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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	May 10, 2019
Subject:	Skyrizi	**Page:**	1 of 6

Last Review Date: March 12, 2021

Skyrizi

Description

Skyrizi (risankizumab-rzaa)

Background
Skyrizi (risankizumab-rzaa) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Skyrizi inhibits the release of pro-inflammatory cytokines and chemokines (1).

Regulatory Status
FDA-approved indication: 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 (1).

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Skyrizi. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Skyrizi. Consider anti-TB therapy prior to initiation of Skyrizi in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving Skyrizi for signs and symptoms of active TB during and after treatment (1).

Skyrizi affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Skyrizi therapy until the infection resolves (1).

Avoid use of live vaccines in patients treated with Skyrizi. There is no data available on the response to live or inactive vaccines (1).

The safety and effectiveness of Skyrizi in pediatric patients less than 18 years old have not been established (1).

Related policies
Ilumya, Stelara, Tremfya

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Skyrizi may be considered **medically necessary** in patients 18 years of age and older with moderate to severe plaque psoriasis (PsO) and if the conditions indicated below are met.

Skyrizi is considered **investigational** for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Moderate to severe plaque psoriasis (PsO)

AND ALL of the following:

a. Inadequate response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
    i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate response, intolerance, or contraindication to the other treatment option
b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 150 mg every 12 weeks

c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
d. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
e. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
f. **NOT** given concurrently with live vaccines
g. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Plaque psoriasis (PsO)

AND ALL of the following:
a. Condition has shown improvement or stabilization
b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 150 mg every 12 weeks
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
d. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
e. **NOT** given concurrently with live vaccines
f. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 12 (75mg) syringes
(2 injections at Week 0, 4, then every 12 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 2 (75mg) syringes per 84 days

Duration 18 months

Rationale

Summary

Skyrizi (risankizumab-rzaa) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Skyrizi inhibits the release of pro-inflammatory cytokines and chemokines. The safety and effectiveness of Skyrizi in pediatric patients less than 18 years old have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Skyrizi while maintaining optimal therapeutic outcomes.

References

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.

Policy History

Date	Action
May 2019	Addition to PA

June 2019	Annual review
September 2019	Annual review
December 2019	Annual review and reference update. Addition of requirement to trial preferred product
September 2020	Annual review and reference update
December 2020	Annual editorial review. Revised requirements to t/f preferred products to apply to Blue Focus patients only. Changed initial approval duration to 12 months. Added requirements to dose within the FDA labeled maintenance dosing
March 2021	Annual editorial review. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq