

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** ENBREL Policy

**Drug(s):** ENBREL (etanercept)

**Covered Uses:** All FDA-approved indications not otherwise excluded from Part D. All criteria in "other criteria" section must be met for coverage.

**Required Medical Information:** TB test result AND

**For a diagnosis of arthritis:** Chart notes including physical exam findings, number of swollen or tender joints, duration of morning stiffness, other symptoms, requested dose and frequency and expected duration of therapy.

**For a diagnosis of ankylosing spondylitis (AS):** chart notes including chart notes including status of back pain and spinal mobility.

**For a diagnosis of psoriasis:** %BSA involvement current and with extension of therapy, previous and current therapies and responses, chart notes indicating relevant information.

**Age Restrictions:** Polyarticular juvenile idiopathic arthritis covered for patients ages 2 and older. Over 18 years old for all other indications.

**Prescriber Restrictions:** Restricted to rheumatologists, immunologists, dermatologists

**Other Criteria:** Must be screened for immunologic and infectious diseases including hepatitis and TB. Enbrel may be used without prior methotrexate trial if the member has acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist.

For the treatment of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living (ADLs), the following criteria must be met:

- Failed to respond to other DMARDs including a two month trial of methotrexate (MTX) before Enbrel is covered. (ACR response of less than 20 after 7.5-20mg of methotrexate for 2 months).
- In the event the member has contraindications or intolerance to methotrexate, the member must have failed to respond to other DMARDs.

For the treatment of active moderate to severe **ankylosing spondylitis** the following criteria must be met:

- Must have failed to respond to physiotherapy.

For the treatment of moderate to severe **polyarticular-course juvenile chronic rheumatoid arthritis** as indicated by five swollen joints and three or more joints with limitation of motion, pain, tenderness or both, or persistent symptoms in oligoarticular disease, the following criteria must be met:

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- Failed to respond to an adequate trial of at least one DMARD listed in Table 1.

For the treatment of moderate to severe **psoriatic arthritis** as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart, the following criteria must be met:

- Must have had an inadequate response to NSAIDs, and
- Failed to respond to an adequate trial of at least one DMARDs listed in Table 1.

Table 1

DMARDs	Minimum Time Required for Adequate Trial
Hydroxychloroquine	2 months
Sulfasalazine	1 month
Methotrexate	2 months
Injectable gold	3 months
Oral gold	4 months
Azathioprine	2 months
Penicillamine	3 months

For the treatment of **plaque psoriasis** the following criteria must be met:

- Members with severe psoriasis or those with functional disability and/or intractable recalcitrant psoriasis which interferes with ADLs due to the affected areas (e.g. hands and/or feet).
- Severe chronic plaque psoriasis with 10% BSA involvement or involvement of the palms, soles of feet and scalp for at least 1 yr.
- Topical corticosteroids are not effective or contraindicated.
- Treatment with other topical agents such as calcipotriene, tazarotene, salicyclates are not effective or contraindicated.
- Treatment with phototherapy or photochemotherapy was not effective or contraindicated.
- An appropriate treatment trial was not effective or contraindicated with at least two of the following agents: MTX, oral retinoids, cyclosporine.
- And who have functional impairment related to symptomatology of psoriasis.

Initial authorization period will be allowed for up to 3 months.

Continuation of therapy will be allowed for up to 6 months and will require documentation of improved patient status in the monitoring parameters of all of the following:

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- At least a 50% improvement of clinical signs/symptoms of psoriasis (eg. itching, redness, scaling, psoriatic body surface area coverage) at three months and 75% improvement at six months.
- Quality of life assessments - improved per patient and/or physician.

**Exclusion Criteria:**

- History of Lupus or multiple sclerosis.
- Members who have not been evaluated for latent TB infection with a tuberculin skin test and treatment of the infection prior to therapy if indicated.
- Not indicated for members with osteoarthritis.
- Pre-existing or recent-onset of CNS demyelinating disorders.
- Caution should be used in treating members with Enbrel who have a history of significant hematologic abnormalities.
- Concomitant therapy with Rituxan and other DMARDs or biologic therapies other than methotrexate.
- Doses greater than 50mg/wk except for the initial 12 weeks for a diagnosis of psoriasis (one induction per lifetime).
- Members for whom these medications are contraindicated as listed in the Drug Prescribing Information.
- Members who have not had plaque psoriasis for more than one year (when prescribed for psoriasis).
- Members who have a clinically important infection or a history of chronic or recurrent infections.
- Members who are receiving concurrent treatment with immunosuppressive therapies or have a history of malignancy.
- Members who have another form of psoriasis other than chronic plaque psoriasis (e.g. guttate, erythrodermic or pustular psoriasis as the sole or predominant form) Initial treatment with Enbrel at doses up to 50mg twice a week is limited to 12 weeks duration.
- Dose escalation beyond the initial 12-week period, including during psoriasis flares, is not a covered benefit.
- Enbrel is not covered for members who are being treated for psoriasis and have arthropathies such as PSA, unless consult with rheumatologist is documented.
- For AS: No trial and failure of physiotherapy.

**Coverage Duration:** Initial approval for 3 months with extensions of up to 6 months intervals