

Policy: MBP 267.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Skyrizi IV (risankizumab intravenous)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Skyrizi IV (risankizumab intravenous)

II. Purpose/Objective:

To provide a policy of coverage regarding Skyrizi IV (risankizumab intravenous).

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION: Risankizumab is a human IgG1 monoclonal antibody which selectively binds to the p19 subunit of interleukin (IL)-23, thereby inhibiting its interaction with the IL-23 receptor, resulting in inhibition of the release of proinflammatory cytokines and chemokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Skyrizi IV (risankizumab intravenous) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Crohn's Disease

- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of Skyrizi 600 mg/ 10 mL vials for IV infusion is being prescribed for induction therapy at weeks 0, 4 and 8.

Ulcerative Colitis

- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one conventional systemic therapy* (e.g. corticosteroids, immunomodulators such as azathioprine, 6 mercaptopurine, cyclosporine, tacrolimus) OR medical record documentation of a therapeutic failure on or intolerance to one prior biologic therapy **AND**
- Medical record documentation of two Skyrizi 600 mg /10 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8.

AUTHORIZATION DURATION: One-time 3-month authorization (maximum of 3 visits for loading dose administration)

Skyrizi IV (risankizumab intravenous) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Crohn's Disease

- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of Skyrizi 600 mg/ 10 mL vials for IV infusion is being prescribed for induction therapy at weeks 0, 4 and 8.

Ulcerative Colitis

- Medical record documentation that Skyrizi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of two Skyrizi 600 mg /10 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8.

AUTHORIZATION DURATION: One-time 3-month authorization (maximum of 3 visits for loading dose administration)

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Skyrizi [prescribing information]. North Chicago, IL: AbbVie Inc; June 2024.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/25/22

Revised: 10/16/23 (Medicaid business segment), 12/28/23 (references added), 10/18/24 (added UC, deleted Medicaid business segment, LOB table, taglines)

Reviewed:

MA UM Committee approval: 12/31/23