UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1293-7
Program	Prior Authorization/Notification
Medication	*Skyrizi® (risankizumab-rzaa) injection *This program applies to the subcutaneous formulations of Skyrizi
P&T Approval Date	9/2019, 9/2020, 9/2021, 3/2022, 8/2022, 7/2023, 5/2024
Effective Date	8/1/2024

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, and moderately to severely active Crohn's disease in adults.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

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

(1) Diagnosis of moderate to severe plaque psoriasis

-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.

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, 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 **both** of the following criteria:

      (1) Diagnosis of active psoriatic arthritis

      -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.

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, 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 **both** of the following criteria:

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

      -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.

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.

[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.

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, Medical Necessity, and/or Step Therapy may be in place.

4. References:

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.

Program	Prior Authorization/Notification – Skyrizi® (risankizumab-rzaa)
Change Control	
9/2019	New program
9/2020	Annual review. Changed reauthorization duration to 12 months. Updated reference.
9/2021	Annual review with no changes to coverage criteria. Updated reference.
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. 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 reference.