SmartHealth Ascension

Risankizumab-rzaa

(Skyrizi®) J2327 (1 mg)

Covered with prior authorization

Risankizumab-rzaa (Skyrizi®) may be authorized when the following criteria are met:

- Diagnosis of moderately to severely active Crohn's disease (CD); **AND**
- Individual is 18 year of age or older; **AND**
- Individual has had a trial and inadequate response or intolerance to at least ONE preferred agent;
    - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
    - 6-mercaptopurine
    - Azathioprine
    - Methotrexate
    - Biologic DMARD; **AND**
- Dosing is 600 mg intravenous infusion administered as administrative therapy at Weeks 0, 4, and 8; **AND**
- Prescribed by or in consultation with a gastroenterologist

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Concurrent use with other biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs or Janus kinase inhibitors for Plaque Psoriasis or Crohn's Disease.

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Skyrizi® is a humanized immunoglobulin G1 (IgG1) monoclonal antibody with selective binding to the p19 subunit of IL-23 cytokine and inhibits its interaction with the IL-23 receptor. It is indicated for:

- Moderate-to-severe Crohn's disease
- Active psoriatic arthritis
- Moderate to severe plaque psoriasis

References:

Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517

Skyrizi (risankizumab-rzaa) Label. (2013, November). Accessdata.fda.gov. Retrieved March 3, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761105s014lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
March 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
April 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
July 2023	Criteria for use summary approved by the Ambulatory Care Leadership Council.
July 2023	Criteria for use summary approved by the Internal Medicine Expert Review Panel (ERP)
August 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.