CARECONTINUUM™

UTILIZATION REVIEW MANAGEMENT POLICY

POLICY: Inflammatory Conditions – Ustekinumab Intravenous Products Utilization Management Medical 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)
- Starjemza™ (ustekinumab-hmny intravenous infusion – BioThera)
- 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: 04/22/2026

OVERVIEW

Ustekinumab intravenous (IV), 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, 14]

- **Crohn's disease** (CD), in adults and pediatric patients ≥ 2 years of age 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 IV infusion. Following induction therapy with the IV product, the recommended maintenance dose is administered as a subcutaneous (SC) injection 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] and the American Gastroenterological Association (AGA) [2025] have guidelines for the management of CD in adults.[2,13] Both guidelines recommend upfront use of advanced therapies, rather than step-up therapy after failure of corticosteroids and/or immunomodulators. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab IV infusion, SC injection), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib extended-release tablets).
- **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 medical benefit coverage of ustekinumab intravenous. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ustekinumab intravenous is recommended in those who meet one of the following criteria:

FDA-Approved Indications

---

1. Crohn's Disease. Approve a single dose if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 2 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.

Dosing. Approve ONE of the following weight-based doses (A, B, C, or D):
- **A)** ≥ 10 kg but ≤ 25 kg (≥ 22 lbs but ≤ 55 lbs): Approve up to 10 mg/kg as an intravenous infusion; OR
- **B)** > 25 kg but ≤ 55 kg (> 55 lbs but ≤ 121 lbs): Approve up to 260 mg as an intravenous infusion; OR
- **C)** > 55 kg but ≤ 85 kg (> 121 lbs but ≤ 187 lbs): Approve up to 390 mg as an intravenous infusion; OR
- **D)** > 85 kg (> 187 lbs): Approve up to 520 mg as an intravenous infusion.

---

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.

Dosing. Approve ONE of the following weight-based doses (A, B, or C):
- **A)** ≤ 55 kg (121 lbs): Approve up to 260 mg as an intravenous infusion; OR
- **B)** > 55 kg but ≤ 85 kg (> 121 lbs but ≤ 187 lbs): Approve up to 390 mg as an intravenous infusion; OR
- **C)** > 85 kg (> 187 lbs): Approve up to 520 mg as an intravenous infusion.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ustekinumab intravenous is not recommended in the following situations:

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 agents (e.g., methotrexate, 6-mercaptopurine, azathioprine, and 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.

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Stelara® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; April 2026.
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. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.
14. Starjemza™ intravenous infusion, subcutaneous injection [prescribing information]. Guangzhou, Guang dong, China: Bio-Thera; May 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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 Recommended for Approval:** 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
Selected Revision	Starjemza intravenous was added to the policy; the same criteria apply as the other ustekinumab intravenous products.	11/05/2025
Selected Revision	**Crohn's Disease:** The following options of approval were removed: The patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated; patient has tried one conventional systemic therapy for Crohn's disease along with the associated Note; patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). **Appendix:** Otezla XR (apremilast extended-release tablets) was added.	02/11/2026
Early Annual Revision	**Crohn's Disease:** The age requirement was modified from ≥ 18 years to ≥ 2 years of age. Dosing was updated to add an option for a patient weighing ≥ 10 kg but ≤ 25 kg. In a patient weighing ≤ 55 kg, specified the lower limit of weight as > 25 kg.	04/22/2026

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, HS, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, JIA, 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
Kineret® (anakinra SC injection)	Inhibition of IL-1	RA
Tocilizumab Products (Actemra® IV, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, RA
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, HS, 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	AS, HS, nr-axSpA, PsO, PsA
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
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 antibody	RA
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Otezla® XR (apremilast extended-release tablets)	Inhibition of PDE4	PsO, PsA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	AA, RA
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, CD, nr-axSpA, PJIA, PsA, RA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	Tablets: AS, PsA, RA, UC
		Oral solution: PJIA, PsA
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	AS, PsA, RA, 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; HS – Hidradenitis Suppurativa; 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; ERA – Enthesitis-related arthritis; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.