

Skyrizi (risankizumab-rzaa)
Effective 01/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Skyrizi is an interleukin (IL)-23 antagonist indicated in adults for:

- Moderate-to-severe plaque psoriasis
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

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 all the following diagnosis-specific criteria have been met:

Plaque psoriasis (PsO)

1. Diagnosis of moderate to severe plaque psoriasis
2. 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. Diagnosis of active psoriatic arthritis
2. 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. Diagnosis of moderately to severely active Crohn's disease
2. ONE of the following:
 - a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
 - i. 6-mercaptopurine
 - ii. Azathioprine
 - iii. Corticosteroids (e.g., prednisone)
 - iv. Methotrexate
 - b. Disease severity warrants systemic biologic as first-line therapy
3. **SC injection:** Member meets ONE of the following:
 - a. Subcutaneous formulation will be used as maintenance therapy following IV induction
 - b. Member has received the IV induction doses and is transitioning to maintenance therapy

Ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
 - a. Member has had a trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
 - i. 6-mercaptopurine
 - ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
 - iii. Azathioprine
 - iv. Corticosteroids (e.g., prednisone)
 - b. Disease severity warrants systemic biologic as first-line therapy
3. **SC injection:** Member meets ONE of the following:
 - a. Subcutaneous formulation will be used as maintenance therapy following IV induction
 - b. Member has received the IV induction doses and is transitioning to maintenance therapy

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be granted when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals of Skyrizi IV will be limited to three infusions over 12 weeks.
2. Initial and reauthorization approvals for Skyrizi SC will be granted for 24 months
3. The following quantity limits apply on the pharmacy benefit:

Drug Name and Dosage Form	Quantity Limitations
Skyrizi SC 150mg prefilled syringe/autoinjector	<u>Psoriatic Arthritis/Plaque Psoriasis:</u> 1 injection every 12 weeks



Skyrizi IV 600mg/10mL	<u><i>Crohn's Disease:</i></u> 600 mg at weeks 0, 4, and 8 <u><i>Ulcerative Colitis:</i></u> 1,200 mg at weeks 0, 4, and 8
Skyrizi SC 180 mg/1.2 mL SC cartridge	<u><i>Ulcerative Colitis and Crohn's Disease</i></u> 1 injection every 8 weeks
Skyrizi SC 360 mg/2.4 mL SC cartridge	<u><i>Ulcerative Colitis and Crohn's Disease</i></u> 1 injection every 8 weeks

References

1. 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.
2. 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
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. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2024.

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 Medical 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.

10/09/2024 – Reviewed and updated for October P&T. Updated Crohn's disease criteria to require moderately to severely active disease. Updated reauthorization criteria to require documentation of clinical improvement to therapy. Effective 1/1/2025.

05/14/2025 – Reviewed and updated for May P&T. Updated criteria for Crohn's disease and ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/01/2025.

07/09/2025 – Reviewed and updated for July P&T. Updated approval length for Skyrizi IV to 12 weeks. Effective 09/01/2025.



10/08/2025 – Reviewed and updated at October P&T. Adding language for the SC formulation to the UC and CD diagnoses to require that either the member has either received IV induction therapy or will use the SC formulation after IV induction. Updating policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

