

5.70.051

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Subsection:	Analgesics and Anesthetics	Original Policy Date:	January 1, 2014
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Last Review Date: December 12, 2025

Simponi / Simponi Aria

Description

Simponi / Simponi Aria (golimumab)

Background

Tumor necrosis factor-alpha (TNF- α) is a protein produced by the body's immune system. In certain autoimmune diseases, such as rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis, there is an overproduction of TNF- α which causes the immune system to attack parts of the body (1). Simponi and Simponi Aria work by binding to the tumor necrosis factor (TNF), preventing the binding of TNF- α to its receptors and reducing inflammation (2-3).

Regulatory Status

FDA-approved indications: Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of: (2-3)

1. Rheumatoid Arthritis (RA) - **Simponi** and **Simponi Aria**, in combination with methotrexate, are indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis
2. Psoriatic Arthritis (PsA) - **Simponi** and **Simponi Aria**, alone or in combination with methotrexate or other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis. Simponi is only indicated in adults while Simponi Aria is indicated in patients 2 years of age and older

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3. Ankylosing Spondylitis (AS) - **Simponi** and **Simponi Aria** alone or in combination with methotrexate or other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of adult patients with active ankylosing spondylitis (and axial spondyloarthritis)
4. Ulcerative Colitis (UC) - **Simponi** is indicated in adult and pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis
5. Polyarticular Juvenile Idiopathic Arthritis (pJIA) - **Simponi Aria** is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Simponi and Simponi Aria carry boxed warnings regarding serious infections and malignancies. Because Simponi and Simponi Aria suppress the immune system, patients are at a greater risk for getting serious infections leading to hospitalization or death, including tuberculosis (TB), invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers (2-3).

Patients should be screened for latent tuberculosis infection. Patients at risk for hepatitis B virus (HBV) infection should be evaluated for evidence of prior HBV infection. Hepatitis B virus carriers should be monitored for reactivation during and several months after therapy. Simponi and Simponi Aria should not be used in combination with other biologic agents. Simponi and Simponi Aria should not be initiated in patients with an active infection. Simponi and Simponi Aria should be discontinued if a patient develops a serious infection during treatment (2-3).

For the treatment of RA, Simponi and Simponi Aria should be used with methotrexate (MTX) or other conventional disease modifying anti-rheumatic drugs (DMARD). Since the presence or absence of concomitant MTX did not appear to influence the efficacy or safety of Simponi and Simponi Aria in the treatment of PsA or AS, Simponi and Simponi Aria can be used with or without MTX in the treatment of PsA and AS (2-3).

An increased risk of serious infections has been seen in clinical RA trials of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of Simponi and Simponi Aria with abatacept or anakinra is not recommended. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF-blocker. The concomitant use of Simponi and Simponi Aria

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with biologics is not recommended because of the possibility of an increased risk of infection (2-3).

The safety and effectiveness of Simponi for ulcerative colitis (UC) in pediatric patients has been established. The safety and effectiveness of Simponi for rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have not been established in pediatric patients less than 2 years of age. The safety and effectiveness of Simponi Aria for rheumatoid arthritis (RA) and ankylosing spondylitis (AS) have not been established in pediatric patients less than 18 years of age (2-3).

Related policies

Cimzia, Enbrel, Humira, Infliximab, Zymfentra

Policy

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

Simponi and Simponi Aria may be considered **medically necessary** if the conditions indicated below are met.

Simponi and Simponi Aria may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

Simponi and Simponi Aria

1. Moderately to severely active Rheumatoid Arthritis (RA)
 - a. 18 years of age or older
 - b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)

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- c. If **NO** contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX) (See Appendix 2)
- d. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
- e. Patient **MUST** have tried the preferred product(s) (see Appendix 4) 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. Simponi **only**: 18 years of age or older
- b. Simponi Aria **only**: 2 years of age or older
- c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
- d. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
- e. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active Ankylosing Spondylitis (axial spondyloarthritis)

- a. 18 years of age or older
- b. Inadequate treatment response, intolerance, or contraindication to at least 2 different NSAIDS (non-steroidal anti-inflammatory drugs) over a 4-week period in total at maximum recommended or tolerated dose
- c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
- d. Patient **MUST** have tried the preferred products (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid

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medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi ONLY

1. Moderately to severely active Ulcerative Colitis (UC)
 - a. Patient weight \geq 15 kg
 - b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 3)
 - c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. **Weight 15 – 39 kg:** 50 mg every 4 weeks
 - ii. **Weight \geq 40 kg:** 100 mg every 4 weeks
 - d. **Age 18+ only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi Aria ONLY

1. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
 - a. 2 years of age or older
 - b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drug (DMARD) (see Appendix 1)
 - c. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg/m^2 (based on body surface area) every 8 weeks

AND ALL of the following for BOTH Simponi and Simponi Aria:

- a. 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
- b. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
- c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- d. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
- e. **NOT** given concurrently with live vaccines

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All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

Simponi and Simponi Aria

1. Rheumatoid Arthritis (RA)
 - a. 18 years of age or older
 - b. Used in combination with methotrexate (MTX) unless contraindication or intolerance (see Appendix 2)
 - c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
 - d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) 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. Simponi **only**: 18 years of age or older
 - b. Simponi Aria **only**: 2 years or age or older
 - c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
 - d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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3. Ankylosing Spondylitis (or axial spondyloarthritis)
 - a. 18 years of age or older
 - b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
 - c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi ONLY

1. Ulcerative Colitis (UC)
 - a. Patient weight \geq 15 kg
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - iii. **Weight 15 – 39 kg:** 50 mg every 4 weeks
 - iv. **Weight \geq 40 kg:** 100 mg every 4 weeks
 - c. **Age 18+ only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi Aria ONLY

1. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
 - a. 2 years of age or older
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg/m^2 (based on body surface area) every 8 weeks

AND ALL of the following for **BOTH Simponi and Simponi Aria:**

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

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All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Diagnosis	Weight	Strength	Quantity
Simponi	Ankylosing Spondylitis	N/A	50 mg	3 units per 84 days
	Psoriatic Arthritis	N/A		
	Rheumatoid Arthritis	N/A		
	Ulcerative Colitis	15 kg to 39 kg	50 mg 100 mg*	15 units per 365 days (Loading dose of 100mg at week 0, followed by 50mg at week 2, then maintenance dosing of 50mg every 4 weeks)
	Ulcerative Colitis	≥40 kg	100 mg*	15 units per 365 days (Loading dose of 200mg at week 0, followed by 100mg at week 2, then maintenance dosing of 100mg every 4 weeks)
Simponi Aria	Ankylosing Spondylitis	N/A	50 mg	2mg/kg every 8 weeks (Loading dose of 2mg/kg at weeks 0 and 4, and every 8 weeks thereafter)
	Psoriatic Arthritis	N/A		
	Rheumatoid Arthritis	N/A		
	Polyarticular Juvenile Idiopathic Arthritis	N/A	50 mg	80 mg/m ² every 8 weeks (Loading dose of 80 mg/m ² at weeks 0 and 4, and every 8 weeks thereafter)

*Simponi 100mg for use only in patients with a diagnosis of UC

Duration 12 months

Prior – Approval Renewal Limits

Quantity

Medication	Diagnosis	Weight	Strength	Quantity
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Simponi	Ankylosing Spondylitis	N/A	50 mg	3 units per 84 days
	Psoriatic Arthritis	N/A		
	Rheumatoid Arthritis	N/A		
	Ulcerative Colitis	15 kg to 39 kg	50 mg	3 units per 84 days
	Ulcerative Colitis	≥40 kg	100 mg*	3 units per 84 days
Simponi Aria	Ankylosing Spondylitis	N/A	50 mg	2mg/kg every 8 weeks
	Psoriatic Arthritis	N/A		
	Rheumatoid Arthritis	N/A		
	Polyarticular Juvenile Idiopathic Arthritis	N/A	50 mg	80 mg/m ² every 8 weeks

***Simponi 100mg for use only in patients with a diagnosis of UC**

Duration 18 months

Rationale

Summary

Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Simponi is also indicated in patients with ulcerative colitis (UC), and Simponi Aria is indicated in patients with polyarticular juvenile idiopathic arthritis (pJIA). Simponi and Simponi Aria carry boxed warnings regarding the increased risk of serious infections and malignancies. The safety and effectiveness of Simponi for ulcerative colitis (UC) in pediatric patients has been established. The safety and effectiveness of Simponi for rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have not been established in pediatric patients less than 2 years of age. The safety and effectiveness of Simponi Aria for rheumatoid arthritis (RA) and ankylosing spondylitis (AS) have not been established in pediatric patients less than 18 years of age (2-3).

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

References

1. American College of Rheumatology. American College of Rheumatology website. http://www.rheumatology.org/practice/clinical/patients/medications/anti_tnf.asp.
2. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2025.
3. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.

