CENTENE Corporation

Clinical Policy: Ustekinumab (Stelara)

Reference Number: CP.PHAR.264
Effective Date: 08.16
Last Review Date: 05.21
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 (IL-12) and -23 (IL-23) antagonist.

FDA Approved Indication(s)

Stelara is indicated for the treatment of:

- Patients 6 years or older with moderate-to-severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Adult patients with active psoriatic arthritis (PsA), alone or in combination with methotrexate
- Adult patients with moderately to severely active Crohn's disease (CD)
- Adult patients with moderately to severely active ulcerative colitis (UC)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) 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. Crohn's Disease (must meet all)**:**

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Medical justification supports inability to use immunomodulators (*see Appendix E*);
5. Failure of a ≥ 3 consecutive month trial of Humira®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Humira*
6. Dose does not exceed:
   a. Initial dose (IV):
      i. Weight ≤ 55 kg: 260 mg once;
      ii. Weight > 55 kg to 85 kg: 390 mg once;

iii. Weight > 85 kg: 520 mg once;
b. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by maintenance dose of 90 mg every 8 weeks.

Approval duration: 6 months

B. Plaque Psoriasis (must meet all)**:**
1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Request is for SC formulation;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 6 years;
5. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
6. For age ≥ 18 years, failure of a ≥ 3 consecutive month trial of Taltz®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Taltz*
7. Dose does not exceed one of the following (*see Appendix G for dose rounding guidelines*) (a or b):
   a. Adult: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i or ii);
      i. Weight ≤ 100 kg: 45 mg per dose;
      ii. Weight > 100 kg: 90 mg per dose;
   b. Pediatrics: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (i, ii, or iii);
      i. Weight < 60 kg: 0.75 mg/kg per dose;
      ii. Weight 60 kg to 100 kg: 45 mg per dose;
      iii. Weight > 100 kg: 90 mg per dose.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Request is for SC formulation;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 18 years;
5. Failure of at least THREE of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated: Enbrel®, Otezla®, Simponi®/Simponi Aria®, Taltz, Xeljanz®/Xeljanz XR®;
   **Prior authorization may be required for Enbrel, Otezla, Simponi/Simponi Aria, Taltz, Xeljanz/Xeljanz XR*

6. Dose does not exceed one of the following (a or b):
   a. 45 mg initially and 4 weeks later, followed by maintenance dose of 45 mg every 12 weeks;
   b. Co-existent PsO and weight > 100 kg: 90 mg initially and 4 weeks later, followed by maintenance dose of 90 mg every 12 weeks.

Approval duration: 6 months

D. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of a Mayo Score ≥ 6 (*see Appendix F*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of a ≥ 3 consecutive month trial of Humira or Simponi®, unless clinically significant adverse effects are experienced or both are contraindicated;
   **Prior authorization may be required for Humira and Simponi*
6. Dose does not exceed:
   a. Initial dose (IV):
      i. Weight ≤ 55 kg: 260 mg once;
      ii. Weight > 55 kg to 85 kg: 390 mg once;
      iii. Weight > 85 kg: 520 mg once;
   b. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by maintenance dose of 90 mg every 8 weeks.

Approval duration: 6 months

E. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid

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;
3. Request is for SC formulation;
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. PsO alone (*see Appendix G for dose rounding guidelines*) (i or ii):
      i. Adults (a or b):
         a) Weight ≤ 100 kg: 45 mg every 12 weeks;
         b) Weight > 100 kg: 90 mg every 12 weeks;
      ii. Pediatrics (a, b, or c):
         a) Weight < 60 kg: 0.75 mg/kg every 12 weeks;
         b) Weight 60 kg to 100 kg: 45 mg every 12 weeks;

c) Weight > 100 kg: 90 mg every 12 weeks;

b. PsA (i or ii):
   i. 45 mg every 12 weeks;
   ii. Co-existent PsO and weight > 100 kg: 90 mg every 12 weeks;

c. CD, UC: 90 mg every 8 weeks.

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.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz®/Xeljanz® XR, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
CD: Crohn's disease
FDA: Food and Drug Administration
GI: gastrointestinal
IL-12: interleukin-12
IL-23: interleukin-23
MTX: methotrexate
PsO: plaque psoriasis
PsA: psoriatic arthritis
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO daily	50 mg/day
azathioprine (Azasan®, Imuran)	**CD** 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	**CD*** prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg PO QD **UC** budesonide (Uceris®) 9 mg PO QD	Various
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
6-mercaptopurine (Purixan®)	**CD** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**CD*** 15 – 25 mg/week IM or SC **PsO** 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Pentasa® (mesalamine)	**CD** 1,000 mg PO QID	4 g/day
Enbrel® (etanercept)	**PsA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**CD, UC** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29	40 mg every other week
Otezla® (apremilast)	**PsA** Initial dose: Day 1: 10 mg PO QAM	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID	
Simponi® (golimumab)	**PsA** 50 mg SC once monthly	50 mg/month
	UC Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks
Simponi Aria® (golimumab)	**PsA** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
Taltz® (ixekizumab)	**PsA** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks **PsO** Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	**PsA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**PsA** 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): clinically significant hypersensitivity to ustekinumab or any of its excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in erythrocyte sedimentation rate/C-reactive protein (ESR/CRP) levels
  - Improvements in activities of daily living
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

