Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: ERX.SPA.161
Effective Date: 10.01.16
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Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Golimumab (Simponi®, Simponi Aria®) is a tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)
Simponi is indicated for the treatment of:
- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with MTX
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with moderately to severely active ulcerative colitis (UC) 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 (6-MP) 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

Simponi Aria is indicated for the treatment of:
- Adult patients with moderately to severely active RA in combination with MTX
- Active PsA in patients 2 years of age and older
- Adult patients with active AS
- Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Simponi and Simponi Aria are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all)**:**

1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for Simponi, member meets both of the following (a and b):
   a. Member has experienced clinically significant adverse effects to Simponi Aria or has contraindication(s) to its excipients;
   b. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: etanercept (*Enbrel*

is preferred), adalimumab (*Humira is preferred*), Cosentyx, infliximab (*Remicade is preferred*);
**Prior authorization may be required for etanercept, adalimumab, Cosentyx, and infliximab*

6. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
2. Request is for Simponi Aria;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years;
5. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (*see Appendix J*);
6. Member meets one of the following (a, b, c, or d):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   d. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (*see Appendix J*);
7. Dose does not exceed 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed in consultation with a dermatologist or rheumatologist;
3. Member meets one of the following (a or b):
   a. Age ≥ 2 years and request is for Simponi Aria;
   b. Age ≥ 18 years;
4. If request is for Simponi, member meets both of the following (a and b):
   a. Member has experienced clinically significant adverse effects to Simponi Aria or has contraindication(s) to its excipients;
   b. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: etanercept (*Enbrel is preferred*), adalimumab (*Humira is preferred*), Coxentyx®, Otezla®, infliximab (*Remicade is preferred*), subcutaneous Stelara, Xeljanz, Xeljanz XR;
   **Prior authorization may be required for etanercept, adalimumab, Cosentyx, Otezla, infliximab, Stelara, Xeljanz, and Xeljanx XR*
5. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria:
      i. Adults: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*);
      ii. Pediatrics: 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 6 months

D. Rheumatoid Arthritis (must meet all)**:**
1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix G*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. If request is for Simponi, member meets both of the following (a and b):
   a. Member has experienced clinically significant adverse effects to Simponi Aria or has contraindication(s) to its excipients;
   b. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: etanercept *(Enbrel® is preferred*), adalimumab *(Humira® is preferred),* infliximab (*Remicade® is preferred*), Rinvoq®, Xeljanz®, Xeljanz XR®;
      **Prior authorization may be required for etanercept, adalimumab, infliximab, Rinvoq, Xeljanz, and Xeljanz XR*
6. Prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX;
7. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix H*);
   b. Routine assessment of patient index data 3 (RAPID) score (*see Appendix I*);
8. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 6 months

E. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Request is for Simponi (SC formulation);
3. Prescribed by or in consultation with a gastroenterologist;
4. Age ≥ 18 years;
5. Documentation of a Mayo Score ≥ 6 (*see Appendix E*);
6. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
7. Failure of 2 of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated: adalimumab (*Humira is preferred*), infliximab (*Remicade is preferred*), subcutaneous Stelara, Xeljanz, Xeljanz XR;
   **Prior authorization may be required for adalimumab, infliximab, Stelara, Xeljanz, and Xeljanz XR*
8. Dose does not exceed 200 mg at week 0, 100 mg at week 2, followed by maintenance dose of 100 mg every 4 weeks.

