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| AETNA BETTER HEALTH®<br>Coverage Policy/Guideline                                                                                                                                                                                                                 |                            |
| Name:               Skyrizi                                                                                                                                                                                                                                       | Page:               1 of 7 |
| Effective Date:   10/1/2026                                                                                                                                                                                                                                       | Last Review Date: 10/2026  |
| Applies to: <input checked="" type="checkbox"/> Florida Kids <input checked="" type="checkbox"/> Maryland <input checked="" type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD<br><input checked="" type="checkbox"/> Illinois |                            |

**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Skyrizi under the patient’s prescription drug benefit.

**Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

**FDA-approved Indications**

- Treatment of moderate-to-severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy
- Treatment of active psoriatic arthritis (PsA) in adults
- Treatment of moderately to severely active Crohn’s disease (CD) in adults
- Treatment of moderately to severely active ulcerative colitis (UC) in adults

All other indications are considered experimental/investigational and not medically necessary.

**Applicable Drug List:**

Skyrizi

**Policy/Guideline:**

**Documentation**

Submission of the following information is necessary to initiate the prior authorization review:

**Plaque psoriasis (PsO)**

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.



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## Psoriatic arthritis (PsA)

### Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Crohn's disease (CD) and Ulcerative Colitis (UC)

Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

## Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Plaque psoriasis: dermatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Crohn's disease and ulcerative colitis: gastroenterologist

## Coverage Criteria

### Plaque psoriasis (PsO)

Authorization of 12 months may be granted for members 6 years of age or older who have previously received a biologic or targeted synthetic drug indicated for the treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderate to severe plaque psoriasis when ANY of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
  - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
  - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).



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### **Psoriatic arthritis (PsA)**

Authorization of 12 months may be granted for members 6 years of age or older who have previously received a biologic or targeted synthetic drug indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for members 6 years of age or older for treatment of active psoriatic arthritis when EITHER of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
  - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
  - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis.
- Member has severe disease.

### **Crohn's disease (CD)**

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

### **Ulcerative colitis (UC)**

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

## **Continuation of Therapy**

### **Plaque psoriasis (PsO)**

Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when EITHER of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

### **Psoriatic arthritis (PsA)**

Authorization of 12 months may be granted for members 6 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:



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- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

### **Crohn's Disease (CD)**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY 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)

### **Ulcerative colitis**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)



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- 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)

### Other

For all indications: Member has been evaluated for tuberculosis (TB) infection prior to initiation of treatment with a biologic or targeted synthetic drug associated with an increased risk of TB.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

### Appendix

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

### Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

### Approval Duration and Quantity Restrictions:

**Initial and Renewal Approval: 12 months**

### Quantity Level Limits:

- Skyrizi (risankizumab-rzaa) 55 mg/0.37 mL single-dose prefilled syringe:
  - 1 syringe per 84 days
  - Exception limit: 2 syringes per 28 days
- Skyrizi (risankizumab-rzaa) 90 mg/mL single-dose prefilled syringe:
  - 4 syringes per 56 days



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- Skyrizi (risankizumab-rzaa) 150 mg/mL single-dose prefilled syringe/pen:
  - 1 syringe/pen per 84 days
  - Exception limit: 2 syringes/pens per 28 days
- Skyrizi (risankizumab-rzaa) 180 mg/1.2 mL single-dose prefilled syringe:
  - 1 syringe per 56 days
- Skyrizi (risankizumab-rzaa) 180 mg/1.2mL single-dose prefilled cartridge with on-body injector:
  - 1 cartridge per 56 days
- Skyrizi (risankizumab-rzaa) 360 mg/2.4mL single-dose prefilled cartridge with on-body injector
  - 1 cartridge per 56 days
- Skyrizi (risankizumab-rzaa) 600 mg/10mL single-dose vial
  - 6 vials per 56 days

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