

**Skyrizi (risankizumab-rzaa)**  
**Effective 12/1/2024**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	Skyrizi IV is only available on the Medical Benefit		

### Overview

Skyrizi is an interleukin (IL)-23 antagonist FDA indicated in adults for: moderate-to-severe plaque psoriasis, moderate-to-severe active Crohn's disease, moderate-to-severe ulcerative colitis, and moderate-to-severe plaque psoriasis, and active psoriatic arthritis. The inhibition of the interaction with the IL-23 receptor results in the inhibition of the of the release of proinflammatory cytokines and chemokines.

### Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program

**OR**

Authorization may be granted when the following criteria are met and documentation has been submitted:

### Plaque psoriasis (PsO)

1. The member has diagnosis of moderate to severe plaque psoriasis
2. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
3. Member meets ONE of the following criteria:
  - a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
    - i. Corticosteroids (e.g., betamethasone, clobetasol)
    - ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
    - iii. Tazarotene
    - iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
    - v. Anthralin
    - vi. Coal tar
  - b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

### **Psoriatic arthritis (PsA)**

1. The member has diagnosis of active psoriatic arthritis
2. The member meets ONE of the following:
  - a. Actively inflamed joints
  - b. Dactylitis
  - c. Enthesitis
  - d. Axial disease
  - e. Active skin and/or nail involvement

### **Crohn's Disease (CD)**

1. The member has diagnosis of active Crohn's disease
2. ONE of the following:
  - a. Frequent diarrhea and abdominal pain
  - b. At least 10% weight loss
  - c. Complications such as obstruction, fever, abdominal mass
  - d. Abnormal lab values (e.g., C-reactive protein [CRP])
  - e. CD Activity Index (CAI) great than 220
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
  - a. 6-mercaptopurine
  - b. Azathioprine
  - c. Corticosteroids (e.g., prednisone)
  - d. methotrexate

### **Ulcerative Colitis (UC)**

1. The member has a diagnosis of moderate-to-severe ulcerative colitis
2. ONE of the following:
  - a. Greater than 6 stools per day
  - b. Frequent blood in stools
  - c. Frequent urgency
  - d. Presence of ulcers
  - e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
  - f. Dependent on, or refractory to, corticosteroids
3. Member has had a trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
  - a. 6-mercaptopurine
  - b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
  - c. Azathioprine
  - d. Corticosteroids (e.g., prednisone)

### **Continuation of Therapy**

Reauthorization approvals will be granted when documentation has been submitted supporting clinical improvement in member's condition.

### **Limitations**

1. Initial approvals for Skyrizi IV will be granted for 8 weeks
2. Initial and reauthorization approvals for Skyrizi SC will be granted for 24 months
3. The following quantity limits apply:



Skyrizi 75mg and 150mg	<u>Psoriatic Arthritis/Plaque Psoriasis:</u> One loading dose: 150mg at weeks 0 and 4 Maintenance dose: 150mg every 12 weeks
Skyrizi IV 600mg/10mL and 180 mg/1.2 mL 360mg/2.4mL	<u>Crohn's Disease:</u> IV Loading dose: 600mg at weeks 0, 4, and 8 Maintenance SC: 180 mg or 360mg at week 12, and every 8 weeks after.
Skyrizi IV 600 mg/10 mL and 180 mg/1.2 mL and 360 mg/2.4 mL	<u>Ulcerative Colitis:</u> IV loading dose: 1,200 mg at weeks 0, 4, and 8 Maintenance SC: 180 mg or 360 mg at week 12, and every 8 weeks thereafter

## References

1. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2024.
2. Flytström I, Stenberg B, Svensson A, Bergbrant IM. Methotrexate vs. ciclosporin in psoriasis: effectiveness, quality of life and safety. A randomized controlled trial. Br J Dermatol 2008; 158:116.
3. Lebwohl M, Drake L, Menter A, et al. Consensus conference: acitretin in combination with UVB or PUVA in the treatment of psoriasis. J Am Acad Dermatol 2001; 45:544
4. Chen X, Yang M, Cheng Y, et al. Narrow-band ultraviolet B phototherapy versus broad-band ultraviolet B or psoralen-ultraviolet A photochemotherapy for psoriasis. Cochrane Database Syst Rev 2013; :CD009481
5. Krueger JG, Ferris LK, Menter A, et al. Anti-IL-23A mAb BI 655066 for treatment of moderate-to-severe psoriasis: Safety, efficacy, pharmacokinetics, and biomarker results of a single-rising-dose, randomized, double-blind, placebo-controlled trial. J Allergy Clin Immunol 2015; 136:116

## Review History

11/20/2019 – Reviewed at P&T

07/22/2020 – Reviewed and Updated July P&T; Updated Program Type to PA and QL; added TB testing requirement under Limitations. Effective 10/01/2020.

03/16/2022 – Reviewed and Updated March P&T; Added new indication psoriatic arthritis; added severe psoriasis may warrant a biologic DMARD as first-line therapy. Effective 05/01/2022

09/21/2022 – Reviewed and Updated for Sept P&T; added new indication for Crohn's disease. Effective 11/1/22

01/11/2023 – Reviewed for Jan P&T; updated 'exceptions' to allow new formulation of Skyrizi IV under the Medial Benefit only. Effective 2/1/2023

06/14/2023 – Reviewed and Updated for Jun P&T; added Skyrizi IV to exceptions as it is available under Medical Benefit Only.

11/15/2023 – Reviewed and Updated for Nov P&T; removed TB requirement. Psoriatic arthritis – removed conventional therapies and added member meets one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis – changed from 5% BSA to 3% BSA. Removed appendix. Consolidated conventional therapies for plaque psoriasis. Crohn's disease – added Frequent diarrhea and abdominal pain, at least 10% weight loss, Complications such as obstruction, fever, abdominal mass, Abnormal lab values (e.g., C-reactive protein [CRP]), or CD Activity Index (CDAI) great than 20. Effective 1/1/24

09/11/2024 – Reviewed and updated for September P&T. Added criteria for ulcerative colitis. Updated approval length for Skyrizi IV to 8 weeks. Effective 12/1/24.

