Clinical Policy Title:	golimumab
Policy Number:	RxA.727
Drug(s) Applied:	Simponi®, Simponi Aria®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Simponi® & Simponi Aria® are tumor necrosis factor (TNF) blocker.

Simponi® is indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate.
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate.
- Active ankylosing spondylitis (AS).
- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
  - inducing and maintaining clinical response
  - improving endoscopic appearance of the mucosa during induction
  - inducing clinical remission
  - achieving and sustaining clinical remission in induction responders.

Simponi Aria® is indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
golimumab (Simponi®)	Active ankylosing spondylitis (AS) Active psoriatic arthritis (PsA) Rheumatoid arthritis (RA)	50 mg subcutaneously once monthly	50 mg/month
	Ulcerative colitis (UC)	<u>Initial dose:</u> 200 mg subcutaneously at week 0, then 100 mg subcutaneously at week 2 <u>Maintenance dose:</u> 100 mg subcutaneously every 4 weeks	100 mg every 4 weeks

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
golimumab (Simponi Aria®)	Active ankylosing spondylitis (AS) Active psoriatic arthritis (PsA) Rheumatoid arthritis (RA)	Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks	2 mg/kg every 8 weeks
	Active polyarticular Juvenile Idiopathic Arthritis (pJIA)	Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 intravenously every 8 weeks	80 mg/m^2 every 8 weeks

Dosage Forms

- Simponi® Injection: 50 mg/0.5 mL, 100 mg/mL in a single-dose prefilled syringe or single-dose prefilled SmartJect® autoinjector
- Simponi Aria®: Injection: 50 mg/4 mL (12.5 mg/mL) solution in a single-dose vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Ankylosing spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years of age;
4. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
   a. For Simponi® dose does not exceed 50 mg/month;
   b. For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Member meets one of the following (a or b):
   a. For Simponi®: Age ≥ 18 years of age;

b. For Simponi Aria®: Age ≥ 2 years of age.

4. Request meets one of the following (a or b):
   a. For Simponi® dose does not exceed 50 mg/month;
   b. For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Rheumatoid arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years of age;
6. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
5. Request meets one of the following (a or b):
   a. For Simponi® dose does not exceed 50 mg/month
   b. For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of Ulcerative Colitis (UC);
2. Request is for Simponi ®;
3. Prescribed by or in consultation with a gastroenterologist;
4. Age ≥ 18 years of age or;
5. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
      *Exception: If one biologic DMARD that is FDA-approved for ulcerative colitis has been previously tried, then trial of a conventional systemic agent is not required;
6. Does does not exceed 100 mg every 4 weeks

Approval Duration
Commercial: 12 months
Medicaid: 12 months

E. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of PolyarticulTar Juvenile Idiopathic Arthritis (PJIA);
2. Request is for Simponi Aria®;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years of age;

5. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX] or leflunomide [Arava®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 80 mg/m^2 every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All indications in section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. Simponi®: For indications Active ankylosing spondylitis (AS), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA): 50 mg/month & for indication Ulcerative colitis (UC): 100 mg every 4 weeks;
   b. Simponi Aria®: For indications Active ankylosing spondylitis (AS), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA): 2 mg/kg every 8 weeks & for indication Active polyarticular Juvenile Idiopathic Arthritis (pJIA): 80 mg/m^2 every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AS: Ankylosing Spondylitis
PsA: Active psoriatic arthritis Rheumatoid arthritis
RA: Rheumatoid arthritis
UC: Ulcerative colitis
pJIA: Active polyarticular Juvenile Idiopathic Arthritis
DMARDs: Disease-Modifying Antirheumatic Drugs
MTX: Methotrexate
TNF: Tumor Necrosis Factor
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA:** 1 mg/kg/day orally once daily or divided twice daily **UC (off-label):** 1.5 – 2 mg/kg/day orally	2.5 mg/kg/day
d-penicillamine (Cuprimine®)	**RA(off-label):** Initial dose: 125 or 250 mg orally once daily Maintenance dose: 500 – 750 mg/day orally once daily	1,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cyclosporine (Sandimmune®, Neoral®)	**RA:** 2.5 – 4 mg/kg/day orally divided twice daily	RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA (off-label):** Initial dose: 400 – 600 mg/day orally once daily Maintenance dose: 200 – 400 mg/day orally once daily	600 mg/day
leflunomide (Arava®)	**PJIA (off-label)** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day **RA:** 100 mg orally once daily for 3 days, then 20 mg orally once daily	PJIA, RA: 20 mg/day
mercaptopurine (Purixan®)	**UC(off-label):** 50 mg orally once daily or 1 – 2 mg/kg/day orally	2 mg/kg/day
methotrexate	**PJIA (off-label):** 10 – 20 mg/m^2/week orally, subcutaneously, or intramuscularly **RA:** 7.5 mg/week orally, subcutaneously, or intramuscularly or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
mesalamine (Pentasa®)	**UC:** 1,000 mg orally four times daily	4 g/day
Ridaura®	**RA:** 6 mg orally once daily or 3 mg orally twice daily	9 mg/day (3 mg Three times daily)
sulfasalazine (Azulfidine®)	**PJIA(off-label):** 30-50 mg/kg/day orally divided twice daily **RA:** 2 g/day orally in divided doses **UC:** Initial dose: Adults: 3 – 4 g/day orally in divided doses (not to exceed Q8 hrs) Pediatrics: 40 – 60 mg/kg/day orally in 3 –6 divided doses Maintenance dose: Adults: 2 g orally once daily Pediatrics: 30 mg/kg/day orally in 4 divided doses	PJIA: 2 g/day RA: 3 g/day UC: 4 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS:** Varies	Varies
Biologic DMARDs		
Actemra®	**PJIA:** Weight < 30 kg: 10 mg/kg intravenously every 4 weeks or 162 mg subcutaneously every 3 weeks. Weight ≥ 30 kg: 8 mg/kg intravenously every 4	Intravenously: 10 mg/kg every 4 weeks Subcutaneously: 162 mg every 2 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	weeks or 162 mg subcutaneously every 2 weeks. **RA:** Intravenously: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneously: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week.	RA: Intravenously: 800 mg every 4 weeks Subcutaneously: 162 mg every week
Cimzia®	**RA, PsA, AS**: Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneously every other week (or 400 mg subcutaneously every 4 weeks)	400 mg every 4 weeks
Cosentyx®	**PsA:** With loading dose: 150 mg subcutaneously at week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks Without loading dose: 150 mg subcutaneously every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. Pediatric Patients 2 years and older: Recommended dosage is administered by subcutaneous injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg **AS:** With loading dose: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks thereafter Without loading dose: 150 mg subcutaneously every 4 weeks If the patient continues to have active ankylosing spondylitis: 300 mg every 4 weeks can be considered	PsA: 300 mg every 4 weeks AS: 300mg every 4 weeks Nr-axSpA: 150 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Enbrel®	**RA, PsA:** 25 mg subcutaneously twice weekly or 50 mg subcutaneously once Weekly **AS:** 50 mg subcutaneously once weekly **PJIA:** Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly	50 mg/week
Entyvio®	**UC:** Initial dose: 300 mg intravenously at weeks 0, 2, and 6 Maintenance dose: 300 mg intravenously every 8 weeks	300 mg every 8 weeks
Humira®	**RA:** 40 mg subcutaneously every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every Week or 80 mg every other week **PJIA:** Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg subcutaneously every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg subcutaneously every other week Weight ≥ 30 kg (66 lbs): 40 mg subcutaneously every other week **PsA, AS:** 40 mg subcutaneously every other week **UC:** Initial dose: Adults:160 mg subcutaneously on Day 1 (given in one day or split over two consecutive days), then 80 mg subcutaneously on Day 15 Pediatrics: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg subcutaneously on Day 8, then 40 mg subcutaneously on day Day 15 Weight ≥ 40 kg(88 lbs): 160 mg subcutaneously Day 1, then 80 mg on day 8 and day 15 Maintenance dose: Adults:40 mg subcutaneously every other week starting on Day 29 Pediatrics: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 40 mg every other week or 20 mg every	RA, PJIA, PsA, AS: 40 mg/week UC: Adults:40 mg every other week Pediatrics: 80 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	week starting on day 29 Weight ≥ 40 kg (88 lbs): 80 mg every other week or 40 mg every week starting on day 29	
Remicade®, Renflexis®, Inflectra®	**UC:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks. Pediatric UC: ≥ 6 years old **PsA:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks **RA:** In conjunction with MTX Initial dose: 3 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg intravenously every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks **AS:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 6 weeks	UC: Adults: 5 mg/kg every 8 weeks Pediatrics: 5 mg/kg every 8 weeks PsA: 5 mg/kg every 8 weeks RA: 10 mg/kg every 4 weeks AS: 5 mg/kg every 6 weeks
Kevzara®	**RA:** 200 mg subcutaneously once every two weeks	200 mg/2 Weeks
Kineret®	**RA:** 100 mg subcutaneously once daily	100 mg/day
Olumiant®	**RA:** 2 mg orally once daily	2 mg/day
Orecia®	**RA, PsA:** Intravenously: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneously: 125 mg once weekly RA and PsA: Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose. (For RA: Prior to the first subcutaneous dose,	RA, PsA: Intravenously: 1,000 mg every 4 weeks Subcutaneously: 125 mg/week PJIA: Intravenously: 1,000 mg every 4 weeks Subcutaneously: 125 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	may administer an optional loading dose as a single intravenous infusion as per body weight categories above.) For PsA: Intravenous loading dose is not recommended **PJIA:** Intravenously: in pediatric patients ≥ 6 years old weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 75 kg: 10 mg/kg per dose Weight 75 to 100 kg: 750 mg per dose Weight >100 kg: 1,000 mg per dose Subcutaneously: In pediatric patients ≥ 2 years old weight-based dose once weekly Weight 10 to < 25 kg: 50 mg per dose Weight 25 to < 50 kg: 87.5 mg per dose Weight ≥ 50 kg: 125 mg per dose	
Otezla®	**PsA:** Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orall in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Rinvoq®	**RA, PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Simponi®	**AS, PsA, RA:** 50 mg subcutaneously once monthly **UC:** Initial dose: 200 mg subcutaneously at week 0, then 100 mg subcutaneously at week 2 Maintenance dose: 100 mg subcutaneously every 4 weeks	AS, PsA, RA: 50 mg/month UC: 100 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Simponi Aria®	**AS, PsA, RA:** Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks **PJIA:** Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 intravenously every 8 weeks	AS, PsA, RA: 2 mg/kg every 8 weeks PJIA: 80 mg/m^2 every 8 weeks
Skyrizi®	**PsA:** 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Stelara®	**PsA:** 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks **UC:** Weight based dosing intravenous at initial dose, followed by 90 mg subcutaneously every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	PsA: 45 mg every 12 weeks UC: 90 mg every 8 weeks
Taltz®	**PsA, AS:** Initial dose: 160 mg (two 80 mg injections) subcutaneously Maintenance dose: 80 mg subcutaneously every 4 weeks	PsA, AS: 80 mg every 4 weeks
Tremfya®	**PsA:** Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	100 mg every 8 weeks
Xeljanz®	**PsA, RA, AS:** 5 mg orally twice daily PsA: use in combination with nonbiologic disease-modifying antirheumatic drugs RA: monotherapy or use in combination with nonbiologic disease-modifying antirheumatic drugs **UC:** Induction:10 mg orally twice daily for at least 8 weeks, based on therapeutic response, may continue 10 mg twice daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue after 16 weeks of 10 mg twice daily if adequate therapeutic benefit is not achieved.	10 mg/day UC: 20 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Maintenance: 5 mg twice daily; if loss of response on 5 mg twice daily, then use 10 mg twice daily after assessing the benefits and risks and use for the shortest duration; use lowest effective dose to maintain response.	
Xeljanz® XR	PsA, RA, AS: 11 mg orally once daily UC: Induction: 22 mg once daily for at least 8 weeks; may continue 22 mg once daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue therapy if inadequate response achieved after 16 weeks using 22 mg once daily. Maintenance: 11 mg once daily; if loss of response on 11 mg once daily; then use 22 mg once daily for the shortest duration; use lowest effective dose to maintain response.	PsA, RA, AS: 11 mg/day UC: 22 mg daily
(Xeljanz® / Xeljanz® oral Solution)	**PJIA:** 5 mg twice daily or weight-based equivalent twice daily: • 10 kg ≤ body weight <20 kg 3.2 mg (3.2 mL oral solution) twice daily • 20 kg ≤ body weight <40 kg: 4 mg (4 mL oral solution) twice daily Body weight ≥40 kg: 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily	PJIA: 5 mg or 5 ml twice daily
Avsola®	**AS:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 6 weeks **PsA:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks **RA:** 3 mg/kg intravenously infusion at 0, 2, and 6 weeks for induction **UC:** 5 mg/kg intravenously infusion at weeks 0, 2, and 6 as induction therapy.	AS: 5 mg/kg every 6 weeks PsA: 5 mg/kg every 8 weeks RA: 3 mg/kg every 8 weeks UC: 5 mg/kg/dose

