

Ustekinumab Intravenous (Stelara®, Wezlana™)

When requesting a 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:
 - o Had ileocolonic resection; OR
 - o Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - o Has tried one other systemic agent for Crohn's disease (e.g., certolizumab pegol, vedolizumab, adalimumab, infliximab, azathioprine, 6-mercaptopurine, methotrexate); OR
 - o Has tried or is currently taking a systemic corticosteroid; OR
 - o Has a contraindication to systemic corticosteroids.
- 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;
- Meets one of the following:
 - o Has tried one other systemic agent for ulcerative colitis (e.g., vedolizumab, adalimumab, golimumab, infliximab, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus, corticosteroid); OR

- o Has pouchitis and has tried one of the following: an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema.
- 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

1. Stelara® injection [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's Disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020 Apr;158(5):1450-1461.
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. Wezlana™ injection [prescribing information]. Thousand Oaks, CA: Amgen Inc.; January 2025.