Enbrel (etanercept)

**Override(s)**

<table>
<thead>
<tr>
<th>Prior Authorization</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity Limit</td>
<td>1 year unless otherwise specified*</td>
</tr>
</tbody>
</table>

**Medications**

<table>
<thead>
<tr>
<th>Medications</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enbrel (etanercept) 25 mg/mL vial*</td>
<td>8 vials</td>
</tr>
<tr>
<td>Enbrel (etanercept) 25 mg/0.5 mL (0.51 mL) prefilled syringe*</td>
<td>8 syringes</td>
</tr>
<tr>
<td>Enbrel (etanercept) 50 mg/mL (0.98 mL) prefilled syringe*, SureClick® autoinjector*</td>
<td>4 syringes/autoinjectors</td>
</tr>
<tr>
<td>Enbrel (etanercept) 50 mg/mL Mini prefilled cartridge with AutoTouch*</td>
<td>4 cartridges</td>
</tr>
</tbody>
</table>

*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional 25 mg vials (25 mg/mL) or syringes [(25 mg/0.5 mL (0.51 mL)] OR 1 (one) additional 50 mg syringe [50 mg/mL (0.98 mL)], pen (50 mg/0.5 mL), autoinjector [50 mg/mL (0.98 mL)], or cartridge (50 mg/mL) per week in the first 3 months (84 days) of treatment.

**APPROVAL CRITERIA**

Requests for Enbrel (etanercept) may be approved for the following:

I. Individual has been on Enbrel (etanercept) in the past 180 days (medications samples/coupons/discount cards are excluded from consideration as a trial); OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA;
   AND
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015); OR

III. Ankylosing spondylitis (AS) when each of the following criteria are met:

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A. Individual is 18 years of age or older with moderate to severe AS;

AND

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)] (ACR 2015);

OR

IV. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA;

AND

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate)] (ACR 2011);

OR

V. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA;

AND

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] (AAD 2011);

OR

VI. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 4 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2011):
      1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); OR
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) (BSA) involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia);

AND

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).

Requests for Enbrel (etanercept) may not be approved for the following:

I. In combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such as abatacept, anakinra, vedolizumab), or cyclophosphamides; OR

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II. Tuberculosis, other active serious infections, or a history of recurrent infections; OR
III. Individual has not had a tuberculin skin test (TST), or a Centers for Disease Control (CDC) and Prevention-recommended equivalent, to evaluate for latent tuberculosis prior to initiating etanercept.

Note:
TNFα have black box warnings for serious infections and malignancy. Individuals treated with TNFα are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFα should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFα use and during therapy. Treatment for latent TB should be initiated prior to TNFα use. Risks and benefits of TNFα should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFα. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFα. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFα at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFα or a TNFα in combination with these other immunosuppressants.

### State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
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<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
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</tbody>
</table>

### Key References:

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.: 2018; Updated periodically.

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