

**Skyrizi (risankizumab-rzaa)**  
**Effective 03/04/2024**

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

### Overview

Skyrizi (Risankizumab-rzaa) is an interleukin (IL)-23 antagonist that works by inhibiting the interaction with the IL-23 receptor which results in the inhibition of the of the release of proinflammatory cytokines and chemokines. It is indicated for the treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis in adults, and moderate-to-severe active Crohn’s disease in adults.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Skyrizi excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

#### OR

Authorization may be granted for members when ALL the following criteria are met:

#### Moderate to severe plaque psoriasis

ALL of the following:

1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
  - a. Inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix A)
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent
  - b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing †
4. Prescriber provides clinical rationale for use of Skyrizi instead of Stelara and Taltz

#### Psoriatic arthritis

**ALL** of the following:

1. Diagnosis of psoriatic arthritis
2. Member meets **BOTH** of the following:
  - a. Inadequate response, adverse reaction, or contraindication to Stelara and Taltz
  - b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agent that is FDA-approved for psoriatic arthritis
3. Appropriate dosing (see appendix and availability and dosage section) †

**Moderate to severe Crohn’s disease** – SC and IV formulations

**ALL** of the following:

1. Diagnosis of moderate to severe Crohn’s disease
2. Appropriate dosing (see appendix and availability and dosage section) †
3. **BOTH** of the following:
  - a. Inadequate response, adverse reaction, or contraindication to Stelara
  - b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for Crohn’s disease

† Requests for more frequent or higher doses – See Appendix

**Pityriasis rubra pilaris (PRP)** – Off Label

**ALL** of the following:

1. Diagnosis of pityriasis rubra pilaris
2. Inadequate response or adverse reaction to **ONE** topical corticosteroid or contraindication to **ALL** topical corticosteroids
3. Clinical rationale for use of Skyrizi® instead of Stelara and Taltz

New members currently stable on Skyrizi® can be approved without documentation of failed trials with the conventional therapies.

### **Continuation of Therapy**

Reauthorization requires physician documentation of a positive response to therapy.

### **Limitations**

1. Initial authorizations will be granted for:
  - a. Plaque Psoriasis and off-label indications: 3 months
  - b. All other indications: 6 months
2. Reauthorizations will be granted for 12 months

### **Appendix A: Conventional Therapies for Plaque Psoriasis**

<b>Conventional Treatment Lines</b>	<b>Agents Used</b>
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)



## Appendix B: Requests for More Frequent or Higher Doses

Requests more frequent or higher doses of injectable biologics, may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
  - a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
  - b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

## References

1. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; January 2022.
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

03/18/2020 – Reviewed at P&T (effective 6/1/20)

10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

11/1/2021 – Reviewed and Updated for Nov P&T; Guideline updated to reflect multiple criteria changes and appendices changes based on clinical literature. Effective 01/01/2022

06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for newly FDA-approved indication: Psoriatic Arthritis. Continuation of therapy language was updated. Added approval duration for initial auths for PsO – 3 months. Updated Overview and Reference sections. Added Appendix B for More Frequent/Higher Doses. Effective 08/01/2022

11/16/2022 – Reviewed and updated for Nov P&T. Guideline was updated following FDA-approval in moderate to severe Crohn's disease. Clarified QLS. Effective 11/01/2022

01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Off-label indications added for: PRP. Clarified initial approval durations: plaque psoriasis/off-label for 3 months, all other indications for 6 months. Effective 3/1/23.

12/13/23 – Reviewed and updated for P&T. Taltz was added as a step through agent for Skyrizi for plaque psoriasis and psoriatic arthritis. Effective 1/2/24

2/14/24 – Reviewed and updated for P&T. Skyrizi IV has been added to medical benefit requiring PA. Skyrizi SC will continue to have PA on pharmacy. Effective 3/4/24.

