

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

Reference Number: CP.PHAR.253

Effective Date: 07.16

Last Review Date: 02.21

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 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 methotrexate
- 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. 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  $\geq$  18 years;
4. Member meets one of the following (a or b):

- a. Failure of a  $\geq 3$  consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a  $\geq 3$  consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of at least TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel<sup>®</sup>, Kevzara<sup>®</sup>, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>;  
*\*Prior authorization may be required for Enbrel, Kevzara, and Xeljanz/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 (RAPID3) 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**

**B. 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  $\geq 2$  years and request is for Simponi Aria;
  - b. Age  $\geq 18$  years;
4. 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**

**C. 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 contraindicated or clinically significant adverse effects are experienced;
5. Failure of at least TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia<sup>®</sup>, Enbrel, Taltz<sup>®</sup>;  
*\*Prior authorization may be required for Cimzia, Enbrel, and Taltz*
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**

**D. 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. 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**

**E. 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: Enbrel, Xeljanz;  
*\*Prior authorization may be required for Enbrel and Xeljanz*
8. Dose does not exceed 80 mg/m<sup>2</sup> IV every 8 weeks (*see Appendix F for dose rounding guidelines*).

**Approval duration: 6 months**

**F. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met all 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 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. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
  - a. RA, PsA, AS (i or ii):
    - i. Simponi: 50 mg SC once monthly;
    - ii. Simponi Aria: 2 mg/kg IV every 8 weeks (*see Appendix F for dose rounding guidelines*);
  - b. UC (Simponi): 100 mg SC every 4 weeks;
  - c. PJIA (Simponi Aria): 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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

1. 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.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

6MP: 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  
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.*

<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
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>	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	10 – 20 mg/m <sup>2</sup> /week PO, SC, or IM	
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
Enbrel <sup>®</sup> (etanercept)	<b>AS</b> 50 mg SC once weekly  <b>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
Taltz <sup>®</sup> (ixekizumab)	<b>AS</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	80 mg every 4 weeks
Xeljanz <sup>®</sup> (tofacitinib)	<b>PsA, RA</b> 5 mg PO BID  <b>UC</b> 10 mg PO BID for 8 weeks; then 5 mg PO BID  <b>pJIA</b>	PJIA, PsA, RA: 10 mg/day  UC maintenance: 10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<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>	
Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<b>PsA, RA</b> 11 mg PO QD  <b>UC</b> 22 mg PO QD for 8 weeks; then 11 mg PO QD	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



- 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) <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
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



CDAI Score	Disease state interpretation
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	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	Adults (AS, PsA, RA): 2
	PsA		

Drug Name	Indication	Dosing Regimen	Maximum Dose
	RA	<u>Adults: Maintenance dose (AS, PsA, RA): 2 mg/kg IV every 8 weeks</u>	mg/kg every 8 weeks
	PJIA	<u>Pediatrics: Initial dose (PsA, PJIA): 80 mg/m<sup>2</sup> IV at weeks 0 and 4</u> <u>Pediatrics: Maintenance dose (PsA, PJIA): 80 mg/m<sup>2</sup> IV every 8 weeks</u>	Pediatrics (PsA, PJIA): 80 mg/m <sup>2</sup> every 8 weeks

## 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

1. Simponi Prescribing Information. Horsham, PA; Janssen Biotech; September 2019. Available at <http://www.simponi.com/shared/product/simponi/prescribing-information.pdf>. Accessed February 26, 2020.
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### Rheumatoid Arthritis

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### Psoriatic Arthritis

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Ankylosing Spondylitis

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Ulcerative Colitis

11. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114:384-413

Juvenile Idiopathic Arthritis

12. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care and Research*. Vol. 71, No. 6, June 2019, pp 717–734. DOI 10.1002/acr.23870.
13. Petty RE, Southwood TR, Manners P, et al. International League of Associations for Rheumatology classification of juvenile idiopathic arthritis: second revision, Edmonton, 2001. *J Rheumatol*. 2004;31(2):390.
14. Backstrom M, Tynjala P, Ylijoki H, et al. Finding specific 10-joint Juvenile Arthritis Disease Activity Score (JADAS10) and clinical JADAS10 cut-off values for disease activity levels in non-systemic juvenile idiopathic arthritis: a Finnish multicentre study. *Rheumatology*. 2016;55:615\_623.
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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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. RA: modified the RA diagnostic criteria from requiring one or more of the following: ≥ 5 inflamed joints, elevation in the ESR and/or CRP concentration; positive rheumatoid factor and/or anticyclic citrullinated peptide) antibodies (present in most patients), evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling, to the ACR diagnostic criteria. Removed requirement for use in combination with MTX.	07.17	07.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
PsA, AS, UC: clarified request must be for Simponi. For UC, limited accepted first line trials to thiopurine.		
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 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.	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 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).	11.17.20	02.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic; updated appendices.		

**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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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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