Enbrel® (etanercept) Sample Letter of Medical Necessity

Physician Letterhead

[Insurance Company]
[Address Line 1]
[Address Line 2]

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____

[Date]

Attn: **[Medical/Pharmacy Director]**, **[Department]**

Dear [**Medical/Pharmacy Director**]:

I am writing on behalf of **[Patient's Name]** to formally document the medical necessity for treatment with ENBREL for a diagnosis of **[patient's diagnosis]**. **[If prior authorization has been submitted previously, indicate date of submission and the outcome.]** This letter provides additional information and clinical rationale in support of the medical necessity for **[continuing/initiating/reinitiating]** treatment with ENBREL.

Patient's Medical History and Treatment Rationale: [You may want to consider including the following information, depending on your patient's history of treatment with ENBREL.]

[FOR ENBREL CONTINUATION - patients who are currently treated with ENBREL]
- Patient's history, diagnosis, and previous therapies
- Dates of ENBREL initiation and last refill, as well as the rationale for delays in refills (if any)
- Summary of clinical response to treatment and impact to patient's daily life

[FOR ENBREL INITIATION - patients who have not been treated with ENBREL previously]
- Patient's history, diagnosis, and current condition (eg, signs, symptoms, functioning)
- Previous therapies used for the treatment of the diagnosed condition and the rationale for initiating ENBREL versus other biologic agents
- Summary of your professional opinion and potential prognosis for treatment with ENBREL

[FOR ENBREL REINITIATION - patients who have interrupted treatment with ENBREL]
- Patient's history, diagnosis, and previous therapies
- Dates of ENBREL initiation and discontinuation
- Evidence of response to treatment and reasons for interrupting therapy
- Summary of the patient's condition and the clinical rationale for reinitiating ENBREL

In summary, treatment with ENBREL is clearly medically necessary for **[Patient's Name]**; it is consistent with the current standard of care and is in accordance with the FDA-approved indication.

Please call my office at **[insert telephone number]** if additional information is required for the approval of this request. Thank you for your consideration and prompt review of this request.

Sincerely,

[Physician's name]

[**List enclosures as appropriate: Examples of enclosures include excerpt(s) from patient's medical record, relevant treatment guidelines, and product Prescribing Information.]**

Please see Important Safety Information on next page.

Content on this page does not need to be sent to the insurance company.

Prescription ENBREL is administered by injection

ENBREL is indicated 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. ENBREL can be initiated in combination with methotrexate (MTX) or used alone.

ENBREL is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.

ENBREL is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). ENBREL can be used with or without MTX.

ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

ENBREL is indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with ENBREL are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids or were predisposed to infection because of their underlying disease. ENBREL should not be initiated in the presence of sepsis, active infections, or allergy to ENBREL or its components. ENBREL should be discontinued if a patient develops a serious infection or sepsis. Reported infections include: 1) Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before ENBREL use and periodically during therapy. Treatment for latent infection should be initiated prior to ENBREL use, 2) Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric antifungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness, and 3) Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with ENBREL should be carefully considered prior to initiating therapy in patients 1) with chronic or recurrent infection, 2) who have been exposed to TB, 3) who have resided or traveled in areas of endemic TB or endemic mycoses, or 4) with underlying conditions that may predispose them to infections such as advanced or poorly controlled diabetes. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with ENBREL, including the possible development of TB in patients who tested negative for latent TB prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including ENBREL.

In adult clinical trials of all TNF blockers, more cases of lymphoma were seen compared to control patients. The risk of lymphoma may be up to several-fold higher in RA patients. The role of TNF blocker therapy in the development of malignancies is unknown.

Cases of acute and chronic leukemia have been reported in association with postmarketing TNF blocker use in RA and other indications. The risk of leukemia may be higher in patients with RA (approximately 2-fold) than the general population.

Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF blockers, including ENBREL. Periodic skin examinations should be considered for all patients at increased risk for skin cancer.

