*. 2010;16(6):402-16. Retrieved on December 10, 2010 from <http://www.amcp.org/data/jmcp/402-416.pdf>

Smith CH, Anstey AV, Barker JN, Burden AD, et al. British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009. *Br J Dermatol* 2009 Nov;161(5):987-1019. Retrieved on December 13, 2010 from <http://guideline.gov/content.aspx?f=rss&id=15883>

Krulig E, Gordon KB. Ustekinumab: an evidence-based review of its effectiveness in the treatment of psoriasis. *Core Evid*. 2010 Jul 27;5:11-22. Retrieved on January 3, 2011 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2915500/?tool=pubmed>

Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) for STELARA™ (ustekinumab) <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM188457.pdf>

Garcia-Valladares I, Cuchacovich R, Espinoza LR. Comparative assessment of biologics in treatment of psoriasis: drug design and clinical effectiveness of ustekinumab. *Drug Des Devel Ther*. 2011; 5: 41–49. Retrieved on December 28, 2011 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3023274/?tool=pubmed>

# Ustekinumab (Stelara)

Specialty Matched Consultant Advisory Panel review 1/2012

## Policy Implementation/Update Information

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- 3/02/10 New policy issued. Ustekinumab (Stelara™) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients who are 18 years of age or older; and have 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 have already been treated with or are not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporin, and acitretin (Soriatane®). Notification date 3/02/10 for effective date of 6/08/10. (adn)
- 8/31/10 Billing Information updated to include code J3490. (mco)
- 1/1/11 J3490 and J3590 deleted from policy. New code specific to injection of Ustekinumab (Stelara™) added to Billing/Coding section: J3357. (mco)
- 2/15/11 Specialty Matched Consultant Advisory Panel review 1/2011. References updated. (mco)
- 7/1/11 Added quantity limitations to Policy Guidelines. Medical director review 6/2011. Notification date 7/1/11 for effective date of 10/1/11. (lpr)
- 2/7/12 Specialty Matched Consultant Advisory Panel review 1/2012. References updated. No changes to Policy Statements. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.