AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Skyrizi	Page:	1 of 6
Effective Date:	10/1/2024	Last Review Date:	11/2023, 3/2024, 9/2024

Applies to:	☐Illinois	☐Florida	☐Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

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:

FDA-Approved Indications

A. Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy (Reference the Biological Response Modifiers (BRMs) in the Treatment of Plaque Psoriasis NJ Protocol)
B. Active psoriatic arthritis (PsA) in adults
C. Treatment of moderately to severely active Crohn's disease (CD) in adults
D. 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:

A. **Psoriatic arthritis (PsA)**
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. **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 Specialty:

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

A. Psoriatic arthritis: rheumatologist or dermatologist

B. Crohn's disease and ulcerative colitis: gastroenterologist

Criteria for Initial Approval:

A. Psoriatic arthritis (PsA)

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

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis.
   ii. Member has severe disease.

B. Crohn's disease (CD)

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

C. Ulcerative colitis (UC)

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

Continuation of Therapy:

A. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain 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:

1. Number of swollen joints
2. Number of tender joints

3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement
6. Functional status
7. C-reactive protein (CRP)

B. Crohn's Disease (CD)

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

2. Authorization of 12 months may be granted for all adult 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Endoscopic appearance of the mucosa
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

C. Ulcerative colitis

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

2. Authorization of 12 months may be granted for all adult 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation

iv. C-reactive protein (CRP)
v. Fecal calprotectin (FC)
vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Other Criteria:
For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

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

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

Appendix
Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding

6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:
Initial and Renewal Approval: 12 months

Quantity Level Limits:

Medication	FDA-recommended dosing
Skyrizi (risankizumab-rzaa) 150 mg/mL single-dose prefilled syringe/pen	**Plaque psoriasis and psoriatic arthritis** • 150 mg at weeks 0, 4, and every 12 weeks thereafter
Skyrizi (risankizumab-rzaa) 180 mg/1.2mL single-dose prefilled cartridge with on-body injector	**Crohn's disease and ulcerative colitis, maintenance** • 180 mg or 360 mg at week 12 (four weeks after the last intravenous induction dose), then every 8 weeks thereafter
Skyrizi (risankizumab-rzaa) 360 mg/2.4mL single-dose prefilled cartridge with on-body injector	
Skyrizi (risankizumab-rzaa) 600 mg/10mL single-dose vial	**Crohn's disease, intravenous induction** • 600 mg at weeks 0, 4, and 8 **Ulcerative colitis, intravenous induction** • 1200 mg at weeks 0, 4, and 8

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