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PHARMACY POLICY STATEMENT
Kentucky 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) QUANTITY LIMIT— 8 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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)) within 12 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 50; 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 30 days of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 30 days of therapy with each NSAID 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.

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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)) within 12 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 30 days;
   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 (PsO)

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)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO 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 30 days of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 30 days 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 30-day trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 30 days.

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8. **Dosage allowed:** For adults: inject 50 mg subcutaneously twice weekly for 3 months then once weekly thereafter. For pediatric members < 63 kg: inject 0.8 mg/kg (maximum dose 50 mg) subcutaneously once per week; for pediatric 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 (e.g., documented member's PASI score improvement, etc.).

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)) within 12 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 30 days of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 30-day trial of sulfasalazine or azathioprine or cyclosporine).
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.

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RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 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 (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days.
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
05/15/2017	New policy for Enbrel created. Policies SRx-0042 and SRx-00423 achieved. For diagnosis of PsO: 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.
02/26/2019	Pediatric dosing added to PsO indication. Clarifications entered for AS and PsA on NSAIDs trial length. References added. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.

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