

Skyrizi (risankizumab-rzaa)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Skyrizi (risankizumab-rzaa) 75 mg/0.83 mL prefilled syringe*	2 prefilled syringes [1 carton] per 84 days (12 weeks)
Skyrizi (risankizumab-rzaa) 150 mg/mL prefilled syringe/pen*	1 prefilled syringe/pen [1 carton] per 84 days (12 weeks)
Skyrizi (risankizumab-rzaa) 180 mg/ 1.2 mL prefilled cartridge with on-body injector	1 kit per 56 days (8 weeks)
Skyrizi (risankizumab-rzaa) 360 mg/ 2.4 mL prefilled cartridge with on-body injector	1 kit per 56 days (8 weeks)
Skyrizi (risankizumab-rzaa) 600 mg/10 mL single-dose vial	3 vials total to last 12 weeks

*Initiation of therapy for Plaque Psoriasis (Ps) (Psoriasis vulgaris) or Psoriatic Arthritis (PsA): May approve up to 1 additional carton [two 75 mg syringes or one 150 mg syringe/pen] in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Initial requests for Skyrizi (risankizumab-rzaa) may be approved for the following:

- I. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
 - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2019):
 1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
 2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia);

AND

- B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
- C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

AND

- D. Individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents. [Current preferred biologics include – adalimumab-

adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Stelara (ustekinumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

- E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Skyrizi (risankizumab-rzaa). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
- F. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
- B. Documentation is provided that individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)]; **OR**
- C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

AND

- D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab)*] Medication samples/coupons/discount cards are excluded from consideration as a trial;

AND

3. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

4. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

- E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Skyrizi (risankizumab-rzaa). Medication samples/coupons/discount cards are excluded from consideration as a trial; **OR**
- F. Documentation provided that individual is pregnant or planning on becoming pregnant;

OR

- III. Crohn's Disease (CD) when each of the following criteria are met:
- A. Individual is 18 years of age or older with moderate to severe CD; **AND**
 - B. Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **OR**
 - C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

AND

- D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Humira (adalimumab) and Stelara (ustekinumab)] Medication samples/coupons/discount cards are excluded from consideration as a trial;

AND

- 1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

- 2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

- E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Skyrizi (risankizumab-rzaa). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

- F. Documentation is provided that individual is pregnant or planning on becoming pregnant;

*Note - Trial of Cosentyx (secukinumab) does not apply in states where not on formulary (CA, CO). Prior trial of Tremfya (guselkumab) not required in states where not covered (CA, CO, GA, IN, KY, ME, MO, NH, NY, OH, VA, WI]

Continuation requests for Skyrizi (risankizumab-rzaa) may be approved if the following criteria are met:

- I. Individual has been receiving and is maintained on a stable dose of Skyrizi. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
- II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Skyrizi (risankizumab-rzaa) may **not** be approved for the following:

- I. In combination with phototherapy; **OR**
- II. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, etrasimod, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**

- III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
- IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent test to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
- V. When the above criteria are not met and for all other indications

Key References:

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: <https://www.cdc.gov/tb/topic/basics/risk.htm>. Last updated: March 18, 2016. Accessed October 15, 2023.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 27, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology* 2021; 160:2496-2508.
5. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450-1461.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019; 80: 1029-72.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum.* 2019; 71(1): 5-32.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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