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Serious infections;
  - Malignancies.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Ankylosing Spondylitis:
  - Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti- TNF agent. A two year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- Polyarticular Juvenile Idiopathic Arthritis:
  - Failure of MTX in PJIA is defined as disease activity remaining moderate to high despite treatment with MTX.
  - In PJIA, response to treatment is reflected by improvement of disease activity level and poor prognostic features including: reduction in the number of active joints, ESR or CRP, Physician global assessment, patient/parent global assessment, arthritis of the hip or cervical spine, positive RF or ACPA, radiographic damage.
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.
- For female patients who are actively attempting to conceive:
  - MTX is a pregnancy category X and is absolutely contraindicated in pregnancy and is not recommended for female patients attempting to conceive.

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Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Simponi®_Simponi Aria® was created based on RxA.592.Biologic_DMARDs 1. Initial Approval Criteria, I.E.5:	02/16/2022	04/18/2022

Updated to remove prior failure and criteria "Failure of a trial of ≥ 3 consecutive months of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced". 2. Initial Approval Criteria, I.E.5: Updated to include new trial and failure criteria Trial and failure of ≥ 3 consecutive months of at least one (1) conventional systemic therapy (methotrexate[MTX] or leflunomide [Arava®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced. 3. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 4. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 5. Appendix D, General Information: Updated to remove information regarding: (a, b, c and d) a. Rheumatoid Arthritis: b. Ulcerative Colitis; c. Definition of failure of MTX or DMARDs; 6. References were reviewed and updated.		