Approval duration: 6 months

F. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member meets one of the following (a, b, or c):

a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
   i. A decrease in CDAI (*see Appendix H*) or RAPID3 (*see Appendix I*) score from baseline;
   ii. Medical justification stating ability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
b. For pJIA: Member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (*see Appendix J*);
c. For all other indications: Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed the following (a, b, c, or d):
   a. RA, PsA, AS (Simponi): 50 mg SC once monthly;
   b. UC (Simponi): 100 mg SC every 4 weeks;
   c. AS, PsA, RA (Simponi Aria) Adults: 2 mg/kg IV every 8 weeks;*
   d. PJIA, PsA (Simponi Aria) Pediatrics: 80 mg/m^2 IV every 8 weeks.*
   **see Appendix F for dose rounding guidelines*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz®/Xeljanz® XR, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
AS: ankylosing spondylitis
CDAI: clinical disease activity index
cJADAS: clinical juvenile arthritis disease activity score
DMARD: disease modifying antirheumatic drug
FDA: Food and Drug Administration
MTX: methotrexate
NSAID: non-steroidal anti-inflammatory drug
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis
RA: rheumatoid arthritis
RAPID3: routine assessment of patient assessment index data 3
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID **UC*** 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg PO QD Maintenance dose: 200 – 400 mg PO QD	600 mg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD **pJIA*** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
6-mercaptopurine (Purixan®)	**UC*** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12hr for 3 doses/week **UC*** 15 – 25 mg/week IM or SC **pJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
Pentasa® (mesalamine)	**UC** 1,000 mg PO QID	4 g/day
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** 2 g/day PO in divided doses **UC** Initial dose: 3 – 4 g/day PO in divided doses(not to exceed Q8 hrs) Maintenance dose: 2 g/day PO QD **pJIA*** 30-50 mg/kg/day PO divided BID	RA: 3 g/day UC: 4 g/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cosentyx® (secukinumab)	**AS** With loading dose: 150 mg at weeks 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks Without loading dose: 150 mg every 4 weeks PsA	150 mg every 4 weeks
Enbrel® (etanercept)	**AS** 50 mg SC once weekly **PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly **pJIA** Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**AS, PsA** 40 mg SC every other week **RA** 40 mg SC every other week (may increase to once weekly) **UC** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29	AS, PsA, UC: 40 mg every other week RA: 40 mg/week
Otezla® (apremilast)	**PsA** Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID	60 mg/day
Remicade® (infliximab)	**AS** Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 6 weeks **PsA**	AS: 5 mg/kg every 6 weeks PsA, UC: 5 mg/kg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks **RA** In conjunction with MTX Initial dose: 3 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg IV every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks **UC** Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks.	RA: 10 mg/kg every 4 weeks
Rinvoq® (upadacitnib)	**RA** 15 mg PO QD	15 mg/day
Stelara® (ustekinumab)	**PsA** 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks **UC** Weight based dosing IV at initial dose, followed by 90 mg SC 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
Xeljanz® (tofacitinib, immediate-release)	**PsA, RA** 5 mg PO BID **UC** 10 mg PO BID for 8 weeks; then 5 mg PO BID **pJIA** • 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID • Body weight ≥ 40 kg: 5 mg PO BID	PJIA, PsA, RA: 10 mg/day UC maintenance: 10 mg/day
Xeljanz XR® (tofacitinib, extended-release)	**PsA, RA** 11 mg PO QD **UC**	11 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	22 mg PO QD for 8 weeks; then 11 mg PO QD	

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

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): serious infections and malignancy

Appendix D: General Information

- Definition of failure of MTX or DMARDs:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

Appendix E: Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- The following may be considered for medical justification supporting inability to use an immunomodulator for ulcerative colitis:
  - Documentation of Mayo Score 6 – 12 indicative of moderate to severe ulcerative colitis.

