Commercial 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. Crohn's disease, in patients with moderate to severe active disease
2. Plaque psoriasis, for treatment of adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
3. Psoriatic arthritis, for treatment of adults with active disease.

Exclusion Criteria:

1. Concurrent use with other Biologics or DMARD

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:
Initiation

1. **Crohn's Disease**
   Initial therapy: Approve if the patient meets the following criteria
   A. According to the prescriber, the patient will receive induction dosing with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous; **AND**
   B. Patient meets ONE of the following conditions (i, ii, iii, **OR** iv):
      i. Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; **OR**
      Note: Examples of corticosteroids re prednisone or methylprednisolone

ii. 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.

iii. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, **OR**

iv. Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence

2. Plaque Psoriasis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has tried at least ONE traditional systemic agent for psoriasis for at least 3 months unless intolerant; **OR**
Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

B. Patient has a contraindication to methotrexate, as determined by the prescriber

3. Psoriatic Arthritis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has clinically diagnosed psoriatic arthritis **AND**

B. Prescribed by or in consultation with a rheumatologist or dermatologist

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.

References:

1. Product Information: SKYRIZI™ subcutaneous injection, risankizumab-rzaa subcutaneous injection. AbbVie Inc (per FDA), North Chicago, IL, 2019.
2. Product Information: SKYRIZI® 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	7/2/2019
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
5	Update Policy	Addition of - Concurrent use with other Biologics or DMARD – to exclusion criteria Removal of Dosages Removed current criteria for PsA/Plaque Psoriasis/Crohn's Disease and replaced with Select criteria for implementation to label use Removal of *Connecticare does not consider alcohol use to be a clinical reason to use Skyrizi over methotrexate. & *Conneticare does not consider needle-phobia to be a clinical reason to use Skyrizi over injectable medications.	Exclusion Criteria	12/19/2023