ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Enbrel® (etanercept) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Enbrel® (etanercept)

Diagnosis (documentation supportive of diagnosis is required)

☐ Moderately to severely active Rheumatoid Arthritis
☐ Chronic plaque psoriasis (moderate to severe) in patients who are candidates for systemic therapy or phototherapy
☐ Moderately to severely active polyarticular juvenile idiopathic arthritis
☐ Psoriatic Arthritis
☐ Active ankylosing spondylitis
☐ Other (please state): _____

Physician Specialty

☐ Rheumatology
☐ Dermatology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

Enbrel® (etanercept)

CLASSIFICATION

- Immune Suppressant, Tumor Necrosis Factor Inhibitor

DESCRIPTION

- Etanercept is a dimeric soluble form of the p75 tumor necrosis factor (TNF) receptor that specifically binds TNF alpha and TNF beta. The binding of etanercept to TNF, a naturally occurring cytokine involved in normal inflammatory and immune responses, renders it biologically inactive. Etanercept also modulates biologic responses that are induced or regulated by TNF, including expression of adhesion molecules responsible for leukocyte migration, serum levels of cytokines, and serum levels of matrix metalloproteinase.
- Etanercept is useful in the treatment of diseases where TNF activity is correlated with disease severity, such as in rheumatoid arthritis. Etanercept is being investigated in refractory bone pain due to metastases, as an orphan treatment for Wegener's granulomatosis, and in systemic juvenile rheumatoid arthritis.
- Etanercept is approved for the treatment of ankylosing spondylitis in adults. Treatment with etanercept resulted in decreased symptoms such as morning stiffness and spinal pain, as well as dose sparing effects for steroids, analgesics, methotrexate, and sulfasalazine.
- Etanercept is indicated for reducing the signs and symptoms of moderately to severely active polyarticular-course juvenile idiopathic arthritis (JIA) in patients 2 years and older, who have been inadequately controlled with one or more disease-modifying anti-rheumatic drugs (DMARDs). Compared to treatment with placebo, etanercept-treated patients may expect less pain and swelling, decreased disease activity, less frequent flare, and a prolonged duration between flares.
- Etanercept is indicated for reducing the signs and symptoms of moderately to severely active arthritis in patient with psoriatic arthritis, with generally good tolerance. Methotrexate and/or steroid dose-saving effects are possible. Additionally, etanercept is indicated for inhibition of the progression of structural damage of active psoriatic arthritis.
- Etanercept is indicated for reducing signs and symptoms, inhibiting progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Treatment with etanercept resulted in a significant reduction in the number of joint erosions and swollen and tender joints.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 5
Commercial Formulary: Tier 6
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Enbrel® (etanercept) meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including the following:

- Ankylosing spondylitis
- Juvenile idiopathic arthritis (Moderate to Severe)
- Plaque psoriasis, chronic (Moderate to Severe), in patients who are candidates for systemic therapy or phototherapy
- Psoriasis with arthropathy
- Rheumatoid arthritis (Moderate to Severe)

Enbrel® (etanercept) is considered **experimental** for the following:

- Autoimmune disorder of inner ear, Behcet's syndrome, Bone metastasis, Crohn's disease, Graft versus host disease, Heart failure, Hemophagocytic lymphohistiocytosis; Reactive, Hidradenitis suppurativa; Severe (refractory), Langerhans cell histiocytosis, Myelosclerosis with myeloid metaplasia, Myositis, Nephrotic syndrome, Pemphigoid, Sarcoidosis, Septic shock; adjunct, Sjogren's syndrome, TNF receptor-associated periodic fever syndrome (TRAPS), Wegener's granulomatosis
- Doses higher than 50mg per week for the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis

Required Provider Specialty:

- Approval is limited to Rheumatology or Dermatology

DOSAGE/ADMINISTRATION:

Adult Dosing:

- Ankylosing spondylitis: 50 mg SUBQ weekly given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly, 72 to 96 hours apart
- Plaque psoriasis, chronic (Moderate to Severe), in patients who are candidates for systemic therapy or phototherapy:
    - Initial: 50 mg SUBQ twice weekly, given 3 to 4 days apart, for 3 months
    - Maintenance: 50 mg SUBQ weekly, given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly, 72 to 96 hours apart
- Psoriasis with arthropathy: 50 mg SUBQ weekly given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly, 72 to 96 hours apart
- Rheumatoid arthritis (Moderate to Severe): 50 mg SUBQ weekly given as one 50 mg injection or two 25 mg injections in one day, or one 25 mg injection given twice weekly, 72 to 96 hours apart

Pediatric Dosing:

- Juvenile idiopathic arthritis (Moderate to Severe): (2 years and older) 0.8 mg/kg/week (maximum of 50 mg per week) SUBQ

PRECAUTIONS:

- BLACK BOX WARNING: Patients treated with etanercept are at increased risk for infections, some progressing to serious infections leading to hospitalization or death. These infections have included bacterial sepsis, tuberculosis, invasive fungal and other opportunistic infections. Evaluate for latent tuberculosis and treat if necessary prior to initiation of therapy. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including etanercept.
- Alcoholic hepatitis, moderate to severe; increased mortality after 6 months of treatment
- Allergic reactions have been reported and require discontinuation of therapy.
- Autoantibody formation has occurred and may develop into lupus-like syndrome or autoimmune hepatitis; discontinue therapy if symptoms occur.
- CNS demyelinating disorders (e.g. transverse myelitis, optic neuritis, multiple sclerosis, seizure disorders); new onset or worsening of preexisting condition may occur.
- Concomitant use of anakinra, cyclophosphamide, or live vaccines is not recommended.
- Congestive heart failure, new-onset or worsening of preexisting disease has been reported even in absence of risk factors; monitoring is recommended and discontinuation of therapy may be necessary.
- Hematological abnormalities, including fatalities, have occurred. Risk is increased in patients with active or history of blood dyscrasias; discontinuation of therapy may be required.
- Hepatitis B, chronic carriers; reactivation has occurred including several months after therapy termination; monitoring recommended; discontinuation and supportive treatment may be necessary.

- Infection, history of or recurring; potential for exacerbation, particularly in patients with predisposition for (e.g. advanced or poorly-controlled diabetes) or underlying conditions; discontinue if serious infection develops.
- Juvenile rheumatoid arthritis patients should be brought up-to-date on all immunization requirements, when possible, prior to beginning treatment with etanercept.
- Latex sensitivity: the needle cover of prefilled syringe and on SureClick autoinjector contains latex.
- Malignancies, history or new-onset including lymphomas and acute and chronic leukemia.
- Varicella virus exposure, significant; temporarily discontinue treatment.
- Wegener's granulomatosis: use with concomitant immunosuppressive agents is not recommended.

Billing/Coding information

CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS Coding:

J1438	injection, etanercept, 25 mg

COST

- AWP (April 2010): Enbrel 50mg/ml syringe (4): $1,994.84
- AWP (November 2011): Enbrel 50mg/ml syringe (4): $2,216.00

COMMITTEE APPROVAL:

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 04/02/2010
- Product Information: ENBREL(R) subcutaneous injection, etanercept subcutaneous injection. Immunex Corporation, Thousand Oaks, CA, 2009.