Clinical Policy: Golimumab (Simponi, Simponi Aria)
Reference Number: CP.PHAR.253
Effective Date: 07.16
Last Review Date: 05.19
Line of Business: Medicaid

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 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
- Adult patients with active PsA
- Adult patients with active AS

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;
      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 contraindicated or clinically significant adverse effects are experienced:
   Enbrel®, Kevzara®, Xeljanz®/Xeljanz XR®;  
   *Prior authorization is required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR

6. Prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX;

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.

**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. 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 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. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced:
      Cimzia®, Enbrel, Taltz®;  
      *Prior authorization is 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.

**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. 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. 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. 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 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 (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
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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>azathioprine (Azasan®, Imuran®)</td>
<td>RA 1 mg/kg/day PO QD or divided BID</td>
<td>2.5 mg/kg/day</td>
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<tr>
<td></td>
<td>UC* 1.5 – 2 mg/kg/day PO</td>
<td></td>
</tr>
<tr>
<td>Cuprimine® (d-penicillamine)</td>
<td>RA* Initial dose: 125 or 250 mg PO QD</td>
<td>1,500 mg/day</td>
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<td></td>
<td>Maintenance dose: 500 – 750 mg/day PO QD</td>
<td></td>
</tr>
<tr>
<td>cyclosporine (Sandimmune®, Neoral®)</td>
<td>RA 2.5 – 4 mg/kg/day PO divided BID</td>
<td>4 mg/kg/day</td>
</tr>
<tr>
<td>hydroxychloroquine (Plaquenil®)</td>
<td>RA* Initial dose: 400 – 600 mg PO QD</td>
<td>600 mg/day</td>
</tr>
<tr>
<td></td>
<td>Maintenance dose: 200 – 400 mg PO QD</td>
<td></td>
</tr>
<tr>
<td>leflunomide (Arava®)</td>
<td>RA 100 mg PO QD for 3 days, then 20 mg PO QD</td>
<td>20 mg/day</td>
</tr>
<tr>
<td>6-mercaptopurine (Purixan®)</td>
<td>UC* 50 mg PO QD or 1 – 2 mg/kg/day PO</td>
<td>2 mg/kg/day</td>
</tr>
<tr>
<td>methotrexate (Rheumatrex®)</td>
<td>RA 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week</td>
<td>30 mg/week</td>
</tr>
<tr>
<td></td>
<td>UC* 15 – 25 mg/week IM or SC</td>
<td></td>
</tr>
<tr>
<td>NSAIDs (e.g., indomethacin, ibuprofen,)</td>
<td>AS Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/ Maximum Dose</td>
</tr>
<tr>
<td>-------------------------------</td>
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<td>--------------------------</td>
</tr>
<tr>
<td>naproxen, celecoxib</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pentasa® (mesalamine)</td>
<td>UC 1,000 mg PO QID</td>
<td>4 g/day</td>
</tr>
</tbody>
</table>
| sulfasalazine (Azulfidine®)   | RA 2 gm/day PO in divided doses | RA: 3 g/day  
                             | UC Initial dose: 3 – 4 g/day PO in divided doses (not to exceed Q8 hrs)  
                             | Maintenance dose: 2 g/day PO QD | UC: 4 g/day |
| Enbrel® (etanercept)          | AS 50 mg SC once weekly | 50 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           |
| Taltz® (ixekizumab)           | AS 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 |
| Xeljanz® (tofacitinib)        | RA 5 mg PO BID | 10 mg/day                |
| Xeljanz XR® (tofacitinib extended-release) | 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

- 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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab (Simponi)</td>
<td>AS</td>
<td>50 mg SC once monthly</td>
<td>50 mg/month</td>
</tr>
<tr>
<td></td>
<td>PsA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance dose: 100 mg SC every 4 weeks</td>
<td>100 mg every 4 weeks</td>
</tr>
<tr>
<td>Golimumab (Simponi Aria)</td>
<td>AS</td>
<td>Initial dose: 2 mg/kg IV at weeks 0 and 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PsA</td>
<td>Maintenance dose: 2 mg/kg IV every 8 weeks</td>
<td>2 mg/kg every 8 weeks</td>
</tr>
<tr>
<td></td>
<td>RA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab (Simponi)</td>
<td>Single-dose prefilled SmartJect® autoinjector: 50 mg/0.5 mL, 100 mg/1 mL</td>
</tr>
<tr>
<td></td>
<td>Single-dose prefilled syringe: 50 mg/0.5 mL, 100 mg/1 mL</td>
</tr>
<tr>
<td>Golimumab (Simponi Aria)</td>
<td>Single-use vial: 50 mg/4 mL</td>
</tr>
</tbody>
</table>

VII. References

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1602</td>
<td>Injection, golimumab, 1 mg, for intravenous use</td>
</tr>
</tbody>
</table>

**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>06.16</td>
<td>07.16</td>
</tr>
</tbody>
</table>

Policy split from CP.PHAR.86.ArthritisTreatments, CP.PHAR.85 Psoriasis Treatments, CP.PHAR.87.IBD Treatment 4.
RA, PsA, AS, UC: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing limits/details; added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated (just Humira for UC);
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 RA only per PI.
Re-auth: combined into All Indications; added criteria related to dosing and reasons to discontinue. Modified approval duration to 6 months for initial and 12 months for renewal. Shortened background section.
PsA: Preferred trial of MTX above other DMARDs per CPC feedback.
UC: removed option of trial of aminosalicylates per 2015 AGA Clinical Care Pathway.
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.
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.

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### Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>02.27.18</td>
<td>05.18</td>
</tr>
<tr>
<td>4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.</td>
<td>09.04.18</td>
<td>11.18</td>
</tr>
<tr>
<td>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.</td>
<td>03.05.19</td>
<td>05.19</td>
</tr>
<tr>
<td>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.</td>
<td>12.13.19</td>
<td></td>
</tr>
</tbody>
</table>

**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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