

ALASKA MEDICAID
Prior Authorization Criteria

Skyrizi[®]
(risankizumab-rzaa)

FDA INDICATIONS AND USAGE¹

Skyrizi[®] is an interleukin-23 antagonist indicated for treatment of:

- Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis in adults.
- Moderately to severely active Crohn's disease in adults.
- Moderately to severely active ulcerative colitis in adults.

APPROVAL CRITERIA^{1,2,3,4}

1. Initial Authorization Request must include:
 - Monitoring plan
 - Previous therapies trialed and the nature of the failure
 - Complete medication regimen
 - Requested dosing which conforms to an FDA approved regimen based on indication

Plaque psoriasis (Ps)

1. Patient meets FDA labeled age **AND;**
2. Has moderate to severe Ps **AND;**
3. Has a Psoriasis Area and Severity Index (PASI) score ≥ 12 (or equivalent) **AND;**
4. Has trialed and failed a TNF blocker and at least one other therapy to include at least one topical agent.

Psoriatic Arthritis (PsA)

1. Patient meets FDA labeled ag; **AND;**
2. Has the diagnosis of active PsA **AND;**
3. One or more of the following apply:
 - i. actively inflamed joints
 - ii. dactylitis
 - iii. enthesitis
 - iv. axial disease
 - v. active skin and/or nail involvement; **AND;**
4. Baseline Health Assessment Questionnaire-Disability Index (HAQ-DI) score (or equivalent) has been submitted **AND;**
5. Has trialed and failed a TNF blocker and at least one other therapy.

Crohn's disease (CD)

1. Patient meets FDA labeled age **AND;**
2. Has moderate to severe active CD **AND;**
3. Baseline Crohn's Disease Activity Score (CDAI) has been submitted **AND;**
4. Patient baseline CDAI ≥ 220 **AND;**
5. Has trialed and failed a TNF blocker and at least one other therapy (e.g. mesalamine, sulfasalazine, corticosteroid, etc.).

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Prior Authorization Criteria

Ulcerative Colitis (UC)

1. Patient meets FDA labeled age **AND**;
2. Has moderate to severely active UC **AND**;
3. Baseline modified Mayo score (mMS) (or equivalent) has been submitted **AND**;
4. Patient baseline mMS ≥ 5 **AND**;
5. Has trialed and failed a TNF blocker and at least one other therapy (e.g. azathioprine, cyclosporine, mesalamine, etc.).

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient has an active clinically significant infection **OR**;
3. Patient is receiving phototherapy **OR**;
4. Patient is receiving another biologic response modifying agent

CAUTIONS¹

- Patients should be evaluated for tuberculosis prior to initiating treatment with Skyrizi. Avoid use in patients with active tuberculosis.
- Monitor liver function tests, alkaline phosphatase, and bilirubin while undergoing Skyrizi treatment for inflammatory bowel disease.
- Live vaccines are not recommended while undergoing Skyrizi treatment.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT¹

- PS, PsA: 150mg subcutaneous injection at week 0, week 4, and every 12 weeks thereafter
- CD:
 - Initial: 600mg intravenous infusion at week 0, week 4, and week 8.
 - Maintenance: 180mg to 360mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter. Lowest effective dose necessary to maintain therapeutic response should be utilized.
- UC:
 - Initial: 1200mg intravenous infusion at week 0, week 4, and week 8.
 - Maintenance: 180mg to 360mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter. Lowest effective dose necessary to maintain therapeutic response should be utilized.

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REFERENCES / FOOTNOTES:

1. Skyrizi [prescribing information]. North Chicago, IL; AbbVie Inc.; June 2024.
2. 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;80:1029-72.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018; 113:481-517.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413