Administrative Policy

IL-23 Inhibitors – Benefit Exception Criteria (Inflammatory Bowel Disease)

(Skyrizi® [risankizumab-rzaa] and Tremfya® [guselkumab])

Policy Number	ADMIL23EX001
Effective Date	09/01/2026
Review Cycle	Annual
Lines of Business	Commercial (including ASO, where applicable) Excludes Medicare, Medicaid, and other government-regulated plans unless expressly adopted

1. Purpose and Intent

This administrative policy establishes the **benefit exception criteria** required for coverage of IL-23 inhibitors **Skyrizi (risankizumab-rzaa)** and **Tremfya (guselkumab)** for the treatment of Crohn's disease and Ulcerative Colitis.

The objectives of this policy are to:

- Ensure use of IL-23 inhibitors only after inadequate response of established therapies for inflammatory bowel disease (IBD)
- Promote appropriate step therapy sequencing
- Standardize exception determinations across IBD indications
- Require documentation of prior therapy outcomes

This policy governs **benefit eligibility** and does not determine overall medical necessity.

2. Policy Scope

This policy applies to the following medications:

- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)

For the following indications:

- **Crohn's disease**
- **Ulcerative Colitis**

This policy does not apply to other indications (e.g., psoriasis, psoriatic arthritis).

3. Definitions

Term	Definition
Benefit Exception	A determination allowing coverage of a medication otherwise restricted by step therapy requirements.
Biologic Failure	Failure to achieve or maintain adequate disease control with a biologic therapy due to inadequate response, loss of response after initial benefit, disease progression despite treatment, or discontinuation because of clinically significant adverse effects.
Conventional Therapy (IBD)	Non-biologic systemic agents used in the treatment of Crohn's disease or Ulcerative Colitis prior to biologic or other advanced therapies.
Inadequate Response	Lack of sufficient clinical improvement following an appropriate trial of therapy, as evidenced by persistent disease activity, ongoing symptoms, objective signs of inflammation, inability to achieve treatment goals, or the need for treatment modification.
Intolerance / Contraindication	A documented clinical reason preventing safe or appropriate use of a therapy due to adverse effects, toxicity, comorbid conditions, safety concerns, or other medically accepted factors.

4. Core Benefit Design

4.1 Default Benefit Position

Coverage of Skyrizi and Tremfya for **Crohn's disease and Ulcerative Colitis** is **excluded unless the benefit exception criteria in this policy are met**.

5. Benefit Exception Criteria (IBD-Specific)

Coverage may be allowed when **ALL of the following criteria are satisfied and supported by documentation**:

5.1 Inadequate Response of Conventional IBD Therapy

The participant has a history of inadequate response to **at least one conventional therapy** at maximally indicated doses unless contraindicated or not tolerated, including:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine
- Azathioprine
- Methotrexate

5.2 Biologic Failure, Inadequate Response or Ineligibility for Key Biologic Therapies

The participant must meet **ONE of the following**:

A. Required Biologic Failure or Inadequate Response

Crohn's disease or Ulcerative Colitis:

Biologic failure or inadequate response following trial ≥12 weeks of therapy with:

- adalimumab **OR** infliximab **AND**
- ustekinumab

B. Intolerance or Contraindication

Documented intolerance or contraindication to **BOTH**:

- adalimumab **OR** infliximab **AND**
- ustekinumab

5.3 Additional Advanced Therapy Requirement

The participant must also meet **ONE of the following based on diagnosis**:

Crohn's Disease

- Inadequate response following trial ≥12 weeks of therapy, or documented intolerance or contraindication, with: Entyvio® (vedolizumab)

Ulcerative Colitis

Inadequate response following trial ≥12 weeks of therapy, or documented intolerance or contraindication with:

- Entyvio® (vedolizumab) **AND**
- tofacitinib

6. Documentation Requirements

Requests must include:

- Confirmed diagnosis (**Crohn's disease or Ulcerative Colitis**)
- Complete treatment history, including:
  - Medication names
  - Duration of therapy
  - Clinical response or reason for discontinuation
- Supporting clinical records substantiating inadequate response, intolerance, or contraindication

7. Claims Processing

- Claims that do not meet the benefit exception criteria will be processed as **non-covered**
- Claims meeting criteria will adjudicate in accordance with applicable plan benefits

8. Limitations

This policy:

- Applies **only to Crohn's disease and Ulcerative Colitis**
- Does not apply to other labeled or off-label indications
- Does not override the member's benefit plan
- Does not independently determine medical necessity

9. Policy History

Date	Description
Draft	Initial IBD-focused IL-23 benefit exception policy

Appendix A – Drugs Subject to This Policy

- Skyrizi® (risankizumab-rzaa)
- Tremfya® (guselkumab)