UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2205-8
Program	Prior Authorization/Medical Necessity
Medication	*Skyrizi® (risankizumab-rzaa) injection *This program applies to the subcutaneous formulations of Skyrizi
P&T Approval Date	5/2020, 5/2021, 6/2021, 3/2022, 8/2022, 7/2023, 5/2024, 7/2024
Effective Date	10/1/2024

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, active psoriatic arthritis in adults, moderately to severely active Crohn's disease in adults, and moderately to severely active ulcerative colitis in adults.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

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

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

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

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

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. 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):

a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
c. Tazarotene
d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
e. Anthralin
f. Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab)].

-OR-

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

i. Patient is currently on Skyrizi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

-AND-

(3) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

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

(1) Diagnosis of active psoriatic arthritis

-AND-

(3) **One** of the following:

(a) History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Rinvoq (upadacitinib), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

-OR-

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

i. Patient is currently on Skyrizi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

-AND-

(3) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Crohn's Disease (CD)

1. **Initial Authorization for Maintenance Dosing**

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

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

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

(a) Patient has been established on therapy with Skyrizi under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active Crohn's disease

-OR-

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

i. Patient is currently on Skyrizi therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

-AND-

(3) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Skyrizi therapy

-AND-

(2) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab)]

Authorization will be issued for 12 months.

D. Ulcerative Colitis (UC)

1. **Initial Authorization for Maintenance Dosing**

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

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

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

(a) Patient has been established on therapy with Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

-OR-

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

i. Patient is currently on Skyrizi therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

-AND-

(3) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), adalimumab]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Skyrizi therapy

-AND-

(2) Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), adalimumab]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky, and Mississippi business only a 30-day trial will be required.

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.; June 2024.
2. 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.

3. 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.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. 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.
7. 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.
8. 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.
9. 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.
10. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517.

Program	Prior Authorization/Medical Necessity – Skyrizi® (risankizumab-rzaa)
Change Control	
5/2020	New program
5/2021	Annual review. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Removed drug documentation where only one drug is required. Reference updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
3/2022	Clinical coverage criteria updated to add active psoriatic arthritis. Updated reference.
8/2022	Clinical coverage criteria and background updated to add Crohn's disease. Added state mandate footnote to include Mississippi. Added Rinvoq as Janus kinase inhibitor example. Updated reference.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
5/2024	Annual review with no changes to coverage criteria. Updated state mandate footnote and references.
7/2024	Updated clinical coverage criteria and background to add ulcerative colitis. Updated active prior authorization verbiage under Crohn's disease with no change to clinical intent. Updated reference.