# PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Skyrizi™ (risankizumab-rzaa subcutaneous injection – Abbvie)

**REVIEW DATE:** 04/29/2020

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## OVERVIEW

Skyrizi is a humanized immunoglobulin (Ig)G monoclonal antibody.[1] It binds to interleukin (IL)-23, a naturally occurring cytokine involved in inflammatory and immune responses, that selectively binds to the p19 subunit of the IL-23 cytokine and inhibits its interaction with the IL-23 receptor. Skyrizi is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In plaque psoriasis, the recommended dose is 150 mg (two injections) subcutaneously (SC) at Weeks 0 and 4 and then once every 12 weeks thereafter. Skyrizi is intended for use under the guidance and supervision of a physician. A patient or care giver trained in SC injection technique may administer Skyrizi, if deemed appropriate.

### Disease Overview

Although the etiology of psoriasis is not fully established, abnormal keratin formation, epidermal proliferation, activation of the immune system, and hereditary factors appear to play roles in the pathogenesis of the disease. In psoriasis, levels of IL-23p40 and IL-12/23p40 messenger RNA are upregulated but decrease with treatment. By blocking the release of proinflammatory cytokines and chemokines, Skyrizi has an inhibitory effect on the inflammatory process.

### Guidelines

Joint guidelines from the American Academy of Dermatology (AAD) 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 (EDF) [2015] recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara SC) 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]

## POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Skyrizi. Because of the specialized skills required for evaluation and diagnosis of patients treated with Skyrizi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Skyrizi 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.

## RECOMMENDED AUTHORIZATION CRITERIA

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

### FDA-Approved Indications

1. **Plaque Psoriasis.** Approve 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.** The patient is an adult ≥ 18 years of age; AND
     - **ii.** The patient meets ONE of the following conditions (a or b):
       - **a)** The patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant.
         Note: Examples of traditional systemic agents for psoriasis include methotrexate (MTX), 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 Refer to Appendix for examples of biologics used for psoriasis. These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis); OR
       - **b)** The patient has a contraindication to methotrexate (MTX), as determined by the prescriber; AND
     - **iii.** The agent is prescribed by or in consultation with a dermatologist.
   - **B)** Patient is Currently Receiving Skyrizi. Approve for 3 years if the patient has responded, as determined by the prescriber.
     Note: The patient may not have a full response, but there should have been a recent or past response to Skyrizi.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Skyrizi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Skyrizi 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 MTX (a traditional systemic agent used to treat psoriasis) in combination with Skyrizi.

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™ [prescribing information]. Thousand Oaks, CA: Amgen; May 2020.
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.

## APPENDIX

| | Mechanism of Action | Examples of Inflammatory Indications for Products* |
|---|---|---|
| **Biologics** | | |
| **Adalimumab SC Products** (Humira®, biosimilars) | Inhibition of TNF | AS, CD, PJIA, PsO, PsA, RA, SJIA, UC |
| **Cimzia®** (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, PsO, PsA, RA |
| **Etanercept SC Products** (Enbrel®, biosimilars) | Inhibition of TNF | AS, PJIA, PsO, PsA, RA, SJIA |
| **Infliximab IV Products** (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PJIA, PsO, PsA, RA, SJIA, UC |
| **Simponi®, Simponi® Aria™** (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PsA, RA |
| **Actemra®** (tocilizumab IV infusion, tocilizumab SC injection) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| **Kevzara®** (sarilumab SC injection) | Inhibition of IL-6 | RA |
| **Orencia®** (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: PJIA, PSA, RA |
| | | IV formulation: PJIA, PsA, RA |
| **Rituximab IV Products** (Rituxan®, biosimilars) | CD20-directed cytolytic antibody | RA |
| **Ilaris (**canakinumab SC injection**)** | Inhibition of IL-1β | SJIA |
| **Kineret®** (anakinra SC injection) | Inhibition of IL-1 | RA, SJIA^ |
| **Stelara®** (ustekinumab SC injection, ustekinumab IV infusion) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Siliq™** (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| **Cosentyx™** (secukinumab SC injection) | Inhibition of IL-17A | AS, PsO, PsA |
| **Taltz®** (ixekizumab SC injection) | Inhibition of IL-17A | AS, PsO, PsA |
| **Ilumya™** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| **Skyrizi™** (risankizumab-rzza SC injection) | Inhibition of IL-23 | PsO |
| **Tremfya™** (guselkumab SC injection) | Inhibition of IL-23 | PsO |
| **Entyvio™** (vedolizumab IV infusion) | Integrin receptor antagonist | CD, UC |
| **Targeted Synthetic DMARDs** | | |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Olumiant®** (baricitinib tablets) | Inhibition of the JAK pathways | RA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of the JAK pathways | RA |
| **Xeljanz®, Xeljanz XR** (tofacitinib tablets, tofacitinib extended-release tablets) | Inhibition of the JAK pathways | RA, PsA, UC |

* Not an all-inclusive list of indication (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; IV – Intravenous, IL – Interleukin; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AS – Ankylosing spondylitis; CD – Crohn's disease; PJIA – Polyarticular juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; SJIA – Systemic juvenile idiopathic arthritis; UC – Ulcerative colitis; ^ Off-label use of SJIA supported in guidelines.