**ENBREL (etanercept)**
**Effective 02/20/19**

<table>
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<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
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<tr>
<td>☐ MassHealth</td>
<td>☒ Prior Authorization</td>
<td>☒ Commercial/Exchange</td>
<td>☐ Quantity Limit</td>
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<td>☒ Commercial/Exchange</td>
<td>☐ Step Therapy</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. |

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
<th>Medical Specialty Medications (NLX)</th>
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</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Phone: 877-433-7643</td>
<td>Phone: 844-345-2803</td>
</tr>
<tr>
<td></td>
<td>Fax: 866-249-6155</td>
<td>Fax: 866-255-7569</td>
<td>Fax: 844-851-0882</td>
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<tr>
<td>MassHealth</td>
<td></td>
<td>Phone: 800-294-5979</td>
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<td>Commercial</td>
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<td>Fax: 888-836-0730</td>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<tr>
<td>Medical Specialty Medications</td>
<td>Phone: 844-345-2803</td>
<td>Phone: 866-255-7569</td>
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<td>All Plans</td>
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| 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.

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**Reactive arthritis**

Authorization may be granted for treatment of reactive arthritis.

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**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.

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**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.

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**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

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**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

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

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

Disclaimer
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