UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Skyrizi

Program	Prior Authorization
Medication	Skyrizi™ (risankizumab-rzaa) injection
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	11/2019
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Skyrizi is an interleukin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

2. Coverage Criteria:

A. Plaque Psoriasis

1. Initial Authorization

a. **Skyrizi** will be approved based on **one** of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of moderate to severe plaque psoriasis

-AND-

(b) Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

(c) **Both** of the following:

1. History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)

- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

2. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

(d) Patient is not receiving Skyrizi in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(e) History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)
- Cimzia (certolizumab)
- Ilumya (tildrakizumab)

-AND-

(f) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

(g) Prescribed by or in consultation with a dermatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Skyrizi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

(b) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(c) Patient is not receiving Skyrizi in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Skyrizi will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Skyrizi therapy

-AND-

(2) Patient is not receiving Skyrizi in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; April 2019.
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3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
4. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
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7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
8. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
9. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.

Program	Prior Authorization –Skyrizi (risankizumab-rzaa)
Change Control	
Date	Change

11/2019	New program
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials.
1/2020	Revised biologic step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.