Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: PA.CP.PHAR.253
Effective Date: 01/18
Last Review Date: 07/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Golimumab (Simponi®/Simponi Aria®) is a human IgG1κ monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNFα. This interaction prevents the binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα (a cytokine protein).

FDA approved indication
Simponi is indicated for the treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Adult patients with active ankylosing spondylitis
- 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 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 rheumatoid arthritis in combination with methotrexate.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® 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 (refer to *Appendix B*);
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 methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;

   b. If intolerance or contraindication to MTX: sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab.*
6. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed:
   a. Simponi: 50 mg once monthly;
   b. Simponi Aria: 2mg/kg dosed at weeks 0 and 4 then every 8 weeks thereafter.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of active psoriatic arthritis (PsA);
2. Prescribed in consultation with a dermatologist or rheumatologist;
3. Request is for Simponi;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. For Axial Disease
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs or
      ii. A documented contraindication or intolerance to NSAIDs
   b. For Peripheral Disease:
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs AND
      ii. A documented history of therapeutic failure of a three (3) or more month trial of methotrexate OR an alternate DEMARD OR
      iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate DMARD.
6. Failure of etanercept *(Enbrel is preferred)* AND adalimumb *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
7. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

C. Ankylosing Spondylitis (must meet all)**:**
1. Diagnosis of active ankylosing spondylitis (AS);
2. Prescribed by or in consultation with a rheumatologist;
3. Request is for Simponi;
4. Age ≥ 18 years;

5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effect are experienced;
6. Failure of etanercept *(Enbrel is preferred)* AND adalimumb *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
7. TB test within past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

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

1. Diagnosis of moderately to severely active ulcerative colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. Request is for Simponi;
4. Age ≥ 18 years;
5. Failure of a thiopurine (6MP, azathioprine) for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of adalimumb *(Humira is preferred)*, used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab*
7. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 200 mg week 0, 100 mg week 2, then maintenance therapy with 100 mg every 4 weeks.

Approval duration: 6 months

E. Other diagnoses/indications: Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Simponi: RA, PsA, AS – 50 mg SC once monthly; UC – 100 mg SC once monthly;
   b. Simponi Aria: RA – 2mg/kg IV infusions every 8 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
CRP: C-reactive protein
DMARD: disease modifying antirheumatic drug
ESR: erythrocyte sedimentation rate
MTX: methotrexate
PsA: psoriatic arthritis
RA: rheumatoid arthritis
SC: subcutaneous
TB: tuberculosis
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: 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	2
	High positive RF *or* high positive ACPA	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal CRP and normal ESR	0
	Abnormal CRP or normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or disease-modifying antirheumatic drug (DMARD) failure

In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count, ≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose

Simponi	RA, PsA, AS	50 mg SC once monthly	50 mg/month
	UC	200 mg SC at week 0 100 mg SC at week 2 100 mg SC every 4 weeks as maintenance therapy	Maintenance: 100 mg/month
Simponi Aria	RA	2 mg/kg IV at weeks 0 and 4, then every 8 weeks	Maintenance: 2 mg/kg every 8 weeks

VI. Product Availability

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

VII. References

1. Simponi Prescribing Information. Horsham, PA; Janssen Biotech; June 2017. Available at http://simponiaria.com/sites/default/files/prescribing-information.pdf. Accessed June 23, 20176.
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treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis & Rheumatology, 2015. DOI 10.1002/ART.39298.
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12. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol.* 2010;105;501-523.
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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	Approval Date