# PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Ustekinumab Intravenous Products Prior Authorization Policy

- Stelara® (ustekinumab intravenous infusion – Janssen Biotech)
- Imuldosa® (ustekinumab-srlf intravenous infusion – Accord)
- Otulfi™ (ustekinumab-aauz intravenous infusion – Formycon/Fresenius)
- Pyzchiva™ (ustekinumab-ttwe intravenous infusion – Sandoz/Samsung)
- Selarsdi™ (ustekinumab-aekn intravenous infusion – Alvotech/Teva)
- Steqeyma™ (ustekinumab-stba intravenous infusion – Celltrion)
- Wezlana™ (ustekinumab-auub intravenous infusion – Amgen)
- Yesintek™ (ustekinumab-kfce intravenous infusion – Biocon)
- Ustekinumab intravenous infusion (Janssen Biotech)
- Ustekinumab-ttwe intravenous infusion (Quallent)

**REVIEW DATE:** 07/23/2025

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## CIGNA NATIONAL FORMULARY COVERAGE:

## OVERVIEW

Ustekinumab intravenous, a monoclonal antibody against the p40 subunit of the interleukin (IL)-12 and IL-23 cytokines, is indicated for the following conditions:[1,6-12]

- **Crohn's disease** (CD), in adults with moderate to severe active disease.
- **Ulcerative colitis** (UC), in adults with moderate to severe active disease.

In CD and UC, a single weight-based dose is administered by intravenous (IV) infusion. Following induction therapy with the IV product, the recommended maintenance is ustekinumab subcutaneous (SC) injection, given as a 90 mg SC injection administered 8 weeks after the initial IV dose, then once every 8 weeks thereafter.

## Guidelines

Guidelines for the treatment of inflammatory conditions recommend use of ustekinumab.

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] has guidelines for the management of CD in adults.[2] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib). If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Guidelines from the American Gastroenterological Association (AGA) [2021] include various biologics among the therapies for moderate to severe CD, for induction and maintenance of remission.[13]
- **Ulcerative Colitis:** The AGA (2024) and the ACG (2025) have clinical practice guidelines on the management of moderate to severe UC.[3,4] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.[4] Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ustekinumab intravenous. Because of the specialized skills required for evaluation and diagnosis of patients treated with ustekinumab intravenous as well as the monitoring required for adverse events and long-term efficacy, approval requires ustekinumab intravenous to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 30 days, which is an adequate duration for the patient to receive one dose.

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**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indications

1. **Crohn's Disease**. Approve a single dose if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR
     - **ii.** Patient has tried one other conventional systemic therapy for Crohn's disease; OR
       Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.
     - **iii.** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR

iv. Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

**D)** The medication is prescribed by or in consultation with a gastroenterologist.

2. **Ulcerative Colitis.** Approve a single dose if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist.

**CONDITIONS NOT COVERED**

- **Stelara® (ustekinumab intravenous infusion – Janssen Biotech)**
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**is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Ankylosing Spondylitis (AS).** There are other biologic therapies indicated in AS. More data are needed to demonstrate efficacy of ustekinumab in this condition. There is a published proof-of-concept trial evaluating ustekinumab in AS (TOPAS – UsTekinumab for the treatment Of Patients with active Ankylosing Spondylitis).[4] TOPAS was a prospective, open-label study evaluating ustekinumab 90 mg subcutaneous at Week 0, 4, and 16 in patients (n = 20) with AS. After Week 16, patients were followed through Week 28. Patients who previously failed to respond to tumor necrosis factor inhibitor (TNFi) were excluded. The primary endpoint was a 40% improvement in disease activity at Week 24 according to the Assessment of SpondyloArthritis International Society (ASAS) criteria (ASAS40) in the intent-to-treat population which included all patients who received at least one dose of ustekinumab. In all, 65% of patients (95% confidence interval [CI]: 41%, 85%; n = 13/20) achieved an ASAS40 response at Week 24. There was at least a 50% improvement of the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) achieved by 55% of patients (95% CI: 32%, 77%; n = 11/20). However, enthesitis (measured by MASES [Maastricht AS Entheses Score] and SPARCC [SPondyloArthritis Research Consortium of Canada] enthesitis indices) and the number of swollen joints were not significantly improved at Week 24.

There was a significant reduction of active inflammation on magnetic resonance imaging at Week 24 compared with baseline in sacroiliac joints.

2. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

3. **Plaque Psoriasis.** Ustekinumab for subcutaneous injection is indicated for treatment of plaque psoriasis.[1] Appropriate dosing of ustekinumab intravenous in plaque psoriasis is unclear.

