CareSource Rxinnovations

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PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Enbrel (etanercept)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Enbrel is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 1998 for Rheumatoid Arthiritis. Since that time, Enbrel has been approved for four additional indications: Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Plaque Psoriasis and Ankylosing Spondylitis.

Enbrel (etanercept) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active ankylosing spondylitis (AS); AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response
8. **Dosage allowed/Quantity limit:** 50 mg subcutaneously once weekly (4 syringes/autoinjectors per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:

1. Member must be 2 years of age or older with moderately to severely active pJIA; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has had a negative tuberculosis test within the past 12 months; AND
4. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated.

5. **Dosage allowed/Quantity limit:** Weight < 63 kg (138 lbs): 0.8 mg/kg once weekly; weight 63 kg (138 lbs) or more: 50 mg once weekly.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease.

If all the above requirements are met, 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. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. 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);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
7. **Dosage allowed/Quantity limit:**
   a) Adults: 50 mg twice weekly for 3 months then once weekly thereafter.
   b) Pediatrics: weight < 63 kg (138 lbs): 0.8 mg/kg once weekly; weight 63 kg (138 lbs) or more: 50 mg once weekly

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, 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. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:

i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life).

6. **Dosage allowed/Quantity limit:** 50 mg once weekly (4 syringes/autoinjectors per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months; *Note*: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 50 mg once weekly. (4 syringes/autoinjectors per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Enbrel (etanercept) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	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.

11/22/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. JIA: Changed trials to require one non-biologic DMARD. Renamed diagnosis to be polyarticular JIA. PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
1/18/2022	Transferred to new template. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. PsA: Clarified reauthorization criteria. Simplified wording for TB requirement. AS/nr-axSpA: Clarified reauthorization criteria. Simplified wording for TB requirement.

References:

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