

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

|   |   |
|---|---|
| DRUG NAME   | Enbrel (etanercept)   |
| BILLING CODE  | Must use valid NDC code   |
| BENEFIT TYPE  | Pharmacy  |
| SITE OF SERVICE ALLOWED                                     | Home  |
| COVERAGE REQUIREMENTS                                       | Prior Authorization Required (Preferred Product)<br>Alternative preferred product includes Humira<br>QUANTITY LIMIT – 8 per 28 days |
| LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY | <a href="#">Click Here</a>  |

Enbrel (etanercept) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:

1. Member must be 18 years of age or older with active AS; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 45; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
  - a) Arthritis;
  - b) Elevated serum C-reactive protein;
  - c) Inflammation at the tendon, ligament or joint capsule insertions;
  - d) Positive HLA-B27 test;
  - e) Limited chest expansion;
  - f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
  - a) Member has Axial (spinal) disease;
  - b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response.
9. **Dosage allowed:** Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## JUVENILE IDIOPATHIC ARTHRITIS (JIA)

For **initial** authorization:

1. Member must be 2 years of age or older with moderate to severe active JIA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member shows at least **one** of the following signs or symptoms:
  - a) Four or fewer joints involved with inadequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (azathioprine, cyclosporine, etc.) AND NSAID treatment for at least 12 weeks;
  - b) Five or more joints involved and inadequate response to methotrexate.
5. **Dosage allowed:** For members <63 kg: inject 0.8 mg/kg (maximum dose 50 mg) subcutaneously once per week; for members ≥63 kg: inject 50 mg subcutaneously once per week.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## PLAQUE PSORIASIS (PP)

For **initial** authorization:

1. Member must be 4 years of age or older; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP involves 10% or more of the body surface area (BSA); AND
5. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
6. Member has tried and failed to respond to treatment with at least **one** of the following:
  - a) At least 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
  - b) At least 12 weeks of phototherapy (i.e. UVB light therapy, Excimer laser treatments) (tanning beds emit mostly UVA light and therefore would not meet this criteria);
  - c) At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
7. Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
8. **Dosage allowed:** Inject 50 mg subcutaneously twice weekly for 3 months then once weekly thereafter.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
  - a) Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence;
  - b) Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;
  - c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID.
5. **Dosage allowed:** Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Member must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least two non-biologic DMARDs OR must have a contraindication to all non-biologic DMARDs. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks (non-biologic DMARDs include: methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide).
5. **Dosage allowed:** Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Enbrel (etanercept) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Alzheimer disease dementia
- Asthma
- Back pain (including discogenic low back pain, radicular pain cause by lumbar spinal stenosis/lumbosacral radiculopathy/sciatica)
- Bronchiolitis obliterans
- Chronic heart failure
- Churg-Strauss syndrome
- Dyshidrotic eczema
- Familial Mediterranean fever
- Graft-versus-host disease
- Hidradenitis suppurativa
- Idiopathic pulmonary fibrosis
- Inclusion-body myositis
- Inflammatory bowel disease (i.e. Crohn's disease)
- Kawasaki disease
- Keloid
- Knee osteoarthritis
- Lumbar disc herniation
- Lupus erythematosus
- Neck pain
- Pyoderma gangrenosum
- Sarcoidosis
- Sjogren's syndrome
- Stroke
- Transplantation-related lung injury after hematopoietic stem cell transplantation
- Traumatic brain injury
- Tumor necrosis factor receptor-associated periodic syndrome (TRAPS), formerly known as Hibernian fever
- Uveitis
- Wegener's granulomatosis

| DATE       | ACTION/DESCRIPTION   |
|------------|--|
| 05/08/2017 | New policy for Enbrel created. Policies SRx-0042 and SRx-00423 achieved. For diagnosis of PP: immunosuppressive drug criterion was separated from phototherapies and topical agents' trials; Psoriasis Area and Severity Index (PASI) score requirement was added; age was adjusted for pediatric indication. For RA: non-biologic DMARDS were listed. List of diagnoses considered not medically necessary was added. |

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