

Ustekinumab Intravenous (Stelara[®], Imuldosa[®], Otulfi[™], Pyzchiva[®], Selarsdi[™], Steqeyma[™], Wezlana[™], Yesintek[™], ustekinumab, ustekinumab-ttwe)

When requesting an ustekinumab intravenous product, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Ustekinumab intravenous is indicated for the treatment of:

- adult patients with moderately to severely active Crohn's disease
- adult patients with moderately to severely active ulcerative colitis

Coverage Guidelines

Crohn's Disease

The individual must meet **all** of the following criteria for approval:

- Is 18 years of age or older;
- Ustekinumab intravenous will be used as induction therapy;
- Meets one of the following:
 - Has tried one other systemic agent for Crohn's disease (e.g., certolizumab pegol, vedolizumab, adalimumab, infliximab, azathioprine, 6-mercaptopurine, methotrexate); OR
Note: Mesalamine products do not count as systemic therapy.
 - Has tried or is currently taking a systemic corticosteroid; OR
 - Has a contraindication to systemic corticosteroids; OR
 - Had ileocolonic resection; OR
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas.
- Ustekinumab intravenous is prescribed by or in consultation with a gastroenterologist.

Ulcerative Colitis

The individual must meet **all** of the following criteria for approval:

- Is 18 years of age or older;
- Ustekinumab intravenous will be used as induction therapy;
- Ustekinumab intravenous is prescribed by or in consultation with a gastroenterologist.

Approval duration: 30 days (approve a single dose)

Dosing Recommendations

Crohn's Disease and Ulcerative Colitis

Intravenous induction dosage regimen (a single intravenous infusion)

- For patients weighing 55 kg or less, the recommended dose is 260 mg.
- For patients weighing more than 55 kg to 85 kg, the recommended dose is 390 mg.
- For patients weighing more than 85 kg, the recommended dose is 520 mg.

References

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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; May 2025.
7. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; December 2024.
8. Selarsdi® intravenous infusion, subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; February 2025.
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; November 2024.
11. Wezlana® intravenous infusion, subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2025.
12. Imuldosa® intravenous infusion, subcutaneous injection [prescribing information]. Raleigh, NC: Accord; October 2024.
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.