Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: PA.CP.PHAR.253
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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

FDA approved indication
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 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
- Adult patients with active PsA
- Adult patients with active AS

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;
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) at up to maximally indicated doses for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effect 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) 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, or member is currently receiving Simponi;
   **Prior authorization is required for etanercept and adalimumab.*
6. Prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX;
7. Dose does not exceed:
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria: 2mg/kg IV at weeks 0 and 4, then every 8 weeks thereafter.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. 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, or member is currently receiving Simponi;
   **Prior authorization is required for etanercept and adalimumab*
5. 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.

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. Age ≥ 18 years;
4. 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;
5. 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, or member is currently receiving Simponi;
   **Prior authorization is required for etanercept and adalimumab*
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.

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 (SC formulation);
4. Age ≥ 18 years;
5. Failure of a ≥ 3 consecutive month trial of azathioprine, 6-MP, or an aminosalicylate (e.g., sulfasalazine) at up to maximally indicated doses, 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, or member is currently receiving Simponi;
   **Prior authorization is required for adalimumab*
7. 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.PMN.53.

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 one of the following (a or b):
   a. RA, PsA, AS (i or ii):
      i. Simponi: 50 mg SC once monthly;
      ii. Simponi Aria: 2 mg/kg IV every 8 weeks;
   b. UC (Simponi): 100 mg SC every 4 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.PMN.53.

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.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

6MP: 6-mercaptopurine
AS: ankylosing spondylitis

DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
MTX: methotrexate
NSAID: non-steroidal anti-inflammatory drug
PsA: psoriatic arthritis
RA: rheumatoid arthritis
TNF: tumor necrosis factor
UC: ulcerative colitis

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID **UC*** 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg PO QD Maintenance dose: 200 – 400 mg PO QD	600 mg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
6-mercaptopurine (Purixan®)	**UC*** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **UC*** 15 – 25 mg/week IM or SC	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
Pentasa® (mesalamine)	**UC** 1,000 mg PO QID	4 g/day

sulfasalazine (Azulfidine®)	**RA** 2 gm/day PO in divided doses **UC** Initial dose: 3 – 4 g/day PO in divided doses (not to exceed Q8 hrs) Maintenance dose: 2 g/day PO QD	RA: 3 g/day UC: 4 g/day
Enbrel® (etanercept)	**AS** 50 mg SC once weekly **PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**AS, PsA** 40 mg SC every other week **RA** 40 mg SC every other week (may increase to once weekly) **UC** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29	AS, PsA, UC: 40 mg every other week RA: 40 mg/week

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

- Ankylosing Spondylitis:
  - Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti-TNF agent. A two year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- 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
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

V. Dosage and Administration

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

VI. 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

VII. References

1. Simponi Prescribing Information. Horsham, PA; Janssen Biotech; May 2018. Available at http://www.simponi.com/shared/product/simponi/prescribing-information.pdf. Accessed February 26, 2019.
2. Simponi Aria Prescribing Information. Horsham, PA; Janssen Biotech; May 2018. Available at http://simponiaria.com/sites/default/files/prescribing-information.pdf. Accessed February 26, 2019.

3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017; 0: 1-18.
4. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guidelines for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research 2015; 68(1):1-26.
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9. 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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12. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726

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
2Q 2018 annual review: added requirement for concomitant use of MTX or another DMARD for RA; modified trial and failure for RA to	02.27.18	

Reviews, Revisions, and Approvals	Date	Approval Date
at least one conventional DMARD, removed TB testing for all indications, added aminosalicylate as an option for trial and failure for UC, references reviewed and updated.		
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.	04.17.19	