



## **MVP Health Care Medical Policy**

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### **Medicare Part B: Risankizumab**

**Type of Policy:** Drug/Medical Therapy

**Prior Approval Date:** 10/01/2024

**Approval Date:** 10/01/2025

**Effective Date:** 12/01/2025

**Related Policies:** Abatacept, Certolizumab, Golimumab, Infliximab, Tocilizumab, Ustekinumab

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

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### **Drugs Requiring Prior Authorization under the medical benefit**

Skyrizi (risankizumab) 60mg/mL solution –J2327

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### **Overview/Summary of Evidence**

Skyrizi (Risankizumab), an interleukin-23 antagonist, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, the treatment of active psoriatic arthritis in adults as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs) and for the treatment of adults with moderate to severely active Crohn's disease (CD) for induction and remission maintenance.

Providers should perform screening for tuberculosis (TB) according to the local practice.

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### **Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, or gastroenterologist
- Must be prescribed for an FDA approved indication

**B. Crohn's Disease**

Risankizumab may be considered for coverage for Crohn's Disease when the following criteria are met:

- Documentation of moderate to severely active Crohn' disease
- Member must be intolerant to two different drug classes (examples such as, but not limited to, corticosteroids and immunomodulators such as azathioprine or mercaptopurine).

**Initial approval** duration will be 6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Plaque Psoriasis**

Risankizumab may be considered for coverage for Plaque Psoriasis when the following criteria are met:

- Documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp.
- An appropriate trial was not effective or contraindicated with one of the following: methotrexate, oral retinoids, cyclosporine.

**Initial approval** duration will be 6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

#### **D. Psoriatic Arthritis (PsA):**

Risankizumab may be considered for coverage for PsA when the following criteria is met:

- Documentation of active psoriatic arthritis with an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs) and one (1) NSAID trial.

**Initial approval** duration will be 6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

#### **E. Ulcerative Colitis**

Risankizumab may be considered for coverage for ulcerative colitis when the following criteria are met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
  - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** duration will be 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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#### **Exclusions**

The use of Skyrizi will not be covered for the following situations:

- Combination therapy that is not supported by current guidelines
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References

1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; June 2024
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:[10.1177/2475530318812244](https://doi.org/10.1177/2475530318812244)
3. Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet*. 2018;392(10148):650-661.
4. Menter, A., Strober, B., Kaplan, D., et al. (2019). Journal of the American Academy of Dermatology. Volume 80, Issue 4, P1029-1072. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)
5. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
6. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. *Lancet*. 2022;399(10340):2015-2030.
7. Lichtenstein, Gary R MD, FACG<sup>1</sup>; Loftus, Edward V MD, FACG<sup>2</sup>; Isaacs, Kim L MD, PhD, FACG<sup>3</sup>; Regueiro, Miguel D MD, FACG<sup>4</sup>; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)<sup>5,†</sup>; Sands, Bruce E MD, MS, FACG<sup>6</sup>. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *American Journal of Gastroenterology*: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27
8. ACG Clinical Guideline: Ulcerative Colitis in Adults. *The American Journal of Gastroenterology*: [March 2019 - Volume 114 - Issue 3 - p 384-413](#) doi:

10.14309/ajg.0000000000000152. Accessed: [ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG \(lww.com\)](#)