BlueCross BlueShield Federal Employee Program.

SKYRIZI
(risankizumab-rzaa)

Pre - PA Allowance

None

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)

4. Moderately to severely active ulcerative colitis (UC)
    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 Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's Disease	600 mg/10 mL vial for IV infusion	3 vials **AND**
	90 mg/mL	24 injections **OR**
	180 mg/1.2 mL	6 injections
	360 mg/2.4 mL	

Plaque Psoriasis	150 mg/mL	6 injections
Psoriatic Arthritis	150 mg/mL	6 injections
Ulcerative Colitis	600 mg/10 mL vial for IV infusion	6 vials **AND**
	90 mg/mL	24 injections **OR**
	180 mg/1.2 mL	6 injections
	360 mg/2.4 mL	

Duration 12 months

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)

4. Ulcerative colitis (UC)
   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

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's Disease	90 mg/mL	4 injections per 56 days **OR**
	180 mg/1.2 mL	1 injection per 56 days
	360 mg/2.4 mL	
Plaque Psoriasis	150 mg/mL	1 injection per 84 days
Psoriatic Arthritis	150 mg/mL	1 injection per 84 days
Ulcerative Colitis	90 mg/mL	4 injections per 56 days **OR**
	180 mg/1.2 mL	1 injection per 56 days
	360 mg/2.4 mL	

Duration 18 months

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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
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
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

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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

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine