BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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SKYRIZI™ (risankizumab-rzaa) subcutaneous injection, 75 mg/0.83 mL syringe

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SKYRIZI™ (risankizumab-rzaa) subcutaneous injection, 75 mg/0.83 mL syringe

Criteria:

- **Criteria for initial therapy:** Skyrizi (risankizumab-rzaa) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in inflammatory disorders or is in consultation with a Dermatologist or Rheumatologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of moderate-to-severe plaque psoriasis

  4. Individual meets **ALL** of the following:
     - Is a candidate photochemotherapy or phototherapy
     - Plaque psoriasis involves ≥ 10% body surface area (BSA) **or** plaque psoriasis involves < 10% BSA but includes sensitive areas or areas that significantly impact daily function (e.g. palms, soles of feet, head/neck, or genitalia)
     - A Psoriasis Area and Severity Index (PASI) of at least 10

  5. Individual has failure (used for > 3 consecutive months), contraindication or intolerance to a treatment regimen that includes **ALL** of the following:
     - A trial of least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
     - A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
     - A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser)
     - A trial of **TWO** Biologic DMARDs: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab)
     - A trial of Otezla (apremilast)

  6. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months.

  7. There is no concurrent use with other biologic and immunologic agents

  8. There is no evidence of active serious infections, including clinically important localized infections or sepsis when initiating or continuing therapy

  9. Individual does not have untreated latent or active tuberculosis

  10. Individual does not have untreated Chronic or Acute Hepatitis B or C

  11. There is no concurrent use of live vaccines

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Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Skyrizi (risankizumab-rzaa) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in inflammatory disorders or is in consultation with a Dermatologist or Rheumatologist

  2. Individual's condition responded while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Achieved and maintains
         - At least a PASI of 90
         - At least a sPGA score of 1 ("almost clear")

  3. Individual has been adherent with the medication

  4. There is no concurrent use with other biologic and immunologic agents

  5. There is no evidence of active serious infections, including clinically important localized infections or sepsis when initiating or continuing therapy

  6. Individual does not have untreated latent or active tuberculosis

  7. Individual does not have untreated Chronic or Acute Hepatitis B or C

  8. There is no concurrent use of live vaccines

  9. There are no significant interacting drugs

Renewal duration: 12 months

- Skyrizi (risankizumab-rzaa) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*
  - Treatment with dosing or frequency outside the FDA-approved dosing and frequency

SKYRIZI™ (risankizumab-rzaa) subcutaneous injection, 75 mg/0.83 mL syringe

Description:

Skyrizi (risankizumab-rzaa) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Risankizumab-rzaa is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines.

Definitions:

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4
7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0% (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.
Scores range from 0 to 72. A score of more than 10 generally translates to "moderate-to-severe."

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Static Physician's Global Assessment (sPGA):

The sPGA is the physician's global assessment of the subject's psoriasis based on severity of erythema, induration, and scaling.The sPGA is a scale from 0 to 5 where 0 indicates clear and 5 indicates severe disease. The final sPGA is an average of the three clinical signs of disease.

Each of the 3 clinical signs of erythema, induration, and scale is assessed on a 0-5 (6 point) scale:
0 = none
1 = minimal
2 = mild
3 = moderate
4 = severe
5 = very severe

Antipsoriatic agents with anti-interleukin-23 activity:

- Tremfya (guselkumab) – subcutaneous injection
  - Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

- Skyrizi (risankizumab-rzaa) –subcutaneous injection
  - Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

- Ilumya (tildrakizumba) – subcutaneous injection
  - Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

- Stelara (ustekinumab) – subcutaneous injection
  - Treatment of moderate-to-severe plaque psoriasis in patients ≥12 years of age who are candidates for phototherapy or systemic therapy
  - Treatment of adults with active psoriatic arthritis (as monotherapy or in combination with methotrexate)
  - Treatment of moderately to severely active Crohn disease in adults who have failed or were intolerant to immunomodulatory or corticosteroid therapy, but never failed tumor necrosis factor (TNF) blocker therapy, or who have failed or were intolerant to treatment with 1 or more TNF blockers

Resources:

Skyrizi (risankizumab-rzaa) product information accessed 07-22-19 at DailyMed

UpToDate: Treatment of psoriasis in adults. Current through Jun 2019