

## Clinical Policy: Ustekinumab (Stelara)

Reference Number: MDN.CP.PHAR.264

Effective Date: 08.16

Last Review Date: 11.21

Line of Business: Meridian IL Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Ustekinumab (Stelara<sup>®</sup>) 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<sup>®</sup> 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  $\geq$  18 years;
4. Member meets one of the following (a or b):
  - a. Failure of a  $\geq$  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  $\geq$  3 consecutive month trial of Humira<sup>®</sup>, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for Humira*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
7. Request meets one of the following (a or b):

- a. Dose does not exceed maximum dose indicated in Section V:
  - i. Initial dose (IV):
    - 1) Weight  $\leq 55$  kg: 260 mg once;
    - 2) Weight  $> 55$  kg to 85 kg: 390 mg once;
    - 3) Weight  $> 85$  kg: 520 mg once;
  - ii. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by maintenance dose of 90 mg every 8 weeks;
- b. If request is for a dose that exceeds 90 mg every 8 weeks, all of the following (i and ii):
  - i. Documentation supports inadequate response to a  $\geq 3$  month trial of the maximum dose indicated in Section V;
  - ii. Dose does not exceed 90 mg every 4 or 6 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.  $\geq 3\%$  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  $\geq 6$  years;
- 5. Member meets one of the following (a,b, or c):
  - a. Failure of a  $\geq 3$  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  $\geq 3$  consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
  - c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
- 6. Failure of TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup>;  
*\*Prior authorization may be required for Cimzia, Enbrel, and Humira*
- 7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 8. Request meets one of the following (a or b):
  - a. Dose does not exceed one of the following (*see Appendix G for dose rounding guidelines*) (i or ii):
    - i. Adult: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (1 or 2);
      - 1) Weight  $\leq 100$  kg: 45 mg per dose;
      - 2) Weight  $> 100$  kg: 90 mg per dose;

- ii. Pediatrics: weight-based dosing initially and 4 weeks later, followed by maintenance dose every 12 weeks (1, 2, or 3);
  - 1) Weight < 60 kg: 0.75 mg/kg per dose;
  - 2) Weight 60 kg to 100 kg: 45 mg per dose;
  - 3) Weight > 100 kg: 90 mg per dose.
- b. If request is for a dose that exceeds 90 mg every 12 weeks, all of the following (i, ii, and iii):
  - i. Documentation supports inadequate response to a  $\geq 3$  month trial of the maximum dose indicated in Section V;
  - ii. Failure of ALL of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel<sup>®</sup> and Cimzia<sup>®</sup>;
  - iii. Dose does not exceed 90 mg every 8 weeks.

**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  $\geq 18$  years;
  - 5. Failure of TWO of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    - a. Cimzia<sup>®</sup>;
    - b. Enbrel<sup>®</sup>;
    - c. Humira<sup>®</sup>;
    - d. Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>;
- \*Prior authorization may be required for Cimzia, Enbrel, Humira, and, Xeljanz/Xeljanz XR*
- 6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
  - 7. Requests meets one of the following (a or b):
    - a. Dose does not exceed one of the following (i or ii):
      - i. 45 mg initially and 4 weeks later, followed by maintenance dose of 45 mg every 12 weeks;
      - ii. Co-existent PsO and weight > 100 kg: 90 mg initially and 4 weeks later, followed by maintenance dose of 90 mg every 12 weeks.
    - b. If request is for a dose that exceeds 45 mg every 12 weeks, there must be documentation that supports inadequate response to a  $\geq 3$  month trial of the maximum dose indicated in Section V;
    - c. Dose does not exceed 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  $\geq$  18 years;
4. Documentation of a Mayo Score  $\geq$  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 ALL of the following, each used for  $\geq$  3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
  - a. Humira<sup>®</sup>;
  - b. Xeljanz/Xeljanz XR<sup>®</sup>;*\*Prior authorization may be required for Humira and Xeljanz/Xeljanz XR*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
8. Request meets one of the following (a or b):
  - a. Dose does not exceed maximum dose indicated in Section V:
    - i. Initial dose (IV):
      - 1) Weight  $\leq$  55 kg: 260 mg once;
      - 2) Weight > 55 kg to 85 kg: 390 mg once;
      - 3) Weight > 85 kg: 520 mg once;
    - ii. Maintenance dose (SC): 90 mg 8 weeks after the initial IV dose, followed by maintenance dose of 90 mg every 8 weeks;
  - b. If request is for a dose that exceeds 90 mg every 8 weeks, all of the following (i and ii):
    - i. Documentation supports inadequate response to a  $\geq$  3 month trial of the maximum dose indicated in Section V;
    - ii. Dose does not exceed 90 mg every 4 or 6 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. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
5. Member meets one of the following (a or b):
  - a. If request is for a dose increase, new dose does not exceed one of the following (i, ii, or iii):
    - i. PsO alone (*see Appendix G for dose rounding guidelines*) (1 or 2):