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Policy History

Date	Action
October 2013	Addition to PA
December 2013	Annual editorial review by the PMPC
March 2014	Addition of other conventional DMARD to RA and remove moderate to severely active from renewal secondary to requiring improvement and the addition of Simponi ARIA
September 2014	Editorial review and reference update and renewal limit to 18 months
September 2016	Annual editorial review and reference update Addition of not to be used in combination with any other biologic DMARD or targeted synthetic DMARD Addition of not given concurrently with live vaccines per SME
December 2016	Annual editorial review and reference update Addition of age criteria to renewal criteria Addition of initiation criteria to RA: Contraindication, intolerance, or inadequate response to at least a 3-month trial of methotrexate therapy despite adequate dosing and if no contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX) Addition of initiation criteria to PsA for the patient to have one of the following: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of methotrexate, sulfasalazine, or leflunomide, active enthesitis and/or dactylitis (sausage digit), or predominantly axial disease (extensive spinal involvement) Addition of initiation criteria to AS: Contraindication, intolerance, or inadequate treatment response to at least 2 different NSAIDS (non-steroidal anti-inflammatory drugs) over a 4-week period in total at maximum recommended or tolerated dose Addition of initiation criteria to UC, patient must have ONE of the following: corticosteroid dependence (member requires continuous corticosteroids or cannot be successfully tapered off of corticosteroids without return of UC symptoms), OR inadequate response, intolerance, or contraindication to at least one conventional therapy
March 2017	Annual review
December 2017	Annual editorial review and reference update Addition of dosing limit requirements Addition of PsA and Ankylosing Spondylitis for Simponi Aria

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	Change of RA requirement of MTX for 3 month trial to DMARD 3 month trial
March 2018	Annual editorial review
June 2018	Addition of Appendix 1 Change of requirements to initiation criteria - For diagnosis of UC: inadequate response, intolerance or contraindication to at least ONE conventional DMARD - For diagnosis of PsA: inadequate response, intolerance or contraindication to at least ONE conventional DMARD Addition of Appendix 2 & 3 Removal of active enthesitis and/or dactylitis (sausage digit) and predominantly axial disease (extensive spinal involvement) from PsA
September 2018	Annual editorial review and reference update
March 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred product
March 2020	Annual review and reference update
August 2020	Clarifying language added to pharmacy benefit
September 2020	Annual review
October 2020	Addition of indication for Simponi Aria: polyarticular juvenile idiopathic arthritis. Also changed age for Simponi Aria for PsA to 2 and older
December 2020	Added Appendix 4 with a list of preferred medications based on diagnosis and plan. Added PA quantity limits for Simponi. Added initiation requirement for Simponi Aria to t/f a biologic or targeted synthetic DMARD per FEP
January 2021	Updated t/f options for Simponi UC diagnosis to require trial of Humira first per FEP
March 2021	Annual review and reference update. 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.
April 2021	Updated Quantity Limit chart to include loading dose of Simponi Aria. Revised Summary section. Removed references 4 and 5.
June 2021	Annual review
January 2022	Added Rinvoq as a preferred PsA product to chart (Appendix 4)
March 2022	Annual review. Added Skyrizi as a preferred PsA product to chart (Appendix 4)
April 2022	Added Rinvoq as a preferred UC product to chart (Appendix 4)
May 2022	Added Rinvoq as a preferred AS product to chart (Appendix 4)
June 2022	Annual review
September 2022	Annual review
December 2022	Annual review

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June 2023	Annual review
March 2024	Annual editorial review. Revised FDA dosing language
June 2024	Annual review
September 2024	Annual review
March 2025	Annual review
October 2025	Per PI update, removed age requirement for UC but patients must weigh at least 15 kg, removed corticosteroid dependence requirement
December 2025	Annual review. Added documentation requirement. Revised Appendix 4

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

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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
infliximab-dyyb	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Illumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla

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baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadacitinib	Rinvoq

Appendix 2 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate	
1.	Alcoholism, alcoholic liver disease or other chronic liver disease
2.	Breastfeeding
3.	Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4.	Elevated liver transaminases
5.	History of intolerance or adverse event
6.	Hypersensitivity
7.	Interstitial pneumonitis or clinically significant pulmonary fibrosis
8.	Myelodysplasia
9.	Pregnancy or planning pregnancy (male or female)
10.	Renal impairment
11.	Significant drug interaction

Appendix 3 – List of Conventional Therapies

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

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Appendix 4 - List of Preferred Products

List of preferred products:

https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>