

## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Skyrizi Intravenous Prior Authorization Policy

- Skyrizi® (risankizumab-rzaa intravenous infusion – Abbvie)

**REVIEW DATE:** 06/26/2024

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### OVERVIEW

Skyrizi intravenous (IV), an interleukin (IL)-23 blocker, is indicated for:<sup>1</sup>

- **Crohn's disease**, in adults with moderate to severe active disease; AND
- **Ulcerative colitis**, in adults with moderate to severe active disease.

#### Crohn's disease

In Crohn's disease, a three-dose induction regimen (600 mg at Weeks 0, 4, and 8) is administered by IV infusion.<sup>1</sup> Following induction therapy with the IV product, the recommended maintenance is Skyrizi subcutaneous injection, given as a 180 mg or 360 mg subcutaneous injection administered at Week 12 (4 weeks following the last induction dose), then once every 8 weeks thereafter.

#### Ulcerative colitis

In ulcerative colitis (UC), a three-dose induction regimen (1,200 mg at Weeks 0, 4, and 8) is administered by IV infusion.<sup>1</sup> Following induction therapy with the IV product, the recommended maintenance is Skyrizi subcutaneous injection, given as a 180 mg or 360 mg subcutaneous injection administered at Week 12 (4 weeks following the last induction dose), then once every 8 weeks thereafter.

### Guidelines

The following guidelines address indications for which Skyrizi IV is indicated.

- **Crohn's Disease:** Skyrizi is not addressed in current guidelines. The American College of Gastroenterology has guidelines for Crohn's disease (2018).<sup>2</sup> Biologics are a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors). Guidelines from the American Gastroenterological Association (2021) include biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.<sup>3</sup>
- **Ulcerative colitis:** Current guidelines do not address the use of Skyrizi for UC. The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults.<sup>4,5</sup> Generally TNF inhibitors, Entyvio® (vedolizumab IV infusion/subcutaneous injection), Stelara® (ustekinumab IV infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence). The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

06/26/2024

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## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Skyrizi IV. Because of the specialized skills required for evaluation and diagnosis of patients treated with Skyrizi IV as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Skyrizi IV to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 3 months, which is an adequate duration for the patient to receive three doses.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Skyrizi IV is recommended in those who meet the following:

### **FDA-Approved Indication**

- 1. Crohn's Disease.** Approve three doses for induction if the patient meets the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** The medication will be used as induction therapy; AND
  - C)** Patient meets ONE of the following (i, ii, iii, or iv):
    - i.** Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR
    - ii.** Patient has tried one other conventional systemic therapy for Crohn's disease; OR  
Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.
    - iii.** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
    - iv.** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
  - D)** The medication is prescribed by or in consultation with a gastroenterologist.
- 2. Ulcerative Colitis.** Approve three doses for induction if the patient meets ALL of the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** The medication will be used as induction therapy; AND
  - C)** Patient meets ONE of the following (i or ii):
    - i.** Patient has tried one systemic therapy; OR  
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for ulcerative colitis.
    - ii.** Patient meets BOTH of the following (a and b):
      - a)** Patient has pouchitis; AND
      - b)** Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

D) The medication is prescribed by or in consultation with a gastroenterologist.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Skyrizi IV is not recommended in the following situations:

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Skyrizi with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.

Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat Crohn's disease) in combination with Skyrizi.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Skyrizi® intravenous infusion, subcutaneous injection [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. 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.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114(3):384-413.

**APPENDIX**

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.