Skyrizi (risankizumab-rzaa)

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

Medications	Quantity Limit
Skyrizi (risankizumab-rzaa) 90 mg/mL pen^	2 prefilled pens per 56 days (8 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	6 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 [one 150 mg syringe/pen] in the first 28 days (4 weeks) of treatment.

^Requests for up to 4 prefilled pens per 56 days (8 weeks) may be approved if the following criteria are met:
Information has been provided for the clinical necessity of the prefilled pen and why the individual is unable to use the 360 mg prefilled cartridge with on-body injector.

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

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

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

III. Crohn's Disease (CD) when each of the following criteria are met:

A. For individuals requesting intravenous induction doses:
   1. Individual is 18 years of age or older with moderate to severe CD; **AND**
   2. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate); **OR**
   3. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

OR

B. For individuals requesting subcutaneous maintenance therapy:
   1. Individual is 18 years of age or older with moderate to severe CD; **AND**
   2. Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy;

AND

C. 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

D. 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

IV. Ulcerative colitis (UC) when the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      1. Individual is 18 years of age or older with moderate to severe UC; **AND**
      2. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
      3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      1. Individual is 18 years of age or older with moderate to severe UC; **AND**
      2. Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy.

   AND

   C. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE preferred biologic agent. [Current preferred biologics include –

adalimumab-adbm, Humira (adalimumab), Simponi (golimumab)]. 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

D. 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.

*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 polices may take precedence over the application of this clinical criteria.