Enbrel (etanercept)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year unless otherwise specified*

Medications	Quantity Limit
Enbrel (etanercept) 25 mg/mL vial*	8 vials per 28 days
Enbrel (etanercept) 25 mg/0.5 mL (0.51 mL) prefilled syringe*	8 syringes per 28 days
Enbrel (etanercept) 50 mg/mL (0.98 mL) prefilled syringe*, SureClick® autoinjector*	4 syringes/autoinjectors per 28 days
Enbrel (etanercept) 50 mg/mL Mini prefilled cartridge with AutoTouch*	4 cartridges per 28 days

*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

Initial requests for Enbrel (etanercept) may be approved for the following:

I. 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 methotrexate titrated to maximally tolerated dose (ACR 2021);
   OR
   C. If methotrexate is not tolerated, the individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

II. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS;
   AND
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

III. 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 or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate;

OR

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PsA;
   AND
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

V. 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 2019):
      1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA);
      OR
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) (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 or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); OR
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporin, and methotrexate;

OR

VI. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
   A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs; **OR**
   B. Stevens-johnson syndrome or toxic epidermal necrolysis;

OR

VII. Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A)
   A. Individual has a diagnosis of steroid-refractory acute or chronic GVHD; **AND**
   B. Individual is initiating etanercept in combination with systemic corticosteroids

Continuation requests for Enbrel (etanercept) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of etanercept. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, cyclophosphamide, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
III. If initiating therapy, 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(unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi 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. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi 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 TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.