Simponi® (golimumab)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans — Phone: 866-814-5506 — Fax: 866-249-6155 **Non-Specialty Medications** MassHealth — Phone: 877-433-7643 — Fax: 866-255-7569 Commercial — Phone: 800-294-5979 — Fax: 888-836-0730 Exchange — Phone: 855-582-2022 — Fax: 855-245-2134 **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 the plan 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:

Rheumatoid Arthritis (RA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe rheumatoid arthritis
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 (see Appendix B)

b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing †
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. Diagnosis of psoriatic arthritis
2. Appropriate dosing †
3. Prescriber provides clinical rationale for use of Simponi instead of Enbrel® and Humira®

Ankylosing spondylitis (AS)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of ankylosing spondylitis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing †
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. Diagnosis of moderate to severe ulcerative colitis
2. Appropriate dosing †
3. Prescriber provides clinical rationale for use of Simponi instead of Humira®

† Requests for more frequent or higher doses – see Appendix C

New members currently stable on Simponi® can be approved without documentation of failed trials with the conventional therapies if they have a documented history of hospitalization for one of the above immune conditions.

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

Appendix A: Dosing

Simponi® (golimumab)	**Ankylosing spondylitis (active), psoriatic arthritis:** 50 mg SQ once monthly **Rheumatoid arthritis (moderate-severe):** 50 mg SQ once monthly in combination with methotrexate **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

Appendix B. Examples of Traditional DMARDs

Traditional DMARDs*
azathioprine
cyclosporine
hydroxychloroquine*
leflunomide
methotrexate*
sulfasalazine*
thalidomide

Appendix C. More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics may be approved if ALL of the following is provided:

1. Severe disease
2. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** other injectable biologic which is FDA-approved for the requested indication
3. Partial response to FDA-approved dosing of current biologic therapy
4. Specialist consult for the requested indication

References

1. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2018.
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4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
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8. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64(Suppl II):ii14–ii17.
9. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. [Published online ahead of print May 8, 2014]. Clin Rheumatol. 2014.Accessed August 22, 2014.
10. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2015: 10.1002/art.39298. [Epub ahead of print].
11. Braun J, Baraliakos X, Hermann KG, et al. The effect of two golimumab doses on radiographic progression in ankylosing spondylitis: results through 4 years of the GO-RAISE trial. Ann Rheum Dis 2014; 73:1107.
12. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.

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
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members with a documented history of hospitalization. Added examples of traditional DMARDs and higher dosing criteria to appendix. Effective 3/1/23.

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