

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 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:
 - 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*).
 - Has tried or is currently taking a systemic corticosteroid; OR
 - Has a contraindication to systemic corticosteroid; OR
 - Had ileocolonic resection; OR
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas.

Ulcerative Colitis

The individual must meet **all** of the following criteria for 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;

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; May 2025.
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. 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. 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.
5. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol*. 2025 June;120(6):1187-1224.