Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Enbrel® (Etanercept)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***November 2001 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *June 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Enbrel® (etanercept).

Enbrel® (etanercept) is indicated for the following:

- 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® (etanercept) can be initiated in combination with methotrexate or used alone.
- Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel® (etanercept) can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
- Reducing signs and symptoms in patients with active ankylosing spondylitis.
- Treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or photo therapy.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Enbrel® (etanercept), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Enbrel

1. Rheumatoid Arthritis:

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

2. Juvenile Idiopathic Arthritis without systemic symptoms, includes polyarticular juvenile arthritis (PJIA):

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis

- Must have an adequate trial (of at least 3 months) of methotrexate or leflunomide with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

3. Psoriatic Arthritis:

- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis

4. Ankylosing Spondylitis and Axial Spondyloarthritis:

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis or axial spondyloarthritis
- Must have an adequate trial with TWO non-steroidal anti-inflammatory drugs (NSAIDs), with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

5. Plaque Psoriasis:

- Must be prescribed by or in consultation with a dermatologist
- Must be age 4 years or older
- Must have a diagnosis of moderate-to-severe chronic plaque psoriasis
- Must have a minimum body surface area involvement of > 5% (members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of either phototherapy (e.g., UVB or PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin with an inadequate response, intolerance/contraindication, or clinical reason not to use these therapies

6. Reactive Arthritis:

- Must be prescribed by or in consultation with a rheumatologist
- Must have a diagnosis of reactive arthritis

Reauthorization Criteria:

Authorization may be extended by 1 year based upon chart documentation showing that the member achieved or maintain positive clinical response after at least 3 months of therapy with Enbrel as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
25mg	8 vials per month
50mg	4 vials/pen injectors/syringes per month • Psoriasis: 8-50mg vials per month covered for the initial 3 months

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 04/17, 6/18*