# Clinical Policy: Ustekinumab (Stelara)

Reference Number: CP.PHAR.264
Effective Date: 08/16
Last Review Date: 05/16

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for ustekinumab (Stelara™).

**Policy/Criteria**
It is the policy of health plans affiliated with Centene Corporation® that Stelara is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Plaque Psoriasis** (must meet all):

1. Prescribed by or in consultation with a dermatologist or rheumatologist;
2. Age ≥ 18 years;
3. Diagnosis of moderate to severe plaque psoriasis (PsO) and one or more of the following:
   a. Greater than 5% of body surface area is affected;
   b. Palms, soles, face and neck, body folds, or genitalia is involved;
4. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
5. Member has failed phototherapy and a topical treatment (e.g., calcipotriene, coal tar preparations, medium-to-high potency corticosteroids, anthralin, tazarotene);
6. Member has failed one of the following therapies unless intolerant or contraindicated:
   a. A biologic for PsO other than Stelara;
   b. One or more systemic therapies (e.g., methotrexate (MTX), cyclosporine, acitretin, thioguanine) for ≥ 3 consecutive months;
7. Member has failed therapy with Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
8. Prescribed dose of Stelara must not exceed the following:
   a. Weight < 100 kg : 45 mg for the first 2 doses (weeks 0 and 4 of therapy), then every 12 weeks thereafter;
   b. Weight > 100 kg: 90 mg for the first 2 doses (weeks 0 and 4 of therapy), then every 12 weeks thereafter;
9. Member has none of the following contraindications:
   a. Hypersensitivity to Stelara or to any of the excipients;
   b. Serious infection.

**Approval duration: 6 months**

**B. Psoriatic Arthritis** (must meet all)**:**

1. Prescribed by or in consultation with a dermatologist or rheumatologist;
2. Age ≥ 18 years;

3. Diagnosis of active psoriatic arthritis (PsA);
4. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
5. Member has failed one of the following therapies unless intolerant or contraindicated:
   a. A biologic for PsA other than Stelara;
   b. Methotrexate (MTX) for ≥ 3 consecutive months;
   c. If intolerance or contraindication to MTX, sulfasalazine, leflunomide, cyclosporine or azathioprine, for ≥ 3 consecutive months;
6. Member has failed therapy with Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
7. Prescribed dose of Stelara does not exceed the following:
   a. For psoriatic arthritis alone: 45 mg for the first 2 doses (weeks 0 and 4), then every 12 weeks thereafter;
   b. For member with co-existent moderate-to severe plaque psoriasis:
      i. Weight < 100 kg : 45 mg for the first 2 doses (weeks 0 and 4 of therapy), then every 12 weeks thereafter;
      ii. Weight > 100 kg: 90 mg for the first 2 doses (weeks 0 and 4 of therapy), then every 12 weeks thereafter;
8. Member has none of the following contraindications:
   a. Hypersensitivity to Stelara or to any of the excipients;
   b. Serious infection.

**Approval duration: 6 months**

**C. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

## II. Continued Approval

**A. All Indications** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. Prescribed dose of Stelara does not exceed the following:
   a. For plaque psoriasis or psoriatic arthritis with co-existent moderate-to severe plaque psoriasis:
      i. Weight < 100 kg : 45 mg every 12 weeks;
      ii. Weight > 100 kg: 90 mg every 12 weeks;
   b. For psoriatic arthritis alone: 45 mg every 12 weeks;
4. Member has none of the following reasons to discontinue:
   a. Hypersensitivity to Stelara or to any of the excipients;
   b. Serious infection;
   c. Active TB;
   d. Reversible posterior leukoencephalopathy syndrome.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

**Background**
*Description/Mechanism of Action:*
Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ 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.

Formulations:
Stelara is available in single-use prefilled syringes or single-use vials containing 45 mg or 90 mg of ustekinumab for subcutaneous use. Stelara does not contain preservatives.

*FDA Approved Indication(s):*
Stelara is a human interluekin-12 and -23 antagonist/injection for subcutaneous use 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.
- Active psoriatic arthritis used alone or in combination with MTX.

**Appendices**
**Appendix A: Abbreviation Key**
DMARDs: disease modifying anti-rheumatic drugs
IL: interleukin
MTX: methotrexate
PsA: psoriatic arthritis
PsO: plaque psoriasis
RPLS: reversible posterior leukoencephalopathy syndrome
TB: tuberculosis

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J3357 | Injection, ustekinumab, 1 mg |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Policy split from CP.PHAR.85.Psoriasis Treatments.<br>Plaque psoriasis: removed criteria related to HBV, malignant disease and concurrent use with another biologic; modified requirement for the use of topical agent and phototherapy to not require 3 consecutive months of treatment; removed Otezla as a DMARD option for trial and failure; added requirement for failure of PDL Enbrel and Humira, unless contraindicated; added max dose requirement; updated contraindications per FDA labeling. Re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement; added max dose requirement. Psoriatic arthritis: modified criteria to require failure of PDL Enbrel and Humira, unless contraindicated; added max dose; updated contraindications per FDA labeling; required trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Re-auth: Combined into "All Indications"; added max dose and reasons to discontinue per PI;Shortened background section. | 06/16 | 08/16 |

**References**

1. Stelara Prescribing Information. Horsham, PA: Janssen Biotech; March 2014. Available at: http://www.stelarainfo.com/. Accessed June 13, 2016.
2. Feldman SR. Treatment of psoriasis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 13, 2016.
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4. Humira Prescribing Information. North Chicago, IL: AbbVie Inc.; March 2016. Available at: https://www.humira.com/. Accessed June 16, 2016.
5. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 13, 2016.
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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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