CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Skyrizi (risankizumab-rzaa)
BILLING CODE	J2327
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Skyrizi is an interleukin-23 (IL-23) antagonist initially approved by the FDA in 2019 for moderate-to-severe plaque psoriasis. Since then, it has also been granted approval for psoriatic arthritis and crohn's disease in adults. This humanized IgG1 monoclonal antibody works by selectively binding to the p19 subunit of human IL-23 cytokine, inhibiting its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses.

Skyrizi (risankizumab-rzaa) will be considered for coverage when the following criteria are met:

Crohn's Disease

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has had a negative tuberculosis test within the past 12 months; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by **one** of the following:
   a) Extensive small bowel disease involving more than 100 cm;
   b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc.).
6. **Dosage allowed:** 600 mg by intravenous infusion over at least one hour at week 0, week 4, and week 8. Maintenance dose: 360 mg via subcutaneous injection at week 12, and every 8 weeks thereafter. Quantity limit:

Note to reviewer: A one-time induction dose is approved on the medical benefit. Maintenance therapy is approved on either pharmacy OR medical benefit. Please inactivate any duplicate prior authorization.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as improved endoscopic response, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each.
8. **Dosage allowed:** 150 mg (two 75 mg injections) administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. Quantity limit: 2 syringes every 12 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:

i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND

5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor (same class as Enbrel); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 150 mg (two 75 mg injections) administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. Quantity limit: 2 syringes every 12 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Skyrizi (risankizumab-rzaa) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/28/2019	New policy for Skyrizi created.
11/18/2020	Removed rheumatologist from prescriber requirement. Removed PsO 6 months or longer. Changed BSA to 3% or sensitive areas. Removed PASI score. Removed repeat TB for reauth. Updated references.
02/02/2022	New indication of PsA added. Changed to new format. Reworded DMARD language for PsA and PsO. Updated references.
06/27/2022	Added new indication of Crohn's disease. Updated references. Added medical benefit for one-time infusion for Crohn's disease. Added quantity limits.

References:

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11. Hibi T, et al. Risankizumab for Crohn’s disease. Lancet. 2022; 399 (10340):1992-1993.
12. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113(4):481-517.
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