



Montana Healthcare Programs Physicians Administered Drug Coverage Interim Criteria

SKYRIZI® (risankizumab-rzaa)

I. Medication Description

Skyrizi® is an interleukin-23 antagonist indicated for:

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

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Active Psoriatic Arthritis:

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have diagnosis of psoriatic arthritis.
- Must be prescribed by or in consult with an appropriate specialist (Rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
 - The member has been screened for tuberculosis (TB) prior to initiating treatment.
 - The provider will monitor for active infection.
 - The member will avoid the use of live vaccines.
- Provider attests member **will not** use Skyrizi® concomitantly with other biologics.

Moderate to Severe Plaque Psoriasis:

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have diagnosis of moderate to severe plaque psoriasis.
- Must be prescribed by or in consult with an appropriate specialist (dermatologist/rheumatologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
 - The member has been screened for TB prior to initiating treatment.

- The provider will monitor for active infection.
 - The member will avoid the use of live vaccines.
- Provider attests member **will not** use Skyrizi® concomitantly with other biologics.

Moderately to Severely Active Crohn's disease

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Member must have a diagnosis of moderately to severely active Crohn's disease.
- Must be prescribed by or in consult with an appropriate specialist (gastroenterologist).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must have a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Prescriber attests to the following:
 - The member has been screened for TB prior to initiating treatment.
 - The provider will monitor for active infection.
 - The member will avoid the use of live vaccines.
 - Provider will monitor liver enzymes and bilirubin levels at baseline, during induction and up to at least 12 weeks of treatment.
- Provider attests member **will not** use Skyrizi® concomitantly with other biologics.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Provider attests member **will not** use Skyrizi® concomitantly with other biologics.

V. Quantity Limitations

Active Psoriatic Arthritis:

- Subcutaneous injection of 150mg given at week 0, week 4 and every 12 weeks thereafter

Moderate to Severe Plaque Psoriasis:

- Subcutaneous injection of 150mg given at week 0, week 4 and every 12 weeks thereafter

Crohn's Disease:

- Initial intravenous infusion for induction is 600mg IV at week 0, week 4 and week 8.
- Maintenance dosage is 180mg or 360mg by subcutaneous injection at week 12, then every 8 weeks thereafter.

VI. Coverage Duration

Initial approval duration:

- Adults with psoriatic arthritis: 3 doses (weeks 0, 4, and 16) Update required prior to dose at 28 weeks
- Adults with plaque psoriasis: 3 doses (weeks 0, 4, and 16) Update required prior to dose at 28 weeks
- Adults with Crohn's disease: 4 doses (infusion weeks 0, 4, and 8. Injection week 12) Update required prior to dose at 20 weeks

Renewal approval duration for all: 1 year