Clinical Policy: Ustekinumab (Stelara)

Reference Number: CP.PHAR.264
Effective Date: 08/16
Last Review Date 08/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

Ustekinumab (Stelara™) is a human interleukin-12 and -23 antagonist.

FDA Approved Indication

Stelara is indicated for the treatment of:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA), alone or in combination with methotrexate
- Moderately to severely active Crohn's disease (CD) who have:
  - Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor blocker (TNF) or
  - Failed or were intolerant to treatment with one or more TNF blocker

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval 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. Diagnosis of PsO and at least one 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;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of at least one oral systemic therapy for plaque psoriasis (e.g., methotrexate, cyclosporine, acitretin, or thioguanine) in combination with phototherapy or topical therapy (e.g., corticosteroids, calcipotriene, tazarotene) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of adalimumab *(Humira is preferred)* used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab*
6. 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;
7. Dose does not exceed:
   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.

Approval duration: 6 months

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

1. Diagnosis of active PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or cyclosporine, for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. 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;
7. Dose does not exceed:
   a. For psoriatic arthritis alone: 45 mg for the first 2 doses (at 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.

Approval duration: 6 months

C. Crohn's Disease (must meet all)**:**

1. Diagnosis of CD and (a or b):
   a. Member is identified as moderate/high risk based on one of the following:
      i. Age at initial diagnosis < 30 years;
      ii. Extensive anatomic involvement (e.g., ileocecal disease, continuous ileocolonic disease, small bowel disease);
      iii. Perianal and/or severe rectal disease;
      iv. Deep ulcers;
      v. Prior surgical resection;
      vi. Stricturing and/or penetrating disease;
   b. Member has failed both of the following, unless contraindicated or clinically significant adverse effects are experienced (i and ii):
      i. An immunomodulator (e.g., azathioprine, mercaptopurine (6MP), MTX) used for ≥ 3 months;
      ii. Adalimumab *(Humira is preferred)* used for ≥ 3 consecutive months;
      **Prior authorization is required for adalimumab*

2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
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. Dose does not exceed:
   a. For intravenous infusion:
      i. Weight < 55 kg: 260 mg IV once;
      ii. Weight 55 kg to 85 kg: 390 mg IV once;
      iii. Weight > 85 kg: 520 mg IV once;
   b. For subcutaneous injection:
      i. 90 mg SC 8 weeks after the initial IV dose, then every 8 weeks thereafter.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity)
3. If request is for a dose increase, new dose does not exceed:
   a. For PsO or PsA with co-existent moderate-to-severe PsO:
      i. Weight < 100 kg: 45 mg every 12 weeks;
      ii. Weight > 100 kg: 90 mg every 12 weeks;
   b. For PsA alone: 45 mg every 12 weeks;
   c. For CD: 90 mg every 8 weeks.

B. Approval duration: 12 months

C. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CD: Crohn's disease FDA: Food and Drug Administration

MTX: methotrexate
PsA: psoriatic arthritis
PsO: plaque psoriasis
TB: tuberculosis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO in adults	SC: • ≤100 kg: 45 mg SC at 0 and 4 weeks, followed by 45 mg every 12 weeks • >100 kg: 90 mg SC at 0 and 4 weeks, followed by 90 mg every 12 weeks	≤100 kg: 45 mg every 12 weeks >100 kg: 90 mg every 12 weeks
PsA in adults	• 45 mg SC at 0 and 4 weeks, followed by 45 mg every 12 weeks	45 mg every 12 weeks
PsA in adults with co-existent mod/severe PsO	SC: • >100 kg: 90 mg SC at 0 and 4 weeks, followed by 90 mg every 12 weeks	>100 kg: 90 mg every 12 weeks
CD in adults	• ≤ 55 kg: 260 mg IV initially, followed by 90 mg SC 8 weeks after initial IV dose, then every 8 weeks thereafter • 55 kg to 85 kg: 390 mg IV initially, followed by 90 mg SC 8 weeks after initial IV dose, then every 8 weeks thereafter • >85 kg: 520 mg IV initially, followed by 90 mg SC 8 weeks after initial IV dose, then every 8 weeks thereafter	90 mg every 8 weeks

VI. Product Availability

- Subcutaneous Injection:
  - Injection: 45 mg/0.5mL or 90 mg/mL in a single-dose prefilled syringe
  - Injection: 45 mb/0.5mL in a single-dose vial
- Intravenous Infusion: 130 mg/26mL (5 mg/mL) solution in a single-dose vial

VII. References

1. Stelara Prescribing Information. Horsham, PA: Janssen Biotech; September 2016. Available at: http://www.stelarainfo.com/. Accessed August 7, 2017.
2. Enbrel Prescribing Information. Thousand Oaks, CA: Amgen Inc.; March 2015. Available at: https://www.enbrel.com/. Accessed June 16, 2016.
3. Humira Prescribing Information. North Chicago, IL: AbbVie Inc.; March 2016. Available at: https://www.humira.com/. Accessed June 16, 2016.
4. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58(5):826-50.
5. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45.

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. 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
Crohn's disease: added criteria related to new FDA-approved indication of Crohn's disease. Edited initial criteria to require trials of another biologic or immunomodulator therapy, as well as Humira. Removed "active TB" under continuation criteria - reasons to discontinue for consistency across similar policies; active TB is covered under "serious inections" under this same section.	11/16	12/16
Converted to the new template. PsO: Preferencing requirement for Enbrel removed; trial requirement modified to require the concomitant use of oral and topical or phototherapy. CD: updated list of poor prognostic indicators per AGA guidelines; examples of extensive disease added. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	08/17	08/17

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 administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.