Clinical Policy: Golimumab (Simponi, Simponi Aria)
Reference Number: ERX.SPMN.151
Effective Date: 10/2016
Last Review Date: 12/2016

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that golimumab (Simponi®/Simponi Aria®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Rheumatoid Arthritis (must meet all):
      1. Prescribed by or in consultation with a rheumatologist;
      2. Age ≥ 18 years;
      3. Diagnosis of moderately to severely active rheumatoid arthritis (RA) and one or more of the following:
         a. At least five inflamed joints;
         b. Elevation in the erythrocyte sedimentation rate (ESR) and/or serum C-reactive protein (CRP) concentration;
         c. Positive rheumatoid factor and/or anticyclic citrullinated peptide (CCP) antibodies (present in most patients);
         d. Evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling;
      4. Member has failed one of the following therapies unless intolerant or contraindicated:
         a. A biologic other than Simponi/Simponi Aria for RA;
         b. Methotrexate (MTX) for ≥ 3 consecutive months;
         c. If intolerance or contraindication to MTX, sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months;
      5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
      6. Simponi/Simponi Aria is prescribed in combination with MTX, or another disease-modifying antirheumatic (DMARD) agent if intolerance or contraindication to MTX;
      7. Prescribed dosage regimen of Simponi/Simponi Aria does not exceed the following:
         a. Simponi: 50 mg once monthly;
         b. Simponi Aria: dosed at weeks 0 and 4, then every 8 weeks thereafter.

   Approval duration: 6 months

   B. Psoriatic Arthritis (must meet all):
      1. Prescribed in consultation with a dermatologist or rheumatologist;
      2. Age ≥ 18 years;
      3. Diagnosis of active psoriatic arthritis (PsA);
      4. Member has failed one of the following therapies unless intolerant or contraindicated:
         a. A biologic for PsA other than Simponi/Simponi Aria;
         b. Methotrexate (MTX) for ≥ 3 consecutive months;
c. If intolerance or contraindication to MTX, sulfasalazine, leflunomide, cyclosporine, or azathioprine, for ≥ 3 consecutive months;
5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
6. Prescribed dosage regimen of Simponi does not exceed 50 mg subcutaneous (SC) once monthly.

Approval duration: 6 months

C. Ankylosing Spondylitis (must meet all):
1. Prescribed by or in consultation with a rheumatologist;
2. Age ≥ 18 years;
3. Diagnosis of active ankylosing spondylitis (AS);
4. Member has failed one of the following therapies unless intolerant or contraindicated:
   a. A biologic other than Simponi/Simponi Aria for AS;
   b. Two or more non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, each for ≥ 4 weeks;
5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
6. Prescribed dosage regimen of Simponi does not exceed 50 mg subcutaneous (SC) once monthly.

Approval duration: 6 months

D. Ulcerative Colitis (must meet all):
1. Prescribed by or in consultation with a gastroenterologist;
2. Age ≥ 18 years;
3. Diagnosis of moderately to severely active ulcerative colitis (UC);
4. Member has failed one of the following therapies for ≥ 3 months unless intolerant or contraindicated:
   a. A biologic for UC other than Simponi/Simponi Aria;
   b. An immunomodulator (e.g., azathioprine, 6MP, MTX) for ≥ 3 consecutive months;
5. Member has failed Humira for ≥ 3 consecutive months unless intolerant or contraindicated;
6. Prescribed dosage regimen of Simponi does not exceed the following:
   a. Subcutaneous (SC): 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 ERX.SPMN.16 - Global Biopharm Policy
II. Continued Approval

A. All Indications (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Member is responding positively to therapy;
   3. Prescribed regimen does not exceed the following:
      a. For RA:
         i. Simponi: 50 mg SC once monthly;
         ii. Simponi Aria: weight-based IV infusions every 8 weeks;
      b. For PsA and AS (Simponi): 50 mg SC once monthly;
      c. For UC (Simponi): 100 mg SC every 4 weeks.

   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Golimumab 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). Elevated TNFα levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. TNFα is an important mediator of the articular inflammation that is characteristic of these diseases. The exact mechanism by which golimumab treats ulcerative colitis is unknown. Golimumab modulated the in vitro biological effects mediated by TNF in several bioassays, including the expression of adhesion proteins responsible for leukocyte infiltration (E-selectin, ICAM-1, and VCAM-1) and the secretion of proinflammatory cytokines (IL-6, IL-8, G-CSF, and GM-CSF).

Formulations:
Simponi
Sterile solution of the golimumab antibody supplied as a:
   • Single-dose prefilled syringe (with a passive needle safety guard)
   • Single-dose prefilled autoinjector.
   Strength:
      o 50 mg golimumab in 0.5 mL of solution
      o 100 mg golimumab in 1 mL of solution

Simponi Aria
Sterile concentrated solution of the golimumab antibody supplied as a:
   • 4-mL glass vial for intravenous infusion.
   Strength:
      o 50 mg golimumab in each 4-mL vial
FDA Approved Indications:
Simponi is a tumor necrosis factor (TNF) blocker/subcutaneous injectable formulation indicated for:

- Rheumatoid arthritis
  - Treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate (MTX).
- Psoriatic arthritis
  - Treatment of adult patients with active psoriatic arthritis alone or in combination with methotrexate.
- Ankylosing spondylitis
  - Treatment of adult patients with active ankylosing spondylitis.
- Ulcerative colitis
  - Treatment of 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 a TNF blocker/intravenous formulation indicated for:

- Rheumatoid arthritis
  - Treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with MTX.

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

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.

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<th>HCPCS Codes</th>
<th>Description</th>
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<td>J1602</td>
<td>Injection, golimumab, 1 mg, for intravenous use</td>
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**Clinical Policy**

### Golimumab

#### Reviews, Revisions, and Approvals

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<tr>
<th>Policy split from USS.SPMN.24 Irritable Bowel Disease (IBD) Treatments, USS.SPMN.41 Psoriasis Treatments, and USS.SPMN.44 Rheumatoid Arthritis and Ankylosing Spondylitis Treatments. Converted to new template. Removed all safety criteria. Added dosing per PI. Added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated (just Humira for UC). Modified approval duration to 6 months for initial and 12 months for renewal. Shortened background section. RA: changed age requirement to 18. Modified criteria to require trial of MTX unless contraindicated. Added sulfasalazine and hydroxychloroquine as alternatives to MTX if contraindicated. Simponi Aria indication for RA only per PI. Re-auth: combined into All Indications. For all trial/failure requirements, indicated that member can also meet criteria if intolerant (as opposed to just contraindicated) to therapy in question. Modified the following initial criteria sets: -RA: indicated that disease must be moderately to severely active. -PsA: modified trial/failure requirement- instead of requiring 2 or more nonbiologic DMARDs (such as cyclosporine, sulfasalazine, azathioprine, hydroxychloroquine), criteria now requires MTX; if MTX is contraindicated, then cyclosporine, sulfasalazine, leflunomide, cyclosporine, or azathioprine may be trialed. -UC: indicated that disease must be moderately to severely active. Removed option for trial/failure of corticosteroid and aminosalicylate.</th>
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#### References


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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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