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Prior Authorization Criteria

Enbrel™ and etancercept biosimiliars (Erelzi™)

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

Drug Name Prior Authorization Criteria:

For all requests for Enbrel™ and etancercept biosimiliars (Erelzi™) all of the following criteria must be met:

Disclaimer: All requests for Enbrel™ and etancercept biosimiliars (Erelzi™) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

The following agents are on formulary:

- Enbrel™
- All other biosimilars are considered non-formulary and require documentation of failure with Enbrel™ in addition to meeting the criteria outlined below.
- Members who are currently established on an Enbrel biosimilar will not be required to change to a preferred/formulary product.

For all requests for Enbrel™ and etancercept biosimiliars all of the following criteria must be met:

- The prescriber must be a rheumatologist, gastroenterologist, or dermatologist.
- Member should not have live vaccines administered when taking Enbrel or etancercept biosimilars.
- 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 documented, significant improvement with prior courses of treatment
  - **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 of the following:

  - The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX or leflonamide.
  - The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra (may require prior authorization).
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
  - **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 must be 18 years of age or older
- Member has moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis.
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
  - Member without axial disease:
    - Four- week trial each of at least 2 NSAIDs.
    - Eight week trial of methotrexate or other DMARD
  - Member with axial disease
    - Four- week trial each of at least 2 NSAIDs.
  - Member with psoriatic arthritis with enthesitis
    - 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 documented, significant improvement with prior courses of treatment
  - **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 documented, significant improvement with prior courses of treatment.
  - **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 5% 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 at least ONE 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 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.

References:

Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; November 2017.

Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2016;68(1):1-25.

Menter A, Korman NJ, Elmets CA, et al. Guidelines of Care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2011;65(1)137-174.

Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-512.

Ward MM, Deodhar A, Akl EA et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. 2015: 10.1002: 1 - 17

Gateway Health

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Enbrel™ and Etancercept 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:
Health Options 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, gastroenterologist, or dermatologist?
   ☐ Yes ☐ No

2. Will the provider attest that member will not have live vaccines administered when taking Enbrel or etancercept biosimilars? ☐ Yes ☐ No

3. Which of the following diagnoses will the medication be used for:
   Please check the one that applies
   - Rheumatoid Arthritis ☐ Yes ☐ No
   - Polyarticular Juvenile Idiopathic Arthritis ☐ Yes ☐ No
   - Psoriatic Arthritis ☐ Yes ☐ No
   - Ankylosing Spondylitis ☐ Yes ☐ No
   - Plaque Psoriasis ☐ Yes ☐ No
   - Other Diagnosis: _____

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

5. 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
6. 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 moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis?
   ☐ Yes ☐ No

   d. Does member have a history of trial and failure, contraindication, or intolerance to any of the following: Please check all that apply
      i. Member without axial disease:
         1. Four week trial each of at least 2 NSAIDs. ☐ Yes ☐ No
         2. Eight week trial of methotrexate or other DMARD ☐ Yes ☐ No
      ii. Member with axial disease
         1. Four week trial each of at least 2 NSAIDs. ☐ Yes ☐ No
      iii. Member with psoriatic arthritis with enthesitis
         1. Four week trial each of at least 2 NSAIDs ☐ Yes ☐ No

7. 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

8. 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: ☐ Yes ☐ No
         1. Immunomodulators (i.e. Methotrexate, Cyclosporine)
         2. Retinoids (i.e. Soriatane)

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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
   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: _____

2. For the diagnoses of Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, or Ankylosing Spondylitis, does the member have documented, significant improvement with prior courses of treatment?
   a. Please Describe:

3. For the diagnosis of Plaque Psoriasis, is there clinical documentation that support a decrease in percent of body surface area involvement when compared to baseline? Clinical documentation must be submitted.

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date