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5.90.038

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	May 10, 2019
Subject:	Skyrizi	**Page:**	1 of 9

Last Review Date: March 8, 2024

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 indications: Skyrizi is an interleukin-23 antagonist indicated for the treatment of: (1)

- moderate-to-severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- active psoriatic arthritis (PsA) in adults.
- moderately to severely active Crohn's disease in adults.

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).

For the treatment of Crohn's disease, there is a risk for hepatotoxicity. Liver enzymes and bilirubin should be evaluated at baseline and during induction at least up to 12 weeks of treatment. They should be monitored thereafter according to routine patient management (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** if the conditions indicated below are met.

Skyrizi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. Inadequate treatment 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 treatment

response, intolerance, or contraindication to the other treatment option

b. Prescriber will not exceed the FDA labeled maintenance dose of 150 mg every 12 weeks
c. 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)

2. Active psoriatic arthritis (PsA)
   a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
   b. Prescriber will not exceed the FDA labeled maintenance dose of 150 mg every 12 weeks
   c. 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)
3. Moderately to severely active Crohn's disease (CD)
   a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
   b. Prescriber will not exceed the FDA labeled maintenance dose of 360 mg every 8 weeks
   c. Prescriber agrees to monitor liver enzymes and bilirubin levels for hepatotoxicity
   d. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following:

a. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
b. 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
c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
d. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 150 mg every 12 weeks
    b. 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)
2. Psoriatic arthritis (PsA)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 150 mg every 12 weeks
    b. 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)
3. Crohn's disease (CD)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 360 mg every 8 weeks
    b. Prescriber agrees to monitor liver enzymes and bilirubin levels for hepatotoxicity
    c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following:

a. Condition has improved or stabilized with Skyrizi
b. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]

d. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's Disease	600 mg/10 mL vial for IV infusion	3 vials **AND**
	180 mg/1.2 mL	6 injections
	360 mg/2.4 mL	
Plaque Psoriasis	75 mg/0.83 mL	12 injections **OR**
	150 mg/mL	6 injections
Psoriatic Arthritis	75 mg/0.83 mL	12 injections **OR**
	150 mg/mL	6 injections

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's Disease	180 mg/1.2 mL	1 injection per 56 days
	360 mg/2.4 mL	
Plaque Psoriasis	75 mg/0.83 mL	2 injections per 84 days **OR**
	150 mg/mL	1 injection per 84 days
Psoriatic Arthritis	75 mg/0.83 mL	2 injections per 84 days **OR**
	150 mg/mL	1 injection per 84 days

Duration 18 months

Rationale

Summary
Skyrizi (risankizumab-rzaa) is an interleukin-23 antagonist indicated for the treatment of plaque psoriasis or psoriatic arthritis. Skyrizi affects the immune system, thus patients may be at greater risk for infection. Patients should be monitored closely for signs and symptoms of infection during treatment and evaluated for tuberculosis (TB) infection prior to initiating treatment with Skyrizi. 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.; January 2024.

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.
May 2021	Revised quantity limits to include the new 150mg/mL strength
September 2021	Annual review
March 2022	Addition of indication: psoriatic arthritis (PsA)
June 2022	Annual review
July 2022	Addition of indication per PI update: Crohn’s disease (CD). Addition of Appendix 2 – Conventional Therapy Options for CD
September 2022	Annual review
October 2022	Addition of 180 mg injection for CD. Changed policy number to 5.90.038
December 2022	Annual review

September 2023	Annual review and reference update
March 2024	Annual editorial review and reference update. Revised FDA dosing language

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

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
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR

upadactinib	Rinvoq

Appendix 2 - List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM