

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Skyrizi Subcutaneous Prior Authorization Policy

- Skyrizi® (risankizumab-rzaa subcutaneous injection – Abbvie)

REVIEW DATE: 06/22/2022; selected revision 07/13/2022

OVERVIEW

Skyrizi subcutaneous (SC), an interleukin (IL)-23 blocker, is indicated for the following uses:¹

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

Skyrizi is also available in an intravenous formulation that is indicated only in Crohn's disease, given as an IV infusion at Weeks 0, 4, and 8 for induction, followed by Skyrizi SC once every 8 weeks thereafter for maintenance. Skyrizi SC is available as a 360 mg single-dose prefilled cartridge for use with an on-body injector for use in Crohn's disease. For other conditions, Skyrizi is available as a 150 mg single-dose prefilled pen and as a 75 mg or 150 mg prefilled syringe.

Guidelines

The following guidelines address conditions for which Skyrizi SC is indicated.

- **Crohn's Disease:** Skyrizi is not addressed in current guidelines. The American College of Gastroenterology has guidelines for Crohn's disease (2018).⁵ Biologics are a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors). Guidelines from the American Gastroenterological Association (2021) include biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.⁶
- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.² These guidelines list Skyrizi as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® [ustekinumab SC injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.³
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (2019) recommend tumor necrosis factor inhibitors over other biologics for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.⁴

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Skyrizi SC. Because of the specialized skills required for evaluation and diagnosis of patients treated with Skyrizi SC as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Skyrizi SC to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

06/22/2022

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RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Skyrizi SC is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Crohn's Disease.** Approve Skyrizi Subcutaneous (on-body injector) 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. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. 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 will receive induction dosing with Skyrizi intravenous within 3 months of 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 A (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.
2. **Plaque Psoriasis.** Approve Skyrizi Subcutaneous (pens or syringes) for the duration noted if the patient meets ONE of the following (A or B):
 - A) **Initial Therapy.** Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
 - i. Patient is ≥ 18 years of age; AND

- ii. Patient meets ONE of the following conditions (a or b):
 - a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, acitretin tablets, 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 drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for psoriasis. 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; AND
- iii. The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving Skyrizi Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient has been established on the requested drug for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
 - iii. Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
- 3. **Psoriatic Arthritis.** Approve Skyrizi Subcutaneous (pens or syringes) 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 criterion A (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).

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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Skyrizi is not recommended in the following situations:

- 1. Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Skyrizi SC with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.⁴

Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Skyrizi SC.

- 2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.** Criteria will be updated as new published data are available.

REFERENCES

1. Skyrizi® subcutaneous injection or intravenous infusion [prescribing information]. North Chicago, IL: AbbVie; June 2022.
2. 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(4):1029-1072.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol.* 2015;29(12):2277-2294.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2018;113(4):481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology.* 2021;160(7):2496-2508.

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Psoriatic Arthritis: This newly approved indication was added to the policy.	01/26/2022
Early Annual Revision	Crohn's Disease: This newly approved indication was added to the policy.	06/22/2022
Selected Revision	<p>Crohn's Disease: Approval was clarified to apply only to the Skyrizi Subcutaneous on-body injector, which is approved for Crohn's disease.</p> <p>Plaque Psoriasis: Approval was clarified to apply only to the Skyrizi Subcutaneous pens and syringes, which are approved for plaque psoriasis.</p> <p>Psoriatic Arthritis: Approval was clarified to apply only to the Skyrizi Subcutaneous pens and syringes, which are approved for psoriatic arthritis.</p>	07/13/2022

APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.