

Skyrizi® Intravenous (risankizumab-rzaa)

When requesting Skyrizi® Intravenous (risankizumab-rzaa), 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

Skyrizi Intravenous is indicated for the treatment of:

- Moderately to severely active Crohn's disease in adults
- Moderately to severely active ulcerative colitis in adults

Coverage Guidelines

Crohn's Disease

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

- Is 18 years of age or older;
- Skyrizi Intravenous is prescribed by or in consultation with a gastroenterologist;
- Will receive Skyrizi Intravenous 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 therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate, adalimumab, infliximab, certolizumab, ustekinumab, vedolizumab); OR
(*Note: A trial of a mesalamine product or a biosimilar of the requested biologic do not count as systemic therapy for Crohn's disease*).
 - o Has tried or is currently taking a systemic corticosteroid; OR
 - o Has a contraindication to systemic corticosteroid.

Approval duration: 3 months

Ulcerative Colitis

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

- Is 18 years of age or older;
- Will receive Skyrizi intravenous as induction therapy;
- Skyrizi intravenous is prescribed by or in consultation with a gastroenterologist;
- Meets one of the following:
 - o Has tried one other systemic therapy (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone, adalimumab, infliximab, mirikinumab, ustekinumab, vedolizumab); OR

(*Note: A trial of a mesalamine product or a biosimilar of the requested biologic do not count as systemic therapy for ulcerative colitis.*)

- 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.

Approval duration: 3 months

Dosing Recommendation

Crohn's Disease:

The recommended induction dosage is 600 mg administered by intravenous infusion at Week 0, Week 4, and Week 8.

Ulcerative Colitis:

The recommended induction dosage is 1,200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8.

References

1. Skyrizi® [prescribing information]. North Chicago, IL: AbbVie; June 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. 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.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.