Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: IL.PHAR.253
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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®, Simponi Aria®) 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 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® 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 ≥ 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, unless contraindicated or clinically significant adverse effects are experienced;
b. If intolerance or contraindication to MTX (*see Appendix D*), 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 contraindicated or clinically significant adverse effects are experienced;

5. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker, contraindicated or clinically significant adverse effects are experienced: Enbrel®, Humira®, Cimzia, Xeljanz®/Xeljanz XR®;
**Prior authorization is required for Enbrel, Humira, Cimzia, 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. 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

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 ≥ 2 years and request is for Simponi Aria;
   b. Age ≥ 18 years;
4. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker) (a, b):
   a. Enbrel®
   b. Humira®,
   c. Cimzia®(
5. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
**Prior authorization is required for Enbrel, Humira, Cimzia, and Xeljanz/Xeljanz XR*
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:
      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

C. 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. Member meets ALLof the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (a and b)
   a. : One of the following (i, ii, or iii, *see Appendix D*):
      i. Failure of both of the following, each used for ≥ 3 consecutive months: Cimzia® and Enbrel®;
      ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Cimzia or Enbrel;
      iii. History of failure of two TNF blockers and request is not for another TNF blocker;
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR® used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

**Prior authorization is required for Enbrel, Humira, Cimzia, and Xeljanz/Xeljanz XR*

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

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 ≥ 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 a ≥ 3 consecutive month trial of adalimumab (*Humira is preferred*) and tofacitinib (*Xeljanz/Xeljanz XR is preferred*), unless contraindicated or clinically significant adverse effects are experienced;
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 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 ≥ 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 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 ≥ 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 two of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated (a and b):
   a. . Enbrel or Humira (unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker)
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for Enbrel, Humira, and Xeljanz*
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^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

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. If request is for a dose increase, new dose does not exceed one of 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. 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®, Enbrel®, Humira® (and its biosimilars), Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., 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) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] 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
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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
corticosteroids	**UC** Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	Varies
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** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 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
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **pJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose:2 gm/day PO in divided doses **pJIA*** 30-50 mg/kg/day PO divided BID	RA: 3 g/day pJIA: 2 g/day
Actemra® (tocilizumab)	**pJIA** • 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 **RA** 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	PJIA: • IV: 10 mg/kg every 4 weeks • SC: 162 mg every 2 weeks RA: IV: 800 mg every 4 weeks SC: 162 mg every week
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Cimzia® (certolizumab)	**AS** Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Kevzara® (sarilumab)	**RA** 200 mg SC once every two weeks	200 mg/2 weeks
Oluminat® (baricitinib)	**RA** 2 mg PO QD	2 mg/day
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
Taltz® (ixekizumab)	**AS, PsA** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PsO Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg SC every 4 weeks	
Xeljanz® (tofacitinib)	**AS, PsA, RA** 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	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**AS, PsA, RA** 11 mg PO QD	11 mg/day

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

- AS and nr-axSpA: Although the 2019 ACR guidelines for AS recommend the use of TNF inhibitors over IL-17A antagonists such as Taltz or Cosentyx, this recommendation was based on "greater experience with TNF inhibitors and familiarity with their long-term safety and toxicity" rather than differences in efficacy.
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®), adalimumab-atto (Amjevita™), infliximab (Remicade®) and infliximab biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

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) *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

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	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	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
	PsA		
	RA		
	PJIA		

Product Availability

Drug Name	Availability
Golimumab (Simponi)	Single-dose prefilled SmartJect® 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

VI. 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)

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PHAR.253 Golimumab (Simponi, Simponi Aria) for migration to HFS PDL.	1.13.2020	
2Q 2021 annual review. Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic; updated appendices. pJIA FDA approved indication added with Enbrel redirection. RT4: PsA FDA approved age extension to pediatrics added (age 2 and older). 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.	4.12.2021	
Clarified pediatric PsA dosing; PJIA clarified dosing to include initial dosing schedule.	7.19.21	
2Q 2022 Annual Review: added redirection to Xeljanz for Ankylosing Spondylitis**;** added redirection to Humira for pJIA; Added requirement against combination use with a bDMARD or potent immunosuppressants in Section III; Updated *Appendix B: Therapeutic Alternatives;* Updated *Appendix D: General Information;* reference reviewed and updated	6.30.22	
2Q 2023 annual review: for AS, pJIA, PsA, and RA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	4.19.23	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.