Evolent Clinical Guideline 5109.CC for Skyrizi (risankizumab-rzaa)

Guideline Number: EVH_CG_5109.CC	**Applicable Codes**	
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
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TABLE OF CONTENTS

STATEMENT **3**
- General Information 3
- Purpose 3
- Scope 3

INITIAL REVIEW CRITERIA **3**
- General Criteria 3
- Crohn's Disease (CD) 4
- Plaque Psoriasis 4
- Psoriatic Arthritis (PsA) 4
- Ulcerative Colitis 5

REAUTHORIZATION CRITERIA **5**
- General Criteria 6
- Crohn's Disease (CD) 6
- Plaque Psoriasis 6
- Psoriatic Arthritis (PsA) 6
- Ulcerative Colitis 7

APPROVAL DURATIONS **7**

APPENDICES **7**
- Appendix 1 – Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide 7
- Table 1 – 2018 ACG Clinical Guidelines Classification of Moderate-to-Severe Disease 8

CODING AND STANDARDS **8**
- Codes 8
- Applicable Lines of Business 8

BACKGROUND **9**

POLICY HISTORY **9**

LEGAL AND COMPLIANCE **9**
- Guideline Approval 9
  - *Committee* *9*

DISCLAIMER 9
REFERENCES 11

STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for Skyrizi (risankizumab-rzaa). The guideline addresses these products for intravenous administration or subcutaneous administration by a healthcare provider through medical buy and bill. Requests for self-administered subcutaneous utilization should be directed to the pharmacy benefit manager (PBM) for review.

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria ***and*** diagnosis-specific sections below.

General Criteria

- Must have a negative tuberculosis skin test collected within the last 6 months
    - Example acceptable testing includes the Tuberculin PPD (purified protein derivative) test or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))
- Must have documentation or an attestation from the provider that the member is updated on all vaccinations in accordance with current vaccination guidelines
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Crohn's Disease (CD)

- Must be prescribed by or in consultation with a gastroenterologist
- Must be 18 years of age or older
- Must have a diagnosis of moderately to severely active Crohn's disease or fistulizing Crohn's disease, as described in the 2018 ACG guidelines (see **Table 1**)
- Must provide baseline liver enzymes and bilirubin levels
- Must not have perianal fistulizing disease
- Must have an adequate trial (of at least 3 months) and failure of at least one (1) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
    - An adalimumab product
    - Cimzia

Plaque Psoriasis

- Must be prescribed by, or in consultation with, a dermatologist
- Must be 18 years of age or older
- Must have a diagnosis of moderate-to-severe chronic plaque psoriasis
- Must have documentation of ONE of the following:
    - Affected area(s) include hands, feet, face, neck, scalp, genitals/groin, intertriginous areas
    - Minimum body surface area (BSA) involvement of >10%
    - At least 3% of BSA affected AND the member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) OR pharmacologic treatment with methotrexate, cyclosporine, or acitretin (unless there is a clinical reason to not take pharmacologic treatment – see **Appendix 1**)
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
    - An adalimumab product
    - Enbrel
    - Xeljanz

Psoriatic Arthritis (PsA)

- Must be prescribed by, or in consultation with, a rheumatologist or dermatologist
- Must be 18 years of age or older
- Must have a diagnosis of active psoriatic arthritis, with the severity of disease

documented

- For mild-to-moderate disease only, must have ONE of the following:
  - Must have had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) or have a contraindication or intolerance to all drugs (see **Appendix 1**)
  - Must have enthesitis
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
  - An adalimumab product
  - Cimzia
  - Cosentyx
  - Enbrel
  - Xeljanz

Ulcerative Colitis

- Must be prescribed by, or in consultation with, a gastroenterologist
- Must be 18 years of age or older
- Must have a diagnosis of moderate to severely active Ulcerative Colitis, as evidenced by ONE of the following:
  - Dependency on or refractory to corticosteroids
  - Severe endoscopic disease activity (e.g., presence of ulcers)
  - High risk of colectomy
  - Mayo Clinic scores of 6-12, with an endoscopic subscore of 2 or 3
  - Hospitalized with ≥6 bloody bowel movements per day with at least 1 marker of systemic toxicity (e.g., heart rate >90 beats/min, temperature >37.8C, hemoglobin <10.5 g/dL, and/or erythrocyte sedimentation rate -30 mm/h)
- Must provide baseline liver enzymes and bilirubin levels
- Must have an adequate trial (of at least 3 months) and failure of EACH of the following unless, contraindicated:
  - An adalimumab product
  - Xeljanz

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the General Criteria ***and*** diagnosis-specific sections below.

General Criteria

- Must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))

Crohn's Disease (CD)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Abdominal pain or tenderness
  - Diarrhea
  - Body weight
  - Abdominal mass
  - Hematocrit
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Plaque Psoriasis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Body surface area (BSA)
  - Signs and Symptoms (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Psoriatic Arthritis (PsA)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Number of swollen joints
  - Number of tender joints

- Dactylitis
- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ulcerative Colitis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Stool frequency
  - Rectal bleeding
  - Urgency of defecation
  - C-reactive protein (CRP)
  - Fecal calprotectin (FC)
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

APPROVAL DURATIONS

If the above criteria are met, the request will be approved for up to the duration of time dictated below:

Initial Authorization	Up to 1 year
Reauthorization	Same as initial

APPENDICES

Appendix 1 – Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease

- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Table 1 – 2018 ACG Clinical Guidelines Classification of Moderate-to-Severe Disease

Moderate-to-Severe Disease	Severe-Fulminant Disease
• CDAI 220-450 • Have failed treatment for mild to moderate disease • Prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia • Moderate to severely active endoscopic mucosal disease	• CDAI >450 • Persistent symptoms despite glucocorticoids or biologic agents • Individuals presenting with high fever, persistent vomiting, intestinal obstruction, peritoneal signs, cachexia, or evidence of an abscess

CODING AND STANDARDS

Codes

Code	Brand	Description
J2327	Skyrizi	Injection, Risankizumab-rzaa, intravenous, 1mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace

☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of:

- Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- Active psoriatic arthritis in adults.
- Moderately to severely active Crohn's disease in adults.
- Moderately to severely active ulcerative colitis in adults

POLICY HISTORY

Date	Summary
October 2025	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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