

## **Clinical Policy: Golimumab (Simponi, Simponi Aria)**

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Line of Business: Medicaid

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Golimumab (Simponi<sup>®</sup>, Simponi Aria<sup>®</sup>) is a tumor necrosis (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 methotrexate
- 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 intolerant to prior treatment or requiring continuous steroid therapy 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.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  18 years;

4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for  $\geq 4$  weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of ALL of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated:
  - a. Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, and Taltz<sup>®</sup>;
  - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

*\*Prior authorization may be required for Cimzia, Enbrel, Xeljanz/Xeljanz XR, and Taltz*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. 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  $\geq 5$  joints with active arthritis;
2. Request is for Simponi Aria;
3. Prescribed by or in consultation with a rheumatologist;
4. Age  $\geq 2$  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  $\geq 3$  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  $\geq 3$  consecutive month trial of sulfasalazine or leflunomide 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  $\geq 4$ -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. Failure of both of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated (a and b):
  - a. Enbrel<sup>®</sup> and Actemra<sup>®</sup>;
  - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

*\*Prior authorization may be required for Actemra, Enbrel, and Xeljanz/Xeljanz XR*

8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed 80 mg/m<sup>2</sup> IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m<sup>2</sup> 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. For members ≥ 18 years, failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
  - a. Enbrel<sup>®</sup>, Otezla<sup>®</sup>, and Taltz<sup>®</sup>;
  - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

*\*Prior authorization may be required for Enbrel, Otezla, Taltz, Xeljanz/Xeljanz XR*
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. 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<sup>2</sup> IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m<sup>2</sup> 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 DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;

5. Failure of ALL of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced (a and b):
  - a. Actemra<sup>®</sup>, Enbrel<sup>®</sup>, and Kevzara<sup>®</sup>;
  - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup> or Olumiant<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;  
*\*Prior authorization may be required for Actemra, Enbrel, Kevzara, Xeljanz/Xeljanz XR, and Olumiant*
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 (RAPID3) score (*see Appendix I*);
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. 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  $\geq 18$  years;
5. Documentation of a Mayo Score  $\geq 6$  (*see Appendix E*);
6. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
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 (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. All Indications in Section I (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 inability 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. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):
  - a. AS, PsA, RA (Simponi): 50 mg SC once monthly;
  - b. AS, PsA, RA (Simponi Aria) Adults: 2 mg/kg IV every 8 weeks\*;
  - c. UC (Simponi): 100 mg SC every 4 weeks;
  - d. PJIA, PsA (Simponi Aria) Pediatrics: 80 mg/m<sup>2</sup> 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

**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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup>, Simponi<sup>®</sup>, Avsola<sup>™</sup>, Inflectra<sup>™</sup>, Remicade<sup>®</sup>, Renflexis<sup>™</sup>], interleukin agents [e.g., Arcalyst<sup>®</sup> (IL-1 blocker), Ilaris<sup>®</sup> (IL-1 blocker), Kineret<sup>®</sup> (IL-1RA), Actemra<sup>®</sup> (IL-6RA), Kevzara<sup>®</sup> (IL-6RA), Stelara<sup>®</sup> (IL-12/23 inhibitor), Cosentyx<sup>®</sup> (IL-17A inhibitor), Taltz<sup>®</sup> (IL-17A inhibitor), Siliq<sup>™</sup> (IL-17RA), Ilumya<sup>™</sup> (IL-23 inhibitor), Skyrizi<sup>™</sup> (IL-23 inhibitor), Tremfya<sup>®</sup> (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR, Cibinqo<sup>™</sup>, Olumiant<sup>™</sup>, Rinvoq<sup>™</sup>], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup>, Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>, Rituxan Hycela<sup>®</sup>], selective co-stimulation modulators [Orencia<sup>®</sup>], and integrin receptor antagonists [Entyvio<sup>®</sup>] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

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

*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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
azathioprine (Azasan <sup>®</sup> , Imuran <sup>®</sup> )	<b>RA</b> 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
corticosteroids	<b>UC</b> budesonide (Uceris <sup>®</sup> ) 9 mg PO QD	Varies



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cuprimine <sup>®</sup> (d-penicillamine)	<b>RA*</b> <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	<b>RA</b> 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil <sup>®</sup> )	<b>RA*</b> <u>Initial dose:</u> 400 – 600 mg PO QD <u>Maintenance dose:</u> 200 – 400 mg PO QD	600 mg/day
leflunomide (Arava <sup>®</sup> )	<b>RA</b> 100 mg PO QD for 3 days, then 20 mg PO QD <b>pJIA*</b> Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
methotrexate (Rheumatrex <sup>®</sup> )	<b>RA</b> 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week <b>UC*</b> 15 – 25 mg/week IM or SC <b>pJIA*</b> 10 – 20 mg/m <sup>2</sup> /week PO, SC, or IM	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	<b>AS</b> Varies	Varies
sulfasalazine (Azulfidine <sup>®</sup> )	<b>RA</b> 2 gm/day PO in divided doses <b>pJIA*</b> 30-50 mg/kg/day PO divided BID	RA: 3 g/day  pJIA: 2 g/day
Actemra <sup>®</sup> (tocilizumab)	<b>pJIA</b> • Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks  <b>RA</b>	PJIA: • IV: 10 mg/kg every 4 weeks • SC: 162 mg every 2 weeks  RA:

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response  SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	IV: 800 mg every 4 weeks SC: 162 mg every week
Enbrel <sup>®</sup> (etanercept)	<b>AS</b> 50 mg SC once weekly  <b>PsA, RA</b> 25 mg SC twice weekly or 50 mg SC once weekly  <b>pJIA</b> Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
Cimzia <sup>®</sup> (certolizumab)	<b>AS</b> <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Kevzara <sup>®</sup> (sarilumab)	<b>RA</b> 200 mg SC once every two weeks	200 mg/2 weeks
Oluminat <sup>®</sup> (baricitinib)	<b>RA</b> 2 mg PO QD	2 mg/day
Otezla <sup>®</sup> (apremilast)	<b>PsA</b> <u>Initial dose:</u> 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  <u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	60 mg/day



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Taltz <sup>®</sup> (ixekizumab)	<p><b>AS, PsA</b>  <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0  <u>Maintenance dose:</u>            80 mg SC every 4 weeks</p> <p><b>PsO</b>  <u>Initial dose:</u>            160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12  <u>Maintenance dose:</u>            80 mg SC every 4 weeks</p>	80 mg every 4 weeks
Xeljanz <sup>®</sup> (tofacitinib)	<p><b>AS, PsA, RA</b>            5 mg PO BID</p> <p><b>pJIA</b></p> <ul style="list-style-type: none"> <li>• 10 kg ≤ body weight &lt; 20 kg: 3.2 mg (3.2 mL oral solution) PO BID</li> <li>• 20 kg ≤ body weight &lt; 40 kg: 4 mg (4 mL oral solution) PO BID</li> <li>• Body weight ≥ 40 kg: 5 mg PO BID</li> </ul>	10 mg/day
Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<p><b>AS, PsA, RA</b>            11 mg PO QD</p>	11 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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

*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) <i>and</i> negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF <i>or</i> low positive ACPA <i>* Low: &lt; 3 x upper limit of normal</i>	2
	High positive RF <i>or</i> high positive ACPA <i>* High: ≥ 3 x upper limit of normal</i>	3

<b>C</b>	<b>Acute phase reactants (at least one test result is needed for classification)</b>	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
<b>D</b>	<b>Duration of symptoms</b>	
	< 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.

<b>CDAI Score</b>	<b>Disease state interpretation</b>
≤ 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.

<b>RAPID3 Score</b>	<b>Disease state interpretation</b>
≤ 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

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

cJADAS-10	Disease state interpretation
> 8.5	High disease activity

## V. Dosage and Administration

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

## VI. Product Availability

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

## VII. References

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***Juvenile Idiopathic Arthritis***

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**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1602	Injection, golimumab, 1 mg, for intravenous use
J3490, C9399	Unclassified drugs or biologicals (subcutaneous golimumab)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added additionally FDA-approved indications of PsA and AS for Simponi Aria. For PsA, removed hydroxychloroquine as an accepted trial and replaced it with cyclosporine to align with similar policies for PsA. This was a typo.	01.11.18	
2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: removed specific diagnosis requirements for RA, modified trial and failure for RA, AS, PsA to require both Humira and Enbrel, removed trial and failure of Enbrel from UC as Enbrel is not indicated; Medicaid: added requirement for concomitant	02.27.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
use of MTX or another DMARD for RA; Medicaid and HIM: modified trial and failure for RA to at least one conventional DMARD, removed TB testing for all indications, added aminosalicylate as an option for trial and failure for UC, modified gastroenterologist specialty requirement to gastrointestinal specialist for UC; references reviewed and updated.		
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 PsA per ACR/NPF 2018 guidelines; revised GI specialist to gastroenterologist for UC; references reviewed and updated.	03.05.19	05.19
Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for RA, removed redirection to adalimumab added redirection to 2 of 3 (Enbrel, Kevzara, Xeljanz/Xeljanz XR); for AS, removed redirection to adalimumab and added redirection to 2 of 3 (Enbrel, Cimzia, Taltz); for PsA, removed redirections to etanercept and adalimumab; for UC, removed redirection to adalimumab.	12.13.19	
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; for UC, revised redirection from AZA, 6-MP, ASA to systemic corticosteroids, added requirement for Mayo score of at least 6; added dose rounding guidelines for Simponi Aria; references reviewed and updated.	04.23.20	05.20
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 with Enbrel redirection. 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
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	
Per August SDC and prior clinical guidance, for AS modified from trial of two to trial of all; for PsA added redirection to Enbrel, Otezla, Taltz, Xeljanz/Xeljanz XR; for RA added Actemra to redirect options and modified to require a trial of all; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and	08.25.21	11.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers; added Legacy WellCare line of business to policy (WCG.CP.PHAR.253 to be retired).		
2Q 2022 annual review: for PJIA, added redirection to Actemra per February SDC; for RA, added redirection to Olumiant per February SDC; for AS, added redirection to Xeljanz if failed prior TNF blocker per August SDC and updated FDA labeling; for PsA, clarified that redirection applies only to age 18 or older; removed legacy Wellcare approval durations; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	02.21.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.11.22	

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.



This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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