Simponi® (golimumab)
Effective 02/20/19

Plan	☒ MassHealth ☐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 treatmentof adult patients with:

1. Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
2. Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
3. Active ankylosing spondylitis (AS)
4. Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy

Coverage Guidelines

Rheumatoid arthritis (RA), Ankylosing spondylitis (AS)/Psoriatic arthritis (PsA)

Authorization may be granted when the following criteria are met:

1. Member has a diagnosis of RA, AS or PsA **AND**
2. Prescriber has provided documentation of ONE of the following*:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
3. Dosing is appropriate (see appendix A) **AND**
4. Prescriber provides clinical rationale for use of requested agent instead of Enbrel and Humira (i.e. member has had an inadequate response, adverse reaction, or contraindication to Humira AND Enbrel.)

**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*

Ulcerative colitis
Authorization may be granted when the following criteria are met:

1. Member has a diagnosis of ulcerative colitis **AND**
2. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
        i. Aminosalicylate
        ii. Corticosteroid
        iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
3. Dosing is appropriate (see appendix A for dosing) **AND**
4. Prescriber provides clinical rationale for use of requested agent instead of Humira (i.e. member has had an inadequate response, adverse reaction, or contraindication to Humira)

** If a request documents severe disease, a trial of an oral immunomodulator may be bypassed*

Continuation of Therapy
Reauthorization requires physician documentation indicating a positive response to therapy.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for up to 12 months.

Appendix

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.
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017;0:1-14.

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.
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 – 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

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