Appendix E: Immunomodulator Medical Justification

- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn's disease:
  - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
  - High-risk factors for intestinal complications may include:
    - Initial extensive ileal, ileocolonic, or proximal GI involvement
    - Initial extensive perianal/severe rectal disease
    - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
    - Deep ulcerations
    - Penetrating, stricturing or stenosis disease and/or phenotype
    - Intestinal obstruction or abscess

Appendix F: Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- The following may be considered for medical justification supporting inability to use an immunomodulator for ulcerative colitis:
  - Documentation of Mayo Score 6 – 12 indicative of moderate to severe ulcerative colitis.

Appendix G: Dose Rounding Guidelines for PsO

Weight-based Dose Range	Quantity Recommendation
Subcutaneous, Syringe	
≤ 46.99 mg	1 syringe of 45 mg/0.5 mL
47 to 94.49 mg	1 syringe of 90 mg/1 mL
94.5 to 141.49 mg	1 syringe of 45 mg/0.5 mL and 1 syringe of 90 mg/1 mL
Subcutaneous, Vial	
≤ 46.99 mg	1 vial of 45 mg/0.5 mL
47 to 94.49 mg	2 vials of 45 mg/0.5 mL
Intravenous, Vial	
94.5 to 136.49 mg	1 vial of 130 mg/26 mL

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO	Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg *Pediatrics (Age 12 years and older):* Weight < 60 kg: 0.75 mg/kg Weight 60 to 100 kg: 45 mg Weight > 100kg: 90 mg	90 mg every 12 weeks
PsA	45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks	45 mg every 12 weeks
PsA with co-existent PsO	Weight > 100 kg: 90 mg SC at weeks 0 and 4, followed by 90 mg every 12 weeks	90 mg every 12 weeks

Indication	Dosing Regimen	Maximum Dose
CD, UC	Weight based dosing IV at initial dose, followed by 90 mg SC every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	90 mg every 8 weeks

VI. Product Availability

- Single-dose prefilled syringe: 45 mg/0.5 mL, 90 mg/mL
- Single-dose vial for SC injection: 45 mg/0.5 mL
- Single-dose vial for IV infusion: 130 mg/26 mL

VII. References

1. Stelara Prescribing Information. Horsham, PA: Janssen Biotech; December 2020. Available at: www.stelarainfo.com. Accessed January 13, 2021.
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6. Menter A, Korman NF, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009; doi: 10.1016/j.jaad.2009.03.027
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8. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018; 113:481-517.
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10. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413

11. Sands BE, Sandborn WJ, Panaccione R, et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *N Engl J Med.* 2019;381:1201-14.
12. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *American College of Rheumatology*. 2019; 71(1):5-32. doi: 10.1002/art.40726
13. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at http://www.clinicalpharmacology-ip.com/.

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	Ustekinumab, for subcutaneous injection,1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
Converted to new template. Updated with new indication for use in adolescent patients with PsO. Modified age limit for PsO.	01.11.18	
2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; For HIM and Medicaid: removed specific diagnosis requirements for PsO and CD, added rheumatologist as prescriber specialty requirement for PsO, removed trial and failure of phototherapy and topical therapy for PsO, modified trial and failure to require use of methotrexate or alternative DMARD in addition to Humira for PsO, modified max dosing requirements per package insert, removed TB testing for all indications; references reviewed and updated.	02.27.18	05.18
4Q 2018 annual review: modified prescriber specialist from GI specialist to gastroenterologist for CD; added trial and failure of immunosuppressants, or medical necessity for use of biologics in CD; allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per ACR/NPF	03.05.19	05.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2018 guidelines; removed redirection to Humira for PsO for members < 18 years old; references reviewed and updated.		
Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for PsA, removed redirection to adalimumab and added redirection to 3 of 5 (Enbrel, Simponi, Taltz, Otezla, Xeljanz/Xeljanz XR); for PsO, removed redirection to adalimumab and added redirection to Taltz; for UC, added redirection to Simponi.	12.13.19	
Criteria added for new FDA indication: ulcerative colitis; RT4: removed language stating for use after failure of other agents for the CD indication per updated FDA labeling; references reviewed and updated.	12.03.19	02.20
2Q 2020 annual review: no significant changes; added dose rounding guidelines for weight based dosing for PsO; references reviewed and updated.	02.28.20	05.20
RT4: updated PsO indication/criteria to reflect pediatric age extension to use in patients 6 years and older; alphabetized indications.	08.17.20	
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added combination of bDMARDs under Section III; references reviewed and updated.	02.23.21	05.21

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.

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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.

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