Enbrel® (etanercept)
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

Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker indicated for:

- Treatment of adults with active ankylosing spondylitis
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with moderate to severe plaque psoriasis (PsO)
- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of adults with moderately to severe polyarticular juvenile idiopathic arthritis (pJIA)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Enbrel excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

Rheumatoid Arthritis (RA) and **Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of **ONE** of the following:
    a. Moderate to severe rheumatoid arthritis
    b. Moderate to severe polyarticular juvenile idiopathic arthritis
2. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** traditional DMARD (See Appendix B) or contraindication to traditional DMARDs

b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing

Psoriatic Arthritis (PsA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of psoriatic arthritis
2. Appropriate dosing †

Ankylosing spondylitis (AS)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of ankylosing spondylitis*
2. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing †

**Requests for Enbrel® in non-radiographic axial spondylarthritis may be approved if all criteria are met excluding NSAID trial requirement*

Moderate to Severe Plaque Psoriasis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see Appendix A)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing †

†Requests for more frequent or higher doses (see appendix C)

<u>Off-Label Indications</u>
Behçet's Disease (BD)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Behçet's Disease
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** topical corticosteroids
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
4. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. azathioprine
    b. colchicine

c. cyclophosphamide
d. cyclosporine
e. methotrexate
f. Otezla® (apremilast)

Synovitis-acne-pustulosis-hyperostosis-osteitis Syndrome (SAPHO)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of SAPHO
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids

Takayasu Arteritis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Takayasu arteritis
2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:
    a. systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

New members currently stable on Enbrel® can be approved without documentation of failed trials with the conventional therapies.

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

Limitations
1. Initial approvals will be granted for:
    a. Plaque Psoriasis and Off-label indications: 3 months.
    b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Enbrel Inj 25mg/0.5mL and 50mg/mL	8 syringes per 28 days
Enbrel 25mg/0.5mL vial	8 vials per 28 days

Appendix A. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix B. Traditional DMARDS

Traditional DMARDS*	

azathioprine	methotrexate*
cyclosporine	sulfasalazine*
hydroxychloroquine*	thalidomide
Leflunomide	
If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.	

Appendix C. More frequent/Higher doses

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

1. Documentation of severe disease
2. Documented partial response to FDA-approved dosing of current biologic therapy
3. Documentation of specialist consult for the requested indication

References

1. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corp; 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. Flagg SD, Meador R, Hsia E, et al. Decreased pain and synovial inflammation after etanercept therapy in patients with reactive and undifferentiated arthritis: an open-label trial. Arthritis Rheum. 2005;53(4):613-617.
4. 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.
5. 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.
6. 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.
7. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
8. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008;58(5):826-850.
9. 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.
10. 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.
11. 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.
12. 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].
13. Signorovitch JE, Betts KA, Yan YS, et al. Comparative efficacy of biological treatments for moderate-to-severe psoriasis: a network meta-analysis adjusting for cross-trial differences in reference arm response. *Br J Dermatol*. 2015;172(2):504-512.[PubMed 25288183]

Review History

03/21/05 – Reviewed
05/15/05 – Effective
02/27/06 – Reviewed
02/25/08 – Reviewed
02/23/09 – Reviewed
02/22/10 – Reviewed
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
02/24/14 – Reviewed
02/23/15 – Reviewed
02/2016 – Reviewed
02/2017 – Reviewed and revised (adopted SGM)
03/01/18 – Reviewed and revised (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
11/17/2021 – Reviewed and Updated Nov P&T; matched with MH UPPL for implementation 1/1/2022; added appendix with traditional DMARDS and off label indications based on evidence. Effective 01/01/2022
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Off-label indications added for: Behcet's disease, SAPHO, TAK. Added language regarding stability of requested medication for new members. Updated Appendix sections by removing off-label indications and dosing information. Effective 3/1/23.

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