Commercial/Healthcare Exchange PA Criteria

Effective: July 22, 2019

Prior Authorization: Skyrizi

Products Affected: Skyrizi (risankizumab) subcutaneous injection

Medication Description: Risankizumab-rzaa, an interleukin-23 (IL-23) antagonist, is a humanized immunoglobulin G1 (IgG1) monoclonal antibody. Risankizumab-rzaa is produced by recombinant DNA technology in Chinese hamster ovary cells and has an approximate molecular weight of 149 kDa.

Covered Uses:

1. Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis in adults
3. Moderately to severely active Crohn's disease in adults

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Must be prescribed by, or in consultation with, a dermatologist, gastroenterologist, or rheumatologist.

Coverage Duration:
Initial: 6 Months
Continuation: 1 year

Other Criteria:

Dosing Limitations: Only allow additional quantity for loading dose purposes.
The recommended dose is 150 mg (two 75 mg injections) administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

Initiation

1. Plaque Psoriasis

**Note: Skyrizi is a preferred product for the diagnosis of Psoriasis*

A. Patient has chronic (greater than or equal to 1 year) plaque psoriasis; **AND**

B. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; (prior to therapy with requested medication) **AND**

C. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed.*

Continuation

A. Patient meets all initial authorization criteria; **AND**

B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Skyrizi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Skyrizi over methotrexate.
*ConnectiCare does not consider needle-phobia to be a clinical reason to use Skyrizi over injectable medications.

Note: Clinical criteria incorporated into the Skyrizi quantity limit edit, approve additional quantity (to allow for loading doses at week 0 and week 4 then every 12 weeks thereafter).

2. **Psoriatic Arthritis** Approve for the duration noted if the patient meets **ONE** of the following (A or B):

A. Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.

B. Patient is Currently Receiving Skyrizi Subcutaneous. Approve for 1 year if the patient meets **BOTH** of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; **AND**
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Skyrizi is reviewed under Initial Therapy.

ii. Patient meets at least **ONE** of the following (a **or** b):

a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi); **OR**
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b. Compared with baseline (prior to initiating Skyrizi), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

3. **Crohn's Disease .** Approve for the duration noted if the patient meets **ONE** of the following (A or B):

A. Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; **AND**

ii. Patient meets **ONE** of the following conditions (a, b, c, or d):
    a. Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; **OR**
    Note: Examples of corticosteroids are prednisone or methylprednisolone.
    b. Patient has tried one other conventional systemic therapy for Crohn's disease; **OR**
    Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.
    c. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; **OR**
    d. Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); **AND**

iii. According to the prescriber, the patient has received (or will receive) induction dosing with Skyrizi intravenous prior to initiating therapy with Skyrizi subcutaneous; **AND**

iv. The medication is prescribed by or in consultation with a gastroenterologist.

B. Patient is Currently Receiving Skyrizi Subcutaneous. Approve for 1 year if the patient meets **BOTH** of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; **AND**
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion Initial Therapy

ii. Patient meets at least one of the following (a or b):
    a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi); **OR**
    Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography, computed tomography enterography), endoscopic assessment, and/or reduced dose of corticosteroids.
    b. Compared with baseline (prior to initiating Skyrizi), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

References:

1. Product Information: SKYRIZI(TM) subcutaneous injection, risankizumab-rzaa subcutaneous injection. AbbVie Inc (per FDA), North Chicago, IL, 2019.
Product Information: SKYRIZI(R) subcutaneous injection, risankizumab-rzaa subcutaneous injection. AbbVie Inc (per FDA), North Chicago, IL, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	7/22/2019
2	Update	Added Dosing Limitations according to FDA label	Other Criteria	5/4/2020
3	Update Policy	Medication Description: updated; Covered Uses: added Psoriatic Arthritis and Crohn's Disease; Prescriber Restrictions: added gastroenterologist and rheumatologist; Other Criteria: added Psoriatic Arthritis and Crohn's Disease; Changed coverage duration: initial was 3 months, now 6 months, Continuation was 3 years, now 1 year	Medication Description, Covered Uses, Prescriber Restrictions, Other Criteria, Coverage duration	7/14/2022
4	Update Policy	Other Criteria: Crohn's (A. iii): clarified induction dosing with IV must be prior to maintenance dosing with SQ Skyrizi	Other Criteria: Crohn's	10/4/2022