Updated: 02/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Enbrel (etanercept)

All requests for Enbrel (etanercept) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

- The prescriber must be a rheumatologist, or dermatologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of **Rheumatoid Arthritis** and the following criteria is met:

- Member is 18 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD.
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Polyarticular Juvenile Idiopathic Arthritis** and the following criteria is met:

- Member is 2 years of age or older.
- Member must meet ONE or the following:
  - The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX or leuflonamide.
  - The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra. (Requires prior authorization)
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Active Joint Count, limitation of motion, physician and patient/parent global assessments, functional assessment, CRP, and/or ESR.
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Psoriatic Arthritis** and the following criteria is met:

- Medication is Enbrel™ (etanercept).
- Member is 18 years of age or older.
- Member has active psoriatic arthritis or clinical features that suggest psoriatic arthritis in the absence of psoriasis.
- **Initial Duration of Approval**:
    - 6 months
- **Reauthorization Criteria**
    - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
    - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Ankylosing Spondylitis** and the following criteria is met:

- Member is 18 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to a four-week trial each of at least 2 NSAIDs.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
    - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, and/or occiput-to-wall measurement.
    - **Reauthorization Duration of Approval**: 12 months
    -

Coverage may be provided with a diagnosis of **Plaque Psoriasis** and the following criteria is met:

- Medication is Enbrel™ (etanercept).
- Member is 4 years of age or older.
- Member must have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 10% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
- Members must have therapeutic failure of a three- month trial or a contraindication to BOTH of the following:
    - Psoralens with UVA light (PUVA) or UVB light
    - Systemic treatments including ONE of the following:
        - Immunomodulators (i.e. Methotrexate, Cyclosporine)
        - Retinoids (i.e. Soriatane)

- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
    - Clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline must be submitted.
    - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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Enbrel™ and Etanercept biosimiliars
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Is the medication being prescribed by or in association with a rheumatologist, or dermatologist? ☐ Yes ☐ No

2. Which of the following diagnoses will the medication be used for:
   Please check the one that applies
   a. Rheumatoid Arthritis ☐ Yes ☐ No
   b. Polyarticular Juvenile Idiopathic Arthritis ☐ Yes ☐ No
   c. Psoriatic Arthritis ☐ Yes ☐ No
   d. Ankylosing Spondylitis ☐ Yes ☐ No
   e. Plaque Psoriasis ☐ Yes ☐ No
   f. Other Diagnosis: _____

3. If member is using for a diagnosis of Rheumatoid Arthritis, answer the following questions:
   a. Is member 18 years of age or older? ☐ Yes ☐ No

   b. Does the member have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD. ☐ Yes ☐ No

4. If member is using for a diagnosis of Polyarticular Juvenile Idiopathic Arthritis, answer the following questions:

a. Is member 2 years of age or older? ☐ Yes ☐ No

b. Does the member must meet ONE or the following? ☐ Yes ☐ No
   i. The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX or leflonamide.
   ii. The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra

5. If member is using for a diagnosis of Psoriatic Arthritis, answer the following questions:
   a. Is the medication being prescribed Enbrel®? ☐ Yes ☐ No

   b. Is member 18 years of age or older? ☐ Yes ☐ No

   c. Does the member have psoriatic arthritis or clinical manifestations of psoriatic arthritis in the absence of psoriasis?
   ☐ Yes ☐ No

6. If member is using for diagnosis of Ankylosing Spondylitis, answer the following questions:

   a. Is member is 18 years of age or older? ☐ Yes ☐ No

   b. Does member have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs? ☐ Yes ☐ No

7. If member using for diagnosis of Plaque Psoriasis and the following criteria is met:

   a. Is the medication being prescribed Enbrel® (etanercept). ☐ Yes ☐ No

   b. Is member 4 years of age or older? ☐ Yes ☐ No

   c. Does member have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals? ☐ Yes ☐ No

   d. Does members have therapeutic failure to a three- month trial or a contraindication to at any of the following:

   Please check all that apply
      i. Psoralens with UVA light (PUVA) or UVB light
      ☐ Yes ☐ No

      ii. Systemic treatments including ONE of the following:
         1. Immunomodulators (i.e. Methotrexate, Cyclosporine)
         2. Retinoids (i.e. Soriatane)
      ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

1. Which of the following diagnoses will the medication be used for:
   Please check the one that applies
   a. Rheumatoid Arthritis ☐ Yes ☐ No
      i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
      ☐ Yes ☐ No

   b. Juvenile Idiopathic Arthritis ☐ Yes ☐ No
      i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Active Joint Count, limitation of motion, physician and patient/parent global assessments, functional assessment, and ESR?
      ☐ Yes ☐ No

   c. Psoriatic Arthritis ☐ Yes ☐ No
      i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
      ☐ Yes ☐ No

   d. Ankylosing Spondylitis ☐ Yes ☐ No
      i. Is yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, and/or occiput-to-wall measurement?
      ☐ Yes ☐ No

   e. Plaque Psoriasis ☐ Yes ☐ No
      i. Is there clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted? Clinical documentation must be submitted.
      ☐ Yes ☐ No

   f. Other Diagnosis: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date