Mass General Brigham
Health Plan

ENBREL (etanercept)
Effective 10/01/2020

Plan	☐ MassHealth UPPL ☒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
Etanercept is a recombinant DNA-derived protein composed of tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. Etanercept binds tumor necrosis factor (TNF) and blocks its interaction with cell surface receptors

Coverage Guidelines
Authorization may be granted for members 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 for members meeting all the following diagnosis-specific criteria and documentation is provided.

1. **Moderately to severely active rheumatoid arthritis (RA)**
   a. 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) **OR**
   b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

2. **Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)**
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate **OR,**
   b. Member has intolerance or contraindication to methotrexate (see Appendix A).

3. **Active psoriatic arthritis (PsA)**
   a. Member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide **OR,**

b. Member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

4. Active ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (nr-axSpA

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

5. Moderate to severe chronic plaque psoriasis

a. Member has 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 **AND**
b. Member meets ANY of the following criteria:
    i. 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 (acitretin, cyclosporine, methotrexate)
        II. 1 topical agent + 1 phototherapy
        III. 1 systemic agent + 1 phototherapy
        IV. 2 systemic agents

OR member meets any of the following:

i. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix B
ii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Continuation of Therapy

Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's 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 Corporation; March 2020
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. 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.
7. Braun J, Pavelka K, Ramos-Remus C, et al. Clinical efficacy of etanercept versus sulfasalazine in ankylosing spondylitis subjects with peripheral joint involvement. J Rheumatol 2012; 39:836
8. 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.
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. 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

03/21/2005 – Reviewed
05/15/2005 – Effective
02/27/2006 – Reviewed
02/25/2008 – Reviewed
02/23/2009 – Reviewed
02/22/2010 – Reviewed

02/28/2011 – Reviewed
02/27/2012 – Reviewed
02/25/2013 – Reviewed
02/24/2014 – Reviewed
02/23/2015 – Reviewed
02/22/2016 – Reviewed
02/2017 – Reviewed (switched to SGM)
02/26/2018 – Reviewed (switched to Custom) in P&T Meeting
02/20/2019 – Reviewed
07/22/2020 – Reviewed and updated July P&T Mtg; reworded overview; removed compendial use of reactive arthritis; changed diagnosis of axial spondyloarthritis to nonradiographic axial spondyloarthritis. Effective 10/01/2020.