Appendix F: Dose Rounding Guidelines

Weight-based Dose Range	Vial Quantity Recommendation
≤ 52.49 mg	1 vial of 50 mg/4 mL
52.5 to 104.99 mg	2 vials of 50 mg/4 mL
105 to 157.49 mg	3 vials of 50 mg/4 mL
157.5 to 209.99 mg	4 vials of 50 mg/4 mL
210 to 262.49 mg	5 vials of 50 mg/4 mL

Appendix G: The 2010 ACR Classification Criteria for RA
Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA ** Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA ** High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix H: Clinical Disease Activity Index (CDAI) Score
The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix I: Routine Assessment of Patient Index Data 3 (RAPID3) Score
The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

Appendix J: Clinical Juvenile Arthritis Disease Activity Score based on 10 joints (cJADAS-10)
The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

**ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both*

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Golimumab (Simponi)	AS PsA RA	50 mg SC once monthly	50 mg/month
	UC	Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks
Golimumab (Simponi Aria)	AS PsA RA PJIA	Adults: Initial dose (AS, PsA, RA): 2 mg/kg IV at weeks 0 and 4 Adults: Maintenance dose (AS, PsA, RA): 2 mg/kg IV every 8 weeks Pediatrics: Initial dose (PsA, PJIA): 80 mg/m^2 IV at weeks 0 and 4 Pediatrics: Maintenance dose (PsA, PJIA): 80 mg/m^2 IV every 8 weeks	Adults (AS, PsA, RA): 2 mg/kg every 8 weeks Pediatrics (PsA, PJIA): 80 mg/m^2 every 8 weeks

VI. Product Availability

Drug Name	Availability
Golimumab (Simponi)	Single-dose prefilled SmartJect® autoinjector: 50 mg/0.5mL, 100 mg/1mL Single-dose prefilled syringe: 50 mg/0.5mL, 100 mg/1mL
Golimumab (Simponi Aria)	Single-use vial: 50 mg/4mL

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review Converted to new template. Removed “active” UC since Simponi is indicated for induction, maintenance, and sustaining remission; RA: removed requirement for another biologic, removed requirement for submission of diagnostic lab since a specialist is required to prescribe or be consulted PsA, AS, UC: specified request is for Simponi not Aria For all indications: Diagnostic criteria modified to require verifiable information; Specified trial of conventional DMARDs for 3 months or greater; Specified max weight-based dose and frequency.	10.01.17	11.17
Added additionally FDA-approved indications of PsA and AS for Simponi Aria	01.11.18	
2Q 2018 annual review: added requirement for concomitant use of MTX or another DMARD for RA; added aminosalicylate as an option for trial and failure for UC; modified preferencing for all indications; references reviewed and updated.	02.27.18	05.18
4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for biologic DMARDs for PsA per ACR/NPF 2018 guidelines; revised requirement of trial and failure of biologics to preferred TNF inhibitors and Otezla for PsA per ACR/NPF 2018 guidelines; added Xeljanz/Xeljanz XR to list of trial options for RA; added Xeljanz to list of trial options for UC and revised requirement to T/F of 2 agents; references reviewed and updated.	03.05.19	05.19
2Q 2020 annual review: for UC, revised redirection from AZA, 6-MP, ASA to systemic corticosteroids, added requirement for Mayo score of at least 6;	02.28.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
added dose rounding guidelines for Simponi Aria; for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy, and added Rinvoq as a preferred option for redirection per formulary status; for PsA, added Cosentyx, Xeljanz, Xeljanz XR, and SC Stelara as preferred options for redirection per formulary status; For UC, added Xeljanz, Xeljanz XR, and SC Stelara as preferred options for redirection per formulary status references reviewed and updated.		
Revised typo in Appendix E from "normal ESR" to "abnormal ESR" for a point gained for ACR Classification Criteria.	11.22.20	
RT2: pJIA FDA approved indication added. RT4: PsA FDA approved age extension to pediatrics added (age 2 and older). Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic; updated appendices.	11.17.20	02.21
Per CVS, removed redirection to Kevzara for RA despite preferred status on Formulary 500/550 files in order to maximize rebates	02.01.21	
2Q 2021 annual review: added combination of bDMARDs under Section III; updated CDAI table with ">" to prevent overlap in classification of severity; references reviewed and updated.	02.23.21	05.21
Clarified pediatric PsA dosing; PJIA clarified dosing to include initial dosing schedule.	07.13.21	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.