

Enbrel®

To Initiate a Coverage Review, call 1 800 753-2851

Covered Medication
etanercept (<i>Enbrel</i> ® Injection)

What it does and How it's Used
<ul style="list-style-type: none"> • <i>Enbrel</i>® binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors. • TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. • Elevated levels of TNF are found in the synovial fluid of rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients. Additionally, elevated levels of TNF are found in the skin lesions of PsA and plaque psoriasis patients. • TNF plays an important role in the inflammatory process of RA, PsA, plaque psoriasis and the resulting joint and skin pathology. Therefore, the blockade of TNF results in decreased overall joint damage as well as a decrease in skin lesions in RA, plaque psoriasis, and PsA. • Plaque psoriasis is a chronic skin disorder characterized by red, scaly, raised lesions that tend to form on the scalp, limbs, back, and genitalia. Chief complaints of patients with moderate to severe psoriasis include scaling, itching, redness, and tightness of the skin, and burning sensations. Exposed skin, especially cracked or bleeding areas, can act as a potential site of infection. • Initial treatment for stable plaque psoriasis is topical, including corticosteroids, emollients, anthralin, tar, retinoids, calcipotriene (Vitamin D analogue), and salicylic acid. Though corticosteroids are the mainstay of topical therapy, continuous use of these agents can cause tachyphylaxis (wearing off effect) and several side effects. Other treatments for plaque psoriasis include phototherapy, immunosuppressants, and systemic retinoids. <i>Enbrel</i>® may be used either after these conventional treatments have failed in continuing to provide benefit or when a patient is not able to receive conventional therapy (drug and phototherapy). The recommended starting dose of <i>Enbrel</i>® for adult patients is a 50-mg dose given twice weekly (administered 3 to 4 days apart) for 3 months followed by a reduction to a maintenance dose of 50-mg per week. • Psoriatic arthritis affects from 5% to 7% of patients with psoriasis. Like RA, this disorder results in joint damage, disability, and increased mortality. • <i>Enbrel</i>® is a disease-modifying antirheumatic drug (DMARD) that slows the disease progression in RA. Its ability to slow disease progression has warranted its use as a first line agent in the treatment of RA. • A treatment program that includes methotrexate is appropriate for most patients as initial therapy of RA or PsA unless a patient has a contraindication or is unable to receive methotrexate (e.g., in the presence of liver or lung disease). • <i>Enbrel</i>® may be used in combination or in place of methotrexate in patients who do not respond adequately to methotrexate alone. • <i>Enbrel</i>® is also effective in treating ankylosing spondylitis (AS): a chronic, slowly progressive disease characterized by mild or moderate inflammation of the sacroiliac, intervertebral, and costovertebral joints within the spine alternating with periods of almost no symptoms. Ankylos in Greek means bent or crooked and spondylos means vertebrae. AS primarily affects the spine or back causing pain and stiffness and in severe cases can result in fusing of the spine leading to a forward-stooped position. AS can damage other joints in the hips and shoulders along with other parts in the body such as the heart, lungs, and eyes. • Though some NSAIDs have the labeled indication for AS, they only provide modest anti-inflammatory analgesic effects for symptoms. <i>Enbrel</i>® has demonstrated the ability to improve several disease parameters e.g., pain, inflammation, disease activity, function, and patient global assessment. This criteria is known as ASAS Ankylosing Spondylitis Assessment criteria and <i>Enbrel</i>® can provide from 20, 50 or 70% improvement in patients. The FDA agreed upon this criteria for assessing efficacy of drugs for AS. NSAIDs were not previously reviewed using the ASAS criteria. Currently, <i>Enbrel</i>® is being examined for its disease controlling effects in AS to prevent permanent deformities (arrest the demineralization of bone and slowing the ossification of ligaments and tendons). DMARDs such as methotrexate are considered 2nd line therapy and have shown limited benefit in the treatment of AS.

Rationale for Coverage Authorization
To reduce exposure to cost associated with <i>Enbrel</i> ® for the treatment of conditions for which its effectiveness is not known (such as for the treatment of congestive heart failure). <i>Enbrel</i> ® has been shown to be effective for the treatment of rheumatoid or psoriatic arthritis, moderate to severe plaque psoriasis, and ankylosing spondylitis.

Benefit Design
Coverage for <i>Enbrel</i> ® is determined through prior authorization for every claim

Coverage Authorization Criteria
Coverage is provided for the treatment of <u>rheumatoid or psoriatic arthritis</u> in the following situations (must meet 1,2 or 3): 1) <i>Enbrel</i> ® is covered when used as first line treatment in combination with methotrexate OR

2) For situations where Enbrel® will first be used alone, the prescriber must indicate that the patient has had an inadequate response to treatment with methotrexate or that the patient is unable to receive methotrexate.

OR

3) Patient requires *Enbrel*® treatment for rapidly advancing, progressive rheumatoid or psoriatic arthritis (previous use of methotrexate is not required)

Coverage is provided for the treatment of ankylosing spondylitis

- in situations where the patient has experienced inadequate symptom relief from treatment with at least two NSAIDs or COX2 inhibitors unless the patient is allergic to NSAIDs or COX2 inhibitors.

Coverage is provided for the treatment of moderate to severe plaque psoriasis in accord with ALL of the following criteria:

- Patient must be ≥ 18 years of age
- Coverage is provided in situations where the patient has already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless phototherapy is not available or contraindicated for the patient
- Coverage is provided in situations where the patient has already been treated with or is not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporine, and acitretin (*Soriatane*®)
- Coverage is not provided for the use of more than one biologic drug simultaneously.

Coverage is not provided for use of *Enbrel*® in combination with another biologic agent; e.g., *Humira*®, *Kineret*®, *Remicade*®, *Orencia*®, *Raptiva*® or *Amevive*®.

Coverage is not provided unless the patient has been evaluated for the presence of latent TB infection.

Coverage duration:

Coverage is provided for 2 years for the treatment of moderate to severe plaque psoriasis or for 5 years for rheumatoid or psoriatic arthritis or ankylosing spondylitis. Renewal coverage is provided where treatment has provided significant improvement in the patient's covered indication.

References

Kremer JM. Rational Use of New and Existing Disease-Modifying Agents in Rheumatoid Arthritis. *Annals of Internal Medicine*. 2001; 134(8): 695-706.

Mease PJ, Goffe BS, Metz J et al. Etanercept in the Treatment of Psoriatic arthritis and psoriasis: a randomized trial. *Lancet*. 2000; 356: 385-90.

Product Information: etanercept injection (*Enbrel*® – Amgen -Immunex) 2006.