

Market Applicability					
Market	GA	KY	MD	NJ	NY
Applicable	X	NA	X	X	X

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)

*Initiation of therapy for Plaque Psoriasis (Ps) (Psoriasis vulgaris): 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, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);
 - AND**
 - C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO preferred biologic agents. [Current preferred biologics include – Avsola (infliximab-axxq), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast)] unless the following criteria is met:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability					
Market	GA	KY	MD	NJ	NY
Applicable	X	NA	X	X	X

1. The individual has been receiving and is maintained on a stable dose of Skyrizi (risankizumab-rzaa).

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

- I. There is confirmation of 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. All other indications not included above; **OR**
- II. In combination with JAK inhibitors, apremilast, other IL-23 inhibitors, other biologic drugs (such as TNF antagonists or ustekinumab) or phototherapy; **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **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 risk factors).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
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 15, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. 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.
6. 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability					
Market	GA	KY	MD	NJ	NY
Applicable	X	NA	X	X	X

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.