

Enbrel® (etanercept)
Effective 01/01/2022

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> 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 AllWays Health Partners 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:

Moderate to Severe Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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

- Appropriate diagnosis
- **ONE** of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to at least **ONE** traditional DMARD (See Appendix C) or contraindication to 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



- Dosing is appropriate

Psoriatic Arthritis (PsA)

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

1. Appropriate diagnosis
2. Appropriate dosing

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)

NOTE: Requests for Enbrel® in non-radiographic axial spondylarthritis may be approved if all criteria are met.

Moderate to Severe Plaque Psoriasis

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 **ONE conventional therapy** (see appendix B)
 - a. topical agent
 - b. phototherapy
 - c. systemic agent
 - b. Contraindication to **ALL conventional therapies**:
 - a. topical agents
 - b. phototherapy
 - c. systemic agents
 - c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

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:
 - a. Plaque Psoriasis: 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

	Pediatric Dosing	Other Dosing
Enbrel® (etanercept)	<p>Juvenile Idiopathic Arthritis (≥ 2 years old, weight < 63 kg): 0.8 mg/kg SQ weekly</p> <p>Juvenile Idiopathic Arthritis (≥ 2 years old, weight ≥ 63 kg): 50 mg SQ weekly; maximum, 50 mg/week</p>	<p>Ankylosing spondylitis, psoriatic arthritis rheumatoid arthritis (moderate-severe): 50 mg SQ weekly (given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly 72-96 hours apart)</p> <p>Plaque psoriasis (mod-severe) chronic: <u>Initial:</u> 50 mg SQ twice weekly 72-96 hours apart for 3 months</p> <p><u>Maintenance:</u> 50 mg SQ weekly given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly 72-96 hours apart)</p>

Appendix B. 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 C: 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 D: Off-Label Indications 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

Takayasu Arteritis (TAK)

Prescriber provides documentation of ALL of the following:

1. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to ALL of the following:
 - a. Systemic glucocorticoids
 - b. **One** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

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.
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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

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