Simponi® (golimumab)
Effective 01/01/21

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☒ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☒ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
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<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
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<tr>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
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Medical Specialty Medications (NLX)
All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |

Exceptions
N/A

Overview
Simponi® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with:
- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis (AS)
- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Simponi excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Moderate to Severe Rheumatoid Arthritis (RA)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to at least ONE traditional DMARD or contraindication to all traditional DMARDs
   b. Paid claims or physician documented inadequate response or adverse reaction to ONE
biologic DMARD that is FDA-approved for the requested indication
3. Dosing is appropriate
4. Prescriber provides clinical rationale for use of Simponi instead of Enbrel® and Humira®

Psoriatic Arthritis (PsA)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Simponi instead of Enbrel® and Humira®

NOTE: DMARD trial is not required in members with active ankylosing spondylitis or psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs.

Ankylosing spondylitis (AS)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to TWO NSAIDs or contraindication to ALL NSAIDs
3. Appropriate dosing (see appendix A)
4. Prescriber provides clinical rationale for use of Simponi instead of Enbrel® and Humira®

Ulcerative colitis (UC)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Simponi instead of Humira®

Continuation of Therapy
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Limitations
1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for up to 12 months.
3. The following quantity limits apply:

| Simponi Inj 100mg/mL  | 1 unit per 28 days |
| Simponi Inj 50mg/0.5mL |               |
Appendix

Appendix A: Dosing

<table>
<thead>
<tr>
<th>Simponi® (golimumab)</th>
<th>Ankylosing spondylitis (active), psoriatic arthritis: 50 mg SQ once monthly</th>
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<tr>
<td></td>
<td>Rheumatoid arthritis (moderate-severe):  50 mg SQ once monthly in combination with methotrexate</td>
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<td>Ulcerative colitis in corticosteroid-dependent patients or who had inadequate response to immunosuppressants (e.g., oral aminosalicylates or corticosteroids, azathioprine or 6-mercaptopurine): 200 mg SQ at week 0, followed by 100 mg SQ at week 2, and then 100 mg SQ every 4 weeks</td>
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References


Review History

02/22/10 – Reviewed
04/05/10 – Effective
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
01/13/14 – Reviewed and revised (Simponi Aria update; 08/26/13 file & plan decision wt-based QL applied to PA)
02/23/15 – Reviewed
02/22/16 – Reviewed
02/27/17 – Reviewed and revised (adopted SGM& ST) in P&T Meeting
03/01/18 – Reviewed (adopted MH RS)
02/20/19 – Reviewed in P&T Meeting

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