289 LaClair Coos Bay OR 97420
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Skyrizi (risankizumab-rzza) Drug Use Criteria

Created: October 2025

Includes:
Skyrizi© (*risankizumab-rzaa)*

GUIDELINE FOR USE:

Initial Request:

1. Is the PA request form complete with member information, diagnosis, prescriber, and prior therapies documented?

    a. If yes, go to 2
    b. If no, request additional information

2. Is the requested indication FDA-approved and OHP-funded?

    a. If yes, go to 3
    b. If no, deny as not meeting criteria

3. Does the member have a covered indication for Skyrizi?
    - Moderate to severe plaque psoriasis (adults)
    - Active psoriatic arthritis (adults)
    - Moderately to severely active Crohn's disease (adults)
    - Moderately to severely active ulcerative colitis (adults)

    a. If yes, go to 4
    b. If no, deny as not meeting criteria

4. Has the member trialed and failed (or has contraindication/intolerance to) conventional systemic therapy as indicated in **TABLE 1** below?

    a. If yes, go to 5
    b. If no, deny as not meeting criteria

5. Has the member trialed and failed treatment with required step therapy as indicated in **TABLE 2** below?

    a. If yes, approve for up to 6 months
    b. If no, deny as not meeting criteria

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Renewal Request:

1. Does a review of claims history support adherence to Skyrizi therapy as prescribed?

    a. If yes, go to 2
    b. If no, deny as not meeting criteria

2. Does documentation support a positive response to treatment with Skyrizi?
    - PASI 75 improvement (psoriasis)
    - CDAI or UCDAI reduction (irritable bowel disease)
    - Improved joint symptoms (psoriatic arthritis)

    a. If yes, go to 3
    b. If no, deny as not meeting criteria

3. Has the member experienced NO unacceptable toxicity to treatment?
    a. If yes, approve for up to 12 months
    b. If no, deny as not meeting criteria

TABLE 1

Condition	Recommended Conventional Therapy Prior to a Targeted Immune Modulator
Moderate to severe plaque psoriasis (adults)	• Topical high potency corticosteroid (e.g., betamethasone dipropionate 0.05%, Clobetasol propionate 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%; triamcinolone 0.5%) for a minimum of 4 weeks; AND • At least one other topical agent: calcipotriene, tazarotene, anthralin for a minimum of 8 weeks; AND • Phototherapy for at least 8 weeks; AND • At least one other systemic therapy: acitretin, cyclosporine, or methotrexate for at least 16 weeks
Active psoriatic arthritis (adults)	• DMARD therapy: Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine for ≥ 6 months; AND • Concurrent DMARD therapy with plans to continue concomitant use. Biologic therapy is recommended in combination with DMARDs (e.g. methotrexate) for those who have had inadequate response with DMARDs.
Moderate to severe active Crohn's disease (adults)	• Mercaptopurine, methotrexate, or azathioprine for ≥6 months
Moderate to severe active ulcerative colitis (adults)	• 5-aminosalicylate products, mercaptopurine, or azathioprine for ≥6 months

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TABLE 2 [Step Therapy required AFTER recommended conventional therapy]

Condition	Step 1	Step 2	Step 3	Step 4
Moderate to severe plaque psoriasis (adults)	**Adalimumab**	**Infliximab**	**Ustekinumab**	**Cosentyx**
Active psoriatic arthritis (adults)	**Adalimumab**	**Infliximab**	**Ustekinumab**	**Cosentyx**
Moderate to severe active Crohn's disease (adults)	**Adalimumab**	**Infliximab**	**Ustekinumab**	
Moderate to severe active ulcerative colitis (adults)	**Adalimumab**	**Infliximab**	**Ustekinumab**	

Rationale: To promote safe and cost-effective use of Skyrizi® (risankizumab-rzaa) for FDA-approved indications by requiring stepwise use of less costly, evidence-based therapies first. This ensures Skyrizi is reserved for patients with inadequate response, contraindication, or intolerance to standard treatments, supporting clinical effectiveness while maintaining responsible resource utilization.

FDA Approved Indication:

Skyrizi® is indicated for the treatment of adults with moderate to severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of **active psoriatic arthritis**, as well as for adults with **moderately to severely active Crohn's disease** and **ulcerative colitis**.

References:

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6. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413. doi:10.14309/ajg.0000000000000152.

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8. Oregon Health Authority, Health Evidence Review Commission (HERC). *Guideline Note 148: Targeted Immune Modulators for Autoimmune Conditions.* Oregon Health Plan; 2024. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC. Accessed October 2, 2025.
9. Advanced Health Pharmacy and Therapeutics Committee. *Approval History for Skyrizi Drug Use Criteria.* Approved: Oct 2025.