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Prior Authorization DRUG Guidelines

ENBREL ®(Etanercept)

Effective Date: 7/28/05

Date Developed: 7/28/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18

(Archived 1/22/19)

Enbrel is an Antirheumatic, Disease Modifying Tumor Necrosis Factor (TNF) Blocking Agent. It is a recombinant DNA-derived protein composed of tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. Etanercept binds tumor necrosis factor (TNF) and blocks its interaction with cell surface receptors. TNF plays an important role in the inflammatory processes of rheumatoid arthritis (RA) and the resulting joint pathology.

Pre-Authorization Criteria:

Ankylosing spondylitis: For reducing signs and symptoms in patients with active ankylosing spondylitis.

Plaque psoriasis: For treatment of adults ≥18 years of age with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Polyarticular juvenile idiopathic arthritis: For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ≥2 years of age.

Psoriatic arthritis: For reducing signs and symptoms, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis. Can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

Rheumatoid arthritis: For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). can Can be initiated in combination with methotrexate.

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VCHCP requires that Enbrel be prescribed by a dermatologist or rheumatologist and PCP after consultation with dermatologist or rheumatologist.

DOSING: ADULTS
Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis:
SubQ: Once-weekly dosing: 50 mg once weekly
Twice-weekly dosing: 25 mg given twice weekly (individual doses should be separated by 72-96 hours)

DOSING: PEDIATRIC
Juvenile rheumatoid arthritis: Children 4-17 years: SubQ:

Once-weekly dosing: 0.8 mg/kg (maximum: 50 mg/dose) once weekly

Twice-weekly dosing: 0.4 mg/kg (maximum: 25 mg/dose) twice weekly (individual doses should be separated by 72-96 hours)

DOSING: ELDERLY - SubQ: Although greater sensitivity of some elderly patients cannot be ruled out, no overall differences in safety or effectiveness were observed.

ADMINISTRATION - Administer subcutaneously. Rotate injection sites. New injections should be given at least one inch from an old site and never into areas where the skin is tender, bruised, red, or hard.

Powder for reconstitution: Follow package instructions carefully for reconstitution. Note: The needle cover of the diluent syringe (multidose vial) may contain dry natural rubber (latex) which should not be handled by persons sensitive to this substance. The maximum amount injected at any single site should not exceed 25 mg.

Prefilled syringe: May be allowed to reach room temperature prior to injection.

CONTRAINDICATIONS - Hypersensitivity to etanercept or any component of the formulation; patients with sepsis (mortality may be increased); active infections (including chronic or local infection)

WARNINGS / PRECAUTIONS - Etanercept may affect defenses against infections and malignancies. Safety and efficacy in patients with immunosuppression or chronic infections have not been evaluated. Rare cases of tuberculosis have been reported.

Discontinue administration if patient develops a serious infection. Do not start drug administration in patients with an active infection. Use caution in patients predisposed to infection, such as poorly-controlled diabetes.

Use caution in patients with pre-existing or recent-onset demyelinating CNS disorders (rare cases described in postmarketing experience). Use caution in patients with CHF. Use caution in patients with a history of significant hematologic abnormalities; has been associated with pancytopenia and aplastic anemia (rare cases in postmarketing experience). Patients must be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinue if significant hematologic abnormalities are confirmed.

Impact on the development and course of malignancies is not fully defined. As compared to the general population, an increased risk of lymphoma has been noted in clinical trials; however, rheumatoid arthritis has been previously associated with an increased rate of lymphoma. Treatment may result in the formation of autoimmune antibodies; cases of autoimmune disease have not been described. Non-neutralizing antibodies to etanercept may also be formed. No correlation of antibody development to clinical response or adverse events has been observed. The long-term immunogenicity, carcinogenic potential, or effect on fertility are unknown. No evidence of mutagenic activity has been observed in vitro or in vivo. The safety of etanercept has not been studied in children <4 years of age.

Allergic reactions may occur (<2%), but anaphylaxis has not been observed. If an anaphylactic reaction or other serious allergic reaction occurs, administration of etanercept should be discontinued immediately and appropriate therapy initiated.

Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently. No data are available concerning secondary transmission of live vaccines in patients receiving etanercept. Patients with a significant exposure to varicella virus should temporarily discontinue etanercept. Treatment with varicella zoster immune globulin should be considered.

DRUG INTERACTIONS
Anakinra: An increased rate of serious infections has been noted with concurrent therapy, without additional improvement in American College of Rheumatology (ACR) response criteria.

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OTHER EXCLUSIONS

Etanercept should not be given in combination with abatacept, adalimumab, alefacept, anakinra, certolizumab pegol, golimumab, infliximab, rituximab, tocilizumab, or ustekinumab. Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[166]

Other indications. Exceptions not recommended. Because of its unique mechanism of action and twice weekly dosing, etanercept is being studied for many other conditions where tumor necrosis factor has a role in the disease process. Many case reports and pilot studies have reported its use for various indications and data are preliminary. Well-designed studies are needed to assess safety and efficacy.
Vaccines: Live vaccines should not be given during therapy. PREGNANCY

RISK FACTOR - B

PREGNANCY IMPLICATIONS - Developmental toxicity studies performed in animals have revealed no evidence of harm to the fetus. There are no studies in pregnant women; this drug should be used during pregnancy only if clearly needed.

LACTATION - Excretion in breast milk unknown/not recommended

BREAST-FEEDING CONSIDERATIONS - It is not known whether etanercept is excreted in human milk or absorbed systemically after ingestion. Because many immunoglobulins are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Enbrel®, a decision should be made whether to discontinue nursing or to discontinue the drug.

PATIENT EDUCATION - If self-injecting, follow instructions for injection and disposal of needles exactly. If redness, swelling, or irritation appears at the injection site, contact prescriber. Do not have any vaccinations while using this medication without consulting prescriber first. You may experience headache or dizziness (use caution when driving or engaging in tasks requiring alertness until response to drug is known). If stomach pain or cramping, unusual bleeding or bruising, persistent fever, paleness, blood in vomitus, stool, or urine occurs, stop taking medication and contact prescriber immediately. Also immediately report skin rash, unusual muscle or bone weakness, or signs of respiratory flu or other infection (eg, chills, fever, sore throat, easy bruising or bleeding, mouth sores, unhealed sores).

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