

Enbrel® (etanercept)

When requesting Enbrel® (etanercept), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

- Ankylosing spondylitis (AS)
- Juvenile idiopathic arthritis (JIA)
- Plaque psoriasis (PsO)
- Psoriatic arthritis (PsA)
- Rheumatoid arthritis (RA)

Approved Off-Label Compendial Uses

- Behcet's Disease
- Graft-Versus-Host Disease (GVHD)
- Pyoderma Gangrenosum
- Still's Disease

Coverage Guidelines

Ankylosing Spondylitis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment

Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- o Experienced an improvement in at least one symptom from baseline, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Juvenile Idiopathic Arthritis

Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthritis/active sacroiliac arthritis.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Meets **one** of the following conditions:
 - o Has tried one other systemic medication for this condition; OR
Note: Examples of other systemic therapy for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count.
 - o Will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; OR
 - o Has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.
 - o Has aggressive disease, as determined by the prescriber;
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Meets at least **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
 - o Experienced an improvement in at least one symptom from baseline, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

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Plaque Psoriasis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 4 years of age;
- Meets **one** of the following conditions:
 - o Has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet a light (PUVA) also counts. An exception can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
 - o Has a contraindication to methotrexate;
- Medication is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis;
- Experienced an improvement in at least one symptom from baseline, such as decreased pain, itching, and/or burning.

Psoriatic Arthritis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Medication is prescribed by or in consultation with a rheumatologist or a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Meets at least **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds

Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- o Experienced an improvement in at least one symptom from baseline, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Rheumatoid Arthritis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has tried **one** conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months;

Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception can be made if the patient has already had a 3-month trial with at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to “step back” and try a conventional synthetic DMARD.

- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;

Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.

- Meets **one** of the following:

- o Experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

- o Experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Behcet's Disease.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Has tried at least one conventional therapy;

Note: Examples include systemic corticosteroids (e.g., methylprednisolone), immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran [chlorambucil], cyclophosphamide, interferon alfa). A patient who has

already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count.

- Medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Experienced a beneficial clinical response from baseline when assessed by at least one objective measure;
Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); ulcer depth, number, and/or lesion size.
- Experienced an improvement in at least one symptom from baseline, such as decreased pain, or improved visual acuity (if ophthalmic manifestations).

Graft-Versus-Host Disease

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 6 years of age;
- Has tried at least one conventional systemic treatment for graft-versus-host disease;
Note: Examples of conventional systemic treatments include systemic corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, and mycophenolate mofetil.
- Medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 1 month;
Note: A patient who has received < 1 month of therapy or who is restarting therapy is reviewed under initial therapy.
- Meets at least **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures are normalization of liver function tests, red blood cell count, or platelet count; or resolution of fever or rash.
 - o Experienced an improvement in at least one symptom from baseline, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).

Pyoderma Gangrenosum.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Meets **one** of the following:
 - o Has tried one systemic corticosteroid (e.g., prednisone); OR
 - o Has tried one other immunosuppressant (e.g., mycophenolate mofetil, cyclosporine) for at least 2 months or was intolerant to one of these medications;
- Medication is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 4 months;
Note: A patient who has received < 4 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Experienced a beneficial clinical response from baseline, defined as improvement in at least one of the following: size, depth, and/or number of lesions;
- Experienced an improvement in at least one symptom from baseline, such as decreased pain and/or tenderness of affected lesion(s).

Spondyloarthritis, Other Subtypes:

Note: This includes undifferentiated arthritis, non-radiographic axial spondyloarthritis, reactive arthritis (Reiter's Disease)

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Meets **one** of the following conditions:
 - o Has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet and has tried at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine); OR
 - o Has axial spondyloarthritis and has objective signs of inflammation, defined as one of the following:
 - C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
 - Sacroiliitis reported on magnetic resonance imaging (MRI);
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Meets **one** of the following:

- o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
- o Experienced an improvement in at least one symptom from baseline, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Still's Disease.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has tried one corticosteroid;
- Has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) given for at least 2 months or was intolerant;
Note: An example of a conventional synthetic DMARD is methotrexate. A previous trial of one biologic other than the requested drug (e.g., Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection], Arcalyst [rilonacept subcutaneous injection], Ilaris [canakinumab subcutaneous injection]) also counts towards a trial of one other systemic agent for Still's disease. A biosimilar of the requested biologic does not count.
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an etanercept product is reviewed under initial therapy.
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
 - o Experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Approval duration (initial):

- Plaque psoriasis/Behcet's Disease 3 months
- GVHD 1 month
- Pyoderma Gangrenosum 4 months
- All others 6 months

Approval duration (renewal):

- GVHD 3 months
- All others 12 months

Dosing Recommendations

Enbrel is administered via subcutaneous injection.

Patient Population	Recommended Dose and Frequency
Adult RA and PsA	50 mg once weekly with or without methotrexate
AS	50 mg once weekly
Adult PsO	50 mg twice weekly for 3 months, followed by 50 mg once weekly
JIA, Pediatric PsO and Juvenile PsA	0.8 mg/kg weekly, with a maximum of 50 mg per week

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