Enbrel® (etanercept)
Effective 01/01/2022

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☒ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
</tr>
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<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

| Speciality 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 severely active 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

<table>
<thead>
<tr>
<th>Enbrel® (etanercept)</th>
<th>Pediatric Dosing</th>
<th>Other Dosing</th>
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<tr>
<td><strong>Juvenile Idiopathic Arthritis</strong>&lt;br&gt;(≥ 2 years old, weight &lt; 63 kg):</td>
<td>0.8 mg/kg SQ weekly</td>
<td><strong>Ankylosing spondylitis, psoriatic arthritis</strong>&lt;br&gt;rheumatoid arthritis (moderate-severe):&lt;br&gt;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)</td>
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<tr>
<td><strong>Juvenile Idiopathic Arthritis</strong>&lt;br&gt;(≥ 2 years old, weight ≥ 63 kg):</td>
<td>50 mg SQ weekly; maximum, 50 mg/week</td>
<td><strong>Plaque psoriasis (mod-severe) chronic:</strong>&lt;br&gt;<strong>Initial:</strong>&lt;br&gt;50 mg SQ twice weekly 72-96 hours apart for 3 months&lt;br&gt;<strong>Maintenance:</strong>&lt;br&gt;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)</td>
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### Appendix B. Conventional Therapies for Plaque Psoriasis

<table>
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<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
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<tbody>
<tr>
<td>Topical Agents</td>
<td>emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors</td>
</tr>
<tr>
<td>Systemic Agents</td>
<td>Traditional DMARDs: methotrexate, apremilast, acitretin,</td>
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<tr>
<td>Phototherapy</td>
<td>ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)</td>
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### Appendix C: Traditional DMARDS

<table>
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<tr>
<th>Traditional DMARDS*</th>
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<tbody>
<tr>
<td>azathioprine</td>
<td>methotrexate*</td>
</tr>
<tr>
<td>cyclosporine</td>
<td>sulfasalazine*</td>
</tr>
<tr>
<td>hydroxychloroquine*</td>
<td>thalidomide</td>
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<tr>
<td>Leflunomide</td>
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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**

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company.
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

**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
- 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

**Disclaimer**
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.