Simponi® (golimumab)
Effective 01/01/21

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 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:

<u>Moderate to Severe Rheumatoid Arthritis (RA)</u>

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

Appendix

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

References

1. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2018.
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3. Smolen JS, Landewé R, Billsma 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 Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
5. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
7. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. Ann Rheum Dis. 2016;75(3):499-510.
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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 – Efective
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

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.