

Ustekinumab Intravenous (Stelara[®], Imuldosa[®], Otulfi[™], Pyzchiva[®], Selarsdi[™], Starjemza[™], 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:

- Crohn's disease, in adults and pediatric patients ≥ 2 years of age with moderately to severely active disease
- Ulcerative colitis, in adult patients with moderately to severely active disease

Coverage Guidelines

Crohn's Disease

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

- Is 2 years of age or older;
- Ustekinumab intravenous will be used as induction therapy;
- 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

Intravenous induction dosage regimen (a single intravenous infusion)

- For patients weighing ≥ 10 kg but ≤ 25 kg, the recommended dose is 10 mg/kg.
- For patients weighing > 25 kg but ≤ 55 kg, the recommended dose is 260 mg.
- For patients weighing > 55 kg but ≤ 85 kg, the recommended dose is 390 mg.
- For patients weighing > 85 kg, the recommended dose is 520 mg.

Ulcerative Colitis

Intravenous induction dosage regimen (a single intravenous infusion)

- For patients weighing ≤ 55 kg, the recommended dose is 260 mg.
- For patients weighing > 55 kg but ≤ 85 kg, the recommended dose is 390 mg.
- For patients weighing > 85 kg, the recommended dose is 520 mg.

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; May 2025.
7. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; November 2025.
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; October 2025.
12. Imuldosa® intravenous infusion, subcutaneous injection [prescribing information]. Raleigh, NC: Accord; October 2024.
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.