Pediatric Patients

In patients who initiated therapy at ≤ 18 years of age, approximately half of the reported malignancies were lymphomas (Hodgkin's and non-Hodgkin's lymphoma). Other cases included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

NEUROLOGIC REACTIONS

Treatment with TNF-blocking agents, including ENBREL, has been associated with rare (< 0.1%) cases of new onset or exacerbation of central nervous system demyelinating disorders, some presenting with mental status changes and some associated with permanent disability, and with peripheral nervous system demyelinating disorders. Cases of transverse myelitis, optic neuritis, multiple sclerosis, Guillain-Barré syndromes, other peripheral demyelinating neuropathies, and new onset or exacerbation of seizure disorders have been reported in postmarketing experience with ENBREL therapy. Prescribers should exercise caution in considering the use of ENBREL in patients with preexisting or recent-onset central or peripheral nervous system demyelinating disorders.

CONGESTIVE HEART FAILURE

Cases of worsening congestive heart failure (CHF) and, rarely, new-onset cases have been reported in patients taking ENBREL. Caution should be used when using ENBREL in patients with CHF. These patients should be carefully monitored.

HEMATOLOGIC REACTIONS

Rare cases of pancytopenia, including aplastic anemia, some fatal, have been reported. The causal relationship to ENBREL therapy remains unclear. Exercise caution when considering ENBREL in patients who have a previous history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs or symptoms of blood dyscrasias or infection. Consider discontinuing ENBREL if significant hematologic abnormalities are confirmed.

HEPATITIS B REACTIVATION

Reactivation of hepatitis B has been reported in patients who were previously infected with hepatitis B virus (HBV) and received concomitant TNF-blocking agents, including ENBREL. Most reports occurred in patients also taking immunosuppressive agents, which may contribute to hepatitis B reactivation. Exercise caution when considering ENBREL in these patients.

ALLERGIC REACTIONS

Allergic reactions associated with administration of ENBREL during clinical trials have been reported in < 2% of patients. If an anaphylactic reaction or other serious allergic reaction occurs, administration of ENBREL should be discontinued immediately and appropriate therapy initiated.

IMMUNIZATIONS

Live vaccines should not be administered to patients on ENBREL. Pediatric patients, if possible, should be brought up to date with all immunizations prior to initiating ENBREL. In patients with exposure to varicella virus, temporarily discontinue ENBREL and consider prophylactic treatment with Varicella Zoster Immune Globulin.

AUTOIMMUNITY

Autoantibodies may develop with ENBREL, and rarely lupus-like syndrome or autoimmune hepatitis may occur. These may resolve upon withdrawal of ENBREL. Stop ENBREL if lupus-like syndrome or autoimmune hepatitis develops.

WEGENER'S GRANULOMATOSIS PATIENTS

The use of ENBREL in patients with Wegener's granulomatosis receiving immunosuppressive agents (eg, cyclophosphamide) is not recommended.

MODERATE TO SEVERE ALCOHOLIC HEPATITIS

Based on a study of patients treated for alcoholic hepatitis, exercise caution when using ENBREL in patients with moderate to severe alcoholic hepatitis.

ADVERSE REACTIONS

The most commonly reported adverse reactions in RA clinical trials were injection site reaction and infection. In clinical trials of all other adult indications, adverse reactions were similar to those reported in RA clinical trials.

In general, the adverse reactions in pediatric patients were similar in frequency and type as those seen in adult patients. The types of infections reported in pediatric patients were generally mild and consistent with those commonly seen in the general pediatric population.

DRUG INTERACTIONS

The use of ENBREL in patients receiving concurrent cyclophosphamide therapy is not recommended. The risk of serious infection may increase with concomitant use of abatacept therapy. Concurrent therapy with ENBREL and anakinra is not recommended. Hypoglycemia has been reported following initiation of ENBREL therapy in patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients.

Please see Prescribing Information, Medication Guide and Instructions for Use.