

ENBREL (etanercept)
Effective 02/20/19

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
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

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA)
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
3. Active psoriatic arthritis (PsA)
4. Active ankylosing spondylitis (AS)
5. Moderate to severe chronic plaque psoriasis (PsO)

Compendial Uses

1. Axial spondyloarthritis
2. Reactive arthritis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)

Authorization may be granted for members who have previously received Enbrel or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

OR



Authorization may be granted for treatment of moderately to severely active RA when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
2. Member has an intolerance or contraindication to methotrexate (see Appendix A).

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

Authorization may be granted for members who have previously received Enbrel or any other biologic DMARD indicated for active polyarticular juvenile idiopathic arthritis.

OR

Authorization may be granted for treatment of active pJIA when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate.
2. Member has intolerance or contraindication to methotrexate (see Appendix A).

Active psoriatic arthritis (PsA)

Authorization may be granted for members who have previously received Enbrel, or any other TNF inhibitor indicated for active psoriatic arthritis (PsA).

OR

Authorization may be granted for treatment of active PsA when ANY of the following criteria is met, and documentation is provided:

1. Member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
2. Member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis (AS) and axial spondyloarthritis

Authorization may be granted for members who have previously received Enbrel or any other biologic DMARD indicated for active ankylosing spondylitis.

OR

Authorizations may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
2. Member has an intolerance or contraindication to two or more NSAIDs.

Moderate to severe chronic plaque psoriasis

Authorization may be granted for members who have previously received Enbrel, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe chronic plaque psoriasis.

OR

Authorization may be granted for treatment of moderate to severe plaque psoriasis when ALL the following criteria are met, and documentation is provided:

1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member meets ANY of the following criteria:
 - a. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
 - i. 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, acitretin)



- ii. 1 topical agent + 1 phototherapy
 - iii. 1 systemic agent + 1 phototherapy
 - iv. 2 systemic agents
- b. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix B
- c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Reactive arthritis

Authorization may be granted for treatment of reactive arthritis.

Continuation of Therapy

Reauthorization may be granted for members, including those who are new to AllWays Health Partners, who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Enbrel as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months.
2. **For all indications**, member must have a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).*
 - a. Note: * Members who have received Enbrel or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from all requirements related to TB screening in this Policy.

Appendices

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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
02/22/16 – Reviewed
02/2017 – Reviewed (switched to SGM)
02/26/18 – Reviewed (switched to Custom) in P&T Meeting
02/20/19 – Reviewed

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