

Skyrizi® (risankizumab-rzaa)

When requesting Skyrizi® (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

Plaque Psoriasis

Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis

Skyrizi is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease

Skyrizi is indicated for the treatment of moderately to severely active Crohn's disease in adults.

Coverage Guidelines

Plaque Psoriasis

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

- Is 18 years of age or older;
- Skyrizi is prescribed by or in consultation with a dermatologist;
- Meets one of the following:
 - Had a 3-month trial or intolerance to at least one biologic agent for psoriasis (e.g., adalimumab, certolizumab, etanercept, ustekinumab); OR
 - Had a 3-month trial or intolerance to at least one traditional systemic agent for psoriasis (e.g., methotrexate, cyclosporine, psoralen plus ultraviolet A light, acitretin tablets); OR
 - Has a contraindication to methotrexate

The individual must meet all of the following criteria for re-authorization:

- Has been established on Skyrizi therapy for at least 90 days (*NOTE: Patients who have received less than 90 days of therapy or those who are restarting therapy with Skyrizi should be considered under initial criteria*);
- Has experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following: estimated body surface area, erythema, induration/thickness and/or scale of areas affected by psoriasis;
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, itching, and/or burning)

Psoriatic Arthritis

The individual must meet the following criteria for initial authorization:

- Skyrizi is prescribed by or in consultation with a rheumatologist or a dermatologist

The individual must meet all of the following criteria for re-authorization:

- Has been established on Skyrizi therapy for at least 6 months (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Skyrizi should be considered under initial criteria*);
- Meets one of the following:
 - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis, Composite Psoriatic Disease Activity Index, Psoriatic Arthritis Impact of Disease); OR
 - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths)

Crohn's Disease

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

- Is 18 years of age or older;
- Skyrizi is prescribed by or in consultation with a gastroenterologist;
- Will receive or has received induction dosage with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous;
- Meets one of the following:
 - Had ileocolonic resection; OR
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - Has tried one other systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate, adalimumab, certolizumab, ustekinumab); OR
 - Has tried or is currently taking a systemic corticosteroid; OR
 - Has a contraindication to systemic corticosteroid

The individual must meet all of the following criteria for re-authorization:

- Has been established on Skyrizi therapy for at least 6 months (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Skyrizi should be considered under initial criteria*);
- Meets one of the following:
 - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool)

Approval durations:

- Initial authorization: 6 months for Crohn's disease and psoriatic arthritis; 3 months for plaque psoriasis
- Reauthorization: 12 months

Dosing Recommendations**Plaque Psoriasis and Psoriatic Arthritis**

The recommended dose is 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

Crohn's Disease

The recommended induction dosage is 600 mg administered by intravenous infusion over a period of at least one hour at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at Week 12 and every 8 weeks thereafter. Use the lowest effective dosage to maintain therapeutic response.

References

1. Skyrizi® [prescribing information]. North Chicago, IL: AbbVie; December 2022.
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. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
5. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.