

5.70.051

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| Section: | Prescription Drugs | Effective Date: | July 1, 2023 |
| Subsection: | Analgesics and Anesthetics | Original Policy Date: | January 1, 2014 |
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Last Review Date: June 15, 2023

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 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 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 patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, achieving and sustaining clinical remission in induction responders
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

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

The safety and effectiveness of Simponi 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 been established in pediatric patients 2 years of age and older (2-3).

Related policies

Cimzia, Enbrel, Humira, Infliximab

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:

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)
 - c. If **NO** contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX) (See Appendix 2)

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- d. Prescriber will be dosing the patient within 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. Simponi **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)
 - f. Simponi Aria **only**: Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit
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 be dosing the patient within 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. Simponi **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)
 - f. Simponi Aria **only**: Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit
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 be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
 - i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks

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- ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
- d. Simponi **only**: Patient **MUST** have tried the preferred products (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- e. Simponi Aria **only**: Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

Simponi ONLY

- 1. Ulcerative Colitis (UC)
 - a. 18 years of age or older
- AND ONE** of the following for **UC**:
- a. Corticosteroid dependence (member requires continuous corticosteroids or cannot be successfully tapered off of corticosteroids without return of UC symptoms)
 - b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 3)
- AND ALL** of the following for **UC**:
- a. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 100 mg every 4 weeks
 - b. Patient **MUST** have tried Humira 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 be dosing the patient within the FDA labeled maintenance dose of 80 mg/m² (based on body surface area) every 8 weeks
 - d. Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

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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

Prior – Approval *Renewal* Requirements

Diagnoses

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

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 be dosing the patient within 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. Simponi **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)
2. Psoriatic Arthritis (PsA)
 - a. Simponi **only**: 18 years of age or older
 - b. Simponi Aria **only**: 2 years of age or older
 - c. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:

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- i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
 - ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
 - d. Simponi **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)
- 3. Ankylosing Spondylitis (or axial spondyloarthritis)
 - a. 18 years of age or older
 - b. Prescriber will be dosing the patient within 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. Simponi **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 ONLY

- 1. Ulcerative Colitis (UC)
 - a. 18 years of age or older
 - b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 100 mg every 4 weeks
 - c. Patient **MUST** have tried Humira 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 be dosing the patient within the FDA labeled maintenance dose of 80 mg/m² (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)]

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- 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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

| Medication | Diagnosis | Strength | Quantity |
|--------------|---|----------|---|
| Simponi | Ankylosing Spondylitis | 50 mg | 3 units per 84 days |
| | Psoriatic Arthritis | | |
| | Rheumatoid Arthritis | | |
| | Ulcerative Colitis | 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 | 50 mg | 2mg/kg every 8 weeks (Loading dose of 2mg/kg at weeks 0 and 4, and every 8 weeks thereafter) |
| | Psoriatic Arthritis | | |
| | Rheumatoid Arthritis | | |
| | Polyarticular Juvenile Idiopathic Arthritis | 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 | Strength | Quantity |
|------------|------------------------|----------|---------------------|
| Simponi | Ankylosing Spondylitis | 50 mg | 3 units per 84 days |
| | Psoriatic Arthritis | | |
| | Rheumatoid Arthritis | | |
| | Ulcerative Colitis | 100 mg* | 3 units per 84 days |

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|--------------|---|-------|------------------------------------|
| Simponi Aria | Ankylosing Spondylitis | 50 mg | 2mg/kg every 8 weeks |
| | Psoriatic Arthritis | | |
| | Rheumatoid Arthritis | | |
| | Polyarticular Juvenile Idiopathic Arthritis | 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 adult 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 in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for active polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have been established in pediatric patients 2 years of age and older (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.; September 2019.
3. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.

Policy History

| Date | Action |
|---------------|-------------------------------------|
| October 2013 | Addition to PA |
| December 2013 | Annual editorial review by the PMPC |

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| 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 Change of RA requirement of MTX for 3 month trial to DMARD 3 month trial |
| March 2018 | Annual editorial review Addition of Appendix 1 |

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| June 2018 | 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 |
| June 2023 | Annual review |

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.

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Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

| Generic Name | Brand Name |
|--------------------|-----------------------------|
| azathioprine | Azasan, Imuran |
| cyclophosphamide | Cytosan |
| 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 |

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| tofacitinib | Xeljanz/XR |
| upadactinib | 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: <ol style="list-style-type: none"> Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine Rectal mesalamine (e.g., Canasa, Rowasa) Rectal hydrocortisone (e.g., Colocort, Cortifoam) Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine |
| 2. Mild to moderate disease – maintenance of remission: <ol style="list-style-type: none"> Oral mesalamine, balsalazide, olsalazine, rectal mesalamine Alternatives: azathioprine, mercaptopurine, sulfasalazine |
| 3. Severe disease – induction of remission: <ol style="list-style-type: none"> Prednisone, hydrocortisone IV, methylprednisolone IV Alternatives: cyclosporine IV, tacrolimus, sulfasalazine |
| 4. Severe disease – maintenance of remission: <ol style="list-style-type: none"> Azathioprine, mercaptopurine Alternative: sulfasalazine |
| 5. Pouchitis: <ol style="list-style-type: none"> Metronidazole, ciprofloxacin Alternative: rectal mesalamine |

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Appendix 4 - List of Preferred Products

| Diagnosis | Standard Option/Basic Option Preferred Products | Blue Focus Preferred Products |
|-----------------------------|---|---|
| Ankylosing spondylitis (AS) | *must try TWO preferred products: Enbrel Humira Rinvoq Taltz | *must try ONE preferred product: Enbrel Humira |
| Psoriatic arthritis (PsA) | *must try TWO preferred products: Enbrel Humira Otezla Rinvoq Stelara (SC) Skyrizi Taltz Tremfya Xeljanz/XR | *must try ONE preferred product: Enbrel Humira |
| Rheumatoid arthritis (RA) | *must try TWO preferred products: Actemra (SC) (<i>Must try Humira first</i>) Enbrel Humira Rinvoq Xeljanz/XR | *must try ONE preferred product: Enbrel Humira |
| Ulcerative colitis (UC)* | *must try Humira first: Humira Rinvoq Stelara (SC) | Humira |

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