Effective Date: 11/01/2025
Reviewed: 09/2025 Scope: Commercial

Skyrizi (risankizumab-rzaa)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

1. Treatment of moderately to severely active Crohn's disease (CD) in adults
2. Treatment of moderately to severely active ulcerative colitis (UC) in adults

Moderate to severe plaque psoriasis and active psoriatic arthritis are not covered indications. Please refer to the Non-Formulary Exception Policy.

All other indications are considered experimental/investigational and not medically necessary.

II. INITIAL CRITERIA

Authorization of 12 months may be granted when one of the following criteria is met:

Crohn's Disease[1,3,4]

A. The medication must be prescribed by or in consultation with a gastroenterologist.
B. The member has a diagnosis of moderately to severely active Crohn's disease.

Ulcerative Colitis[1,5-7]

A. The medication must be prescribed by or in consultation with a gastroenterologist.
B. The member has a diagnosis of moderately to severely active ulcerative colitis.

III. CONTINUATION OF THERAPY

Crohn's Disease[1,3,4]

A. Authorization of 12 months may be granted for all members (including new members) have documentation (chart notes or medical record documentation) that the member achieves or maintains remission OR that the member achieves or maintains a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Abdominal pain or tenderness
    b. Diarrhea
    c. Body Weight

d. Abdominal mass
e. Hematocrit
f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Ulcerative Colitis[1,5-7]

A. Authorization of 12 months may be granted for all members (including new members) have documentation (chart notes or medical record documentation) that the member achieves or maintains remission OR that the member achieves or maintains a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Stool frequency
    b. Rectal bleeding
    c. Urgency of defecation
    d. C-reactive protein (CRP)
    e. Fecal calprotectin (FC)
    f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

IV. OTHER[1,2]

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
2. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 22, 2025 from: https://www.cdc.gov/tb/testing/index.html.
3. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. Lancet. 2022;399(10340):2015-2030.
4. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.
5. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
6. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114:384-413.
7. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158:1450.