- 1) Adults (a or b):
  - a) Weight  $\leq$  100 kg: 45 mg every 12 weeks;
  - b) Weight  $>$  100 kg: 90 mg every 12 weeks;
- 2) 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;
- ii. PsA (1 or 2):
  - 1) 45 mg every 12 weeks;
  - 2) Co-existent PsO and weight  $>$  100 kg: 90 mg every 12 weeks;
- iii. CD, UC: 90 mg every 8 weeks;
- b. If request is for a dose increase and new maintenance dose exceeds the maximum dose and frequency indicated in Section V, all of the following (i, ii and iii):
  - i. Documentation supports inadequate response to a  $\geq$  3 month trial of the maximum dose indicated in Section V;
  - ii. One of the following (1, 2, 3 or 4):
    - 1) CD: Failure of a trial of  $\geq$  3 consecutive months of Humira unless contraindicated or clinically significant adverse effects are experienced;
    - 2) UC: Failure of ALL of the following, each used for  $\geq$  3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated: Humira, Xeljanz/Xeljanz XR;
    - 3) For PsO: Failure of ALL of the following, each used for  $\geq$  3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated: Cimzia, Enbrel/Humira;
    - 4) For PsA: Failure of ALL of the following, each used for  $\geq$  3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated: Cimzia, Enbrel/Humira, Xeljanz/Xeljanz XR;
  - iii. Dose does not exceed 90 mg every 4 or 6 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 with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Simponi<sup>®</sup>, Avsola<sup>™</sup>, Inflectra<sup>™</sup>, Remicade<sup>®</sup>, Renflexis<sup>™</sup>], interleukin agents [Arcalyst<sup>®</sup> (IL-1 blocker), Ilaris<sup>®</sup> (IL-1 blocker),

Kineret<sup>®</sup> (IL-1RA), Actemra<sup>®</sup> (IL-6RA), Kevzara<sup>®</sup> (IL-6RA), Stelara<sup>®</sup> (IL-12/23 inhibitor), Cosentyx<sup>®</sup> (IL-17A inhibitor), Taltz<sup>®</sup> (IL-17A inhibitor), Siliq<sup>™</sup> (IL-17RA), Ilumya<sup>™</sup> (IL-23 inhibitor), Skyrizi<sup>™</sup> (IL-23 inhibitor), Tremfya<sup>®</sup> (IL-23 inhibitor), janus kinase inhibitors (JAKi) [Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR, Rinvoq<sup>™</sup>], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup>, Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>, and Rituxan Hycela<sup>®</sup>], selective co-stimulation modulators [Orencia<sup>®</sup>], or integrin receptor antagonists [Entyvio<sup>®</sup>] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

#### 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 <sup>®</sup> )	<b>PsO</b> 25 or 50 mg PO daily	50 mg/day
azathioprine (Azasan <sup>®</sup> , Imuran)	<b>CD</b> 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	<b>CD*</b> prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week  budesonide (Entocort EC <sup>®</sup> ) 6 – 9 mg PO QD  <b>UC</b> budesonide (Uceris <sup>®</sup> ) 9 mg PO QD	Various
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	<b>PsO</b> 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
6-mercaptopurine (Purixan <sup>®</sup> )	<b>CD</b> 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex <sup>®</sup> )	<b>CD*</b> 15 – 25 mg/week IM or SC	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<b>PsO</b> 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	
Pentasa <sup>®</sup> (mesalamine)	<b>CD</b> 1,000 mg PO QID	4 g/day
Enbrel <sup>®</sup> (etanercept)	<b>PsA</b> 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira <sup>®</sup> (adalimumab)	<b>CD, UC</b> <u>Initial dose:</u> 160 mg SC on Day 1, then 80 mg SC on Day 15  <u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29	40 mg every other week
Otezla <sup>®</sup> (apremilast)	<b>PsA</b> <u>Initial dose:</u> Day 1: 10 mg PO QAM 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  <u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	60 mg/day
Simponi <sup>®</sup> (golimumab)	<b>UC</b> <u>Initial dose:</u> 200 mg SC at week 0, then 100 mg SC at week 2 <u>Maintenance dose:</u> 100 mg SC every 4 weeks	100 mg every 4 weeks
Taltz <sup>®</sup> (ixekizumab)	<b>PsA</b> <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0	80 mg every 4 weeks



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<u>Maintenance dose:</u> 80 mg SC every 4 weeks  <b>PsO</b> <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	
Xeljanz <sup>®</sup> (tofacitinib)	<b>PsA</b> 5 mg PO BID	<b>PsA, RA</b> 10 mg/day
Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<b>PsA</b> 11 mg PO QD	<b>PsA, RA</b> 11 mg/day
Zeposia <sup>®</sup> (ozanimod)	<b>UC</b> Days 1-4: 0.23 mg PO QD Days 5-7: 0.46 mg PO QD Day 8 and thereafter: 0.92 mg PO QD	<b>UC</b> 0.92 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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
<b>Subcutaneous, Syringe</b>	
≤ 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
<b>Subcutaneous, Vial</b>	
≤ 46.99 mg	1 vial of 45 mg/0.5 mL
47 to 94.49 mg	2 vials of 45 mg/0.5 mL
<b>Intravenous, Vial</b>	
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  <i>Adult:</i> Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg  <i>Pediatrics (Age 12 years and older):</i> 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
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: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761044s008lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761044s008lbl.pdf). Accessed February 21, 2022.

2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80:1029-72. doi:10.1016/j.aad.201811.057.
3. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79:700–712. doi:10.1136/annrheumdis-2020-217159
4. 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
5. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn’s disease. *Gastroenterology* 2021; 160:2496-2508. <https://doi.org/10.1053/j.gastro.2021.04.022>.  
Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology* 2020;158:1450–1461. <https://doi.org/10.1053/j.gastro.2020.01.006>

### 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.

HCPSC 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	02.27.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
insert, removed TB testing for all indications; references reviewed and updated.		
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 2018 guidelines; removed redirection to Humira for PsO for members < 18 years old; references reviewed and updated.	03.05.19	05.19
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
Per August SDC and prior clinical guidance, for PsA removed Simponi as a redirect option and modified to require a trial of all; for UC added requirement for trial of Humira, Simponi, and Zeposia in a step-wise manner. Add coverage for dose escalation with Stelara for CD (per A&G report) and UC (per SDC direction) requiring redirection to preferred agents [Humira, Simponi, Zeposia, infliximab (Avsola, Inflectra and Renflexis are preferred)] per SDC; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers; added Legacy WellCare line of business to policy	08.16.21	11.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
(WCG.CP.PHAR.264 to be retired) and revised its initial approval duration from 12 months to 6 months.		
For PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; fixed the following typos: removed “for CD and UC” in continued therapy section for off-label dose requests, as preferred agents should be tried for all indications prior to off-label dose escalation; references reviewed and updated	8.22.22	

### **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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