CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Marketplace

| DRUG NAME | Skyrizi (risankizumab-rzaa) |
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| BENEFIT TYPE | Medical or Pharmacy |
| 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, Crohn's disease and ulcerative colitis 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 (CD)

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 documented trial and inadequate response, or intolerance to **ONE** of the following
4. conventional therapies:
   a) Corticosteroid;
   b) 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Provider attests member has severe disease that requires immediate use of an advanced therapy (biologic, JAK inhibitor, etc.) agent such as penetrating or fistulizing disease, multiple resections, etc.; AND
6. Baseline liver function tests (LFTs) have been or will be completed; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed:** 600 mg by intravenous infusion at week 0, week 4, and week 8. Then 180 or 360 mg via subcutaneous injection at week 12, and every 8 weeks thereafter. Quantity limit: 1 cartridge per 8 weeks for maintenance therapy.

***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 such 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 is 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 has tried and failed to respond to treatment with **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);
   d) At least a 12-week trial of a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin); AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed:** 150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. Quantity limit: 1 pen or syringe per 12 weeks for maintenance therapy.

***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 such as 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 is 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 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 conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      **i)** Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional 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 had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. Quantity limit: 1 pen or syringe per 12 weeks for maintenance therapy.

***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 of signs and symptoms of disease such as 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.***

## Ulcerative Colitis (UC)

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND
4. Member must have a documented trial and inadequate response with **ONE** of the following:
   a) 6-mercaptopurine or azathioprine;
   b) Corticosteroid (e.g., budesonide, prednisone, methylprednisolone);
   c) 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
5. Baseline liver function tests (LFTs) have been or will be completed; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 1,200 mg administered by intravenous infusion at week 0, week 4, and week 8. Then 180 mg or 360 mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter. Quantity limit: 1 cartridge per 8 weeks for maintenance therapy.

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, or improved endoscopic appearance of the mucosa, 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. |
| **07/09/2024** | Added/removed references. Ulcerative colitis indication added. Added quantity limit for UC.<br>PsA: increased initial authorization length from 6 months to 12 months. Clarified dosing and changed quantity limit from 2 syringes per 12 weeks to 1 pen or syringe per 12 weeks.<br>CD: clarified dosing and clarified quantity limit. Removed internal reviewer note. Added that baseline LFTs must be done or will be done. |

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| | PsO: clarified dosing and changed quantity limit from 2 syringes per 12 weeks to 1 pen or syringe per 12 weeks. |
| **09/26/2024** | PsO: converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options and removed trial and failure of **TWO** preferred biologic DMARDs for 3 months each<br>PsA: removed trial and failure of TWO preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor |
| **08/18/2025** | Updated references.<br>UC: removed duration from trials<br>CD: removed duration from trials, replaced “biologics” with “advanced therapies (biologic, JAK inhibitor, etc.)”, added provider attestation to severe disease that requires immediate use of advanced therapy and replaced requirements with examples of severe disease<br>PsA and PsO: replaced “non-biologic" with “conventional” |

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