4. **Psoriatic Arthritis.** Ustekinumab for subcutaneous injection is indicated for treatment of psoriatic arthritis.[1] Appropriate dosing of ustekinumab intravenous in psoriatic arthritis is unclear.

## REFERENCES


1. Stelara® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; November 2024.
2. Lichtenstein G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025 June;120(6):1225-1264.
3. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
4. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224.
5. Poddubnyy D, Hermann KG, Callhoff J, et al. Ustekinumab for the treatment of patients with active ankylosing spondylitis: results of a 28-week, prospective, open-label, proof-of-concept study (TOPAS). *Ann Rheum Dis*. 2014;73(5):817-823.
6. Otulfi® intravenous infusion, subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius; December 2024.
7. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; June 2024.
8. Selarsdi® intravenous infusion, subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; October 2024.
9. Steqeyma® intravenous infusion, subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Celltrion; December 2024.
10. Yesintek® intravenous infusion, subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; December 2024.
11. Wezlana® intravenous infusion, subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2025.
12. Imuldosa® intravenous infusion, subcutaneous injection [prescribing information]. Raleigh, NC: Accord; October 2025.
13. 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(7):2496-2508.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 06/28/2022 |
| Annual Revision | **Ulcerative Colitis:** A note was added that a trial of a mesalamine product does not count as a systemic agent for ulcerative colitis. | 07/24/2024 |
| Selected Revision | **Conditions Not Covered :** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug). | 09/11/2024 |
| Selected Revision | Policy name was changed to more generally list Ustekinumab Intravenous Products; previously policy was specific to Stelara Intravenous. Wezlana intravenous was added to the policy; the same criteria apply for Wezlana and for Stelara intravenous. | 12/18/2024 |
| Selected Revision | Otulfi, Pyzchiva, Selarsdi, Steqeyma, and Yesintek intravenous were added to the policy; the same criteria apply for all ustekinumab intravenous products. | 01/29/2025 |
| Selected Revision | Ustekinumab-ttwe intravenous was added to the policy; the same criteria apply as the other ustekinumab intravenous products. | 02/19/2025 |
| Selected Revision | Ustekinumab intravenous (unbranded Stelara) was added to the policy; the same criteria apply as the other ustekinumab intravenous products. | 04/23/2025 |
| Selected Revision | Imuldosa intravenous was added to the policy; the same criteria apply for all ustekinumab intravenous products. | 06/25/2025 |
| Annual Revision | **Ulcerative Colitis:** Removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. | 07/23/2025 |

## APPENDIX

| | Mechanism of Action | Examples of Indications* |
|---|---|---|
| **Biologics** | | |
| **Adalimumab SC Products** (Humira®, biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC |
| **Cimzia®** (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, nr-axSpA, PsO, PsA, RA |
| **Etanercept SC Products** (Enbrel®, biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA, RA |
| **Infliximab IV Products** (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| **Zymfentra®** (infliximab-dyyb SC injection) | Inhibition of TNF | CD, UC |
| **Simponi®, Simponi Aria®** (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PJIA, PsA, RA |
| **Tocilizumab Products** (Actemra® IV, biosimilar; Actemra SC, biosimilar) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| **Kevzara®** (sarilumab SC injection) | Inhibition of IL-6 | RA |
| **Orencia®** (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA |
| | | IV formulation: JIA, PsA, RA |
| **Rituximab IV Products** (Rituxan®, biosimilars) | CD20-directed cytolytic antibody | RA |
| **Kineret®** (anakinra SC injection) | Inhibition of IL-1 | JIA^, RA |
| **Omvoh®** (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | UC, CD |
| **Ustekinumab Products** (Stelara® SC injection, biosimilar; Stelara IV infusion, biosimilar) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Siliq®** (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| **Cosentyx®** (secukinumab SC injection; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
| | | IV formulation: AS, nr-axSpA, PsA |
| **Taltz®** (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| **Bimzelx®** (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F | PsO, AS, nr-axSpA, PsA |
| **Ilumya®** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| **Skyrizi®** (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC |
| | | IV formulation: CD, UC |
| **Tremfya®** (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: PsA, PsO, UC |
| | | IV formulation: UC |
| **Entyvio®** (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |
| **Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs** | | |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Cibinqo™** (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | RA, AA |

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|---|---|---|
| **Litfulo®** (ritlecitinib capsules) | Inhibition of JAK pathways | AA |
| **Leqselvi®** (deuruxolitinib tablets) | Inhibition of JAK pathways | AA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, CD, UC |
| **Rinvoq® LQ** (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |
| **Sotyktu®** (deucravacitinib tablets) | Inhibition of TYK2 | PsO |
| **Xeljanz®** (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |
| **Zeposia®** (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |
| **Velsipity®** (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.