

Market Applicability												
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

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 per 84 days (12 weeks)

*Initiation of therapy for Plaque Psoriasis (Ps) (Psoriasis vulgaris): May approve 2 additional syringes (75 mg/0.83 mL) [1 carton] in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

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 2011):
 1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); **OR**
 2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) 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 – Enbrel (etanercept), Humira (adalimumab) unless the following criteria is met:
 1. The individual has been receiving and is maintained on a stable dose of Skyrizi (risankizumab-rzaa); **OR**

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New Program Date 05/14/2019

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.

CRX-ALL-0404-19

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2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Skyrizi (risankizumab-rzaa) does; **OR**
 3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Skyrizi (risankizumab-rzaa); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis;
- OR**
4. The individual has either concomitant clinical condition:
 - a. Demyelinating disease; **OR**
 - b. Heart failure with documented left ventricular dysfunction; **OR**
 5. The preferred agent(s) do not have activity against a concomitant clinical condition and Skyrizi (risankizumab-rzaa) does. Examples include but may not be limited to the following:
 - a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
 - b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

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

- I. In combination with other biologic drugs or phototherapy; **OR**
- II. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- III. 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 prior to initiating tildrakizumab-asmn.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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Applicable	X	X	NA	NA	X	X	X	X	X	NA	NA	NA

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Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: March 21, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*. 2011; 65: 137-174.

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CRX-ALL-0404-19