MVP Health Care Medical Policy

Medicare Part B: Risankizumab

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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.

Drugs Requiring Prior Authorization under the medical benefit

Skyrizi (risankizumab) 60mg/mL solution – C9399, J3590, J2327

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.

Caution may be necessary when co-administered with certain drugs that inhibit or induce certain CYP isoenzymes. Use with potent CYP3A4 inducers may result in loss of or reduced clinical response to upadacitinib. Providers should perform screening for tuberculosis (TB) according to the local practice.

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 is met:

- Documentation of moderate to severely active Crohn' disease
- Patient 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 3 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 is 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.

Exclusions

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

- Dosing, age, and/or frequency outside of the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines
- History of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients

---

References

1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; June 2022
2. Singh, Jasvinder A., et al. "2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis." *Arthritis & Rheumatology* 71.1 (2019): 5-32. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2022.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management

and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009;61(3):451-485.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
5. 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.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
7. 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.
8. 